



April 2022

To our stockholders:

As we approach this year's annual meeting, I want to provide you with an update on our recent progress.

2021 in Review

Despite all of the ongoing challenges that we faced during the year, including hospital restrictions, elective surgery disruptions, staffing shortages, and supply chain issues, we had a highly productive 2021. We significantly expanded our installed base, delivered the highest annual procedure volumes in our commercial history, and made substantial progress in the development and expansion of our portfolio. We believe this performance validates the clinical utility that Senhance delivers to patients, surgeons, and hospitals, and reinforces our understanding that there is a critical unmet need in the market to elevate the way surgery is performed globally.

Performance-Guided Surgery

As an organization, our goal is to revolutionize the way surgery is performed. The fact that there are complications with one in five surgeries is unacceptable, and, more importantly, avoidable. The Company is helping to unlock clinical intelligence and capabilities to reduce surgical variability and the complications associated with it. Our Performance-Guided Surgery™ (PGS) initiative builds upon the foundation of Digital Laparoscopy by adding machine vision, augmented intelligence, and deep learning capabilities. These capabilities shift the promise of consistently superior surgery into practice regardless of a surgeon's experience or skill level by guiding improved decision making, enriching collaboration, and enhancing predictability.

We are extremely excited about the future at Asensus as we seek to make PGS a reality by bringing advanced intelligent capabilities to the entire surgical paradigm.

Additional key highlights from the year included:

- We initiated ten clinical programs.
- Over 2,100 Senhance® procedures were performed during the year, representing 44% growth compared to 2020. These procedures included general surgery, gynecology, urology, bariatric and colorectal surgical cases.
- We received four key regulatory clearances:
 - FDA 510(k) clearance for expansion of machine vision capabilities for the Intelligent Surgical Unit™ (ISU™)
 - FDA 510(k) clearance for articulating instruments
 - Expanded FDA 510(k) clearance for general surgery indication
 - CE Mark approval for the ISU
- There were 21 peer-reviewed clinical papers published providing further support for the clinical utility of the Senhance System across a variety of surgical specialties.

Looking ahead to 2022

As we moved into 2022, we continued to be highly focused on market development efforts. This includes increasing awareness of the platform, having impactful data published that reinforces the clinical benefits Senhance brings to patients, surgeons and hospitals while expanding the capabilities of the platform; all to facilitate increased adoption and utilization across the globe.

In 2022, we expect to initiate 10 - 12 new Senhance Surgical Systems globally.

During the second half of 2022, we expect to achieve the following commercial and regulatory milestones:

- Full scale commercialization of articulating instruments globally
- File a 510(k) for FDA clearance of Senhance for pediatric indication
- Receive CE Mark for expanded machine vision capabilities for the ISU

Thank you all for your continued support.

Best Regards,

A handwritten signature in black ink, appearing to read 'Anthony Fernando', with a stylized flourish at the end.

Anthony Fernando
President and Chief Executive Officer

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

FORM 10-K

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

For the fiscal year ended December 31, 2021

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

ASENSUS SURGICAL, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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:

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

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

None
(Title of class)

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

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

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

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

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

Large accelerated filer ☒
Non-accelerated filer ☐

Accelerated filer ☐
Smaller reporting company ☐
Emerging growth company ☐

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, 2021, 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 \$742.5 million.

The number of shares outstanding of the registrant's common stock as of February 25, 2022 was 236,408,339.

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 2022 Annual Meeting of Stockholders.

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

DECEMBER 31, 2021

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FORWARD-LOOKING STATEMENTS

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

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

- our history of operating losses;
- our ability to successfully grow the 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 increase use of our products by existing and new customers;
- competition from existing and new market entrants;
- our ability to successfully develop, clinically test and commercialize our new products;
- our ability to identify and pursue development of additional products;
- the timing and outcome of the regulatory review process for our products;
- 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., Asensus International, Inc.; Asensus Surgical Italia S.r.l.; Asensus Surgical Europe S.à.r.l.; Asensus Surgical Taiwan Ltd; Asensus Surgical Japan K.K.; 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 laparoscopic surgery. This builds upon the foundation of Digital Laparoscopy with our 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 utilize them 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 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 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, but we also believe it will ultimately help reduce the cognitive load of the surgeons.
- Post-operative – finally, by tapping into the vast amount of data captured during procedures, surgeons and operating room staff will be able to get “performance analytics” with actionable assessments of their performance giving them the information needed to improve performance over time. We intend to establish a new standard of analytics to improve not only the skills of all surgeons but move towards best-practice-sharing that bridges the global surgeon community.

We continue 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 multi-port, digital laparoscopy platform designed to maintain laparoscopic MIS standards while providing digital benefits such as haptic feedback, robotic precision, comfortable ergonomics, advanced instrumentation including 3mm microlaparoscopic instruments, 5mm articulating instruments, eye-sensing camera control and fully-reusable standard instruments to help maintain per-procedure costs similar to traditional laparoscopy.

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

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

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

- laparoscopic 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 3DHD, vision, and open architecture consistent with current laparoscopic surgery procedures; and
- patients will continue to seek a minimally invasive option, offering minimal scarring and fewer incisions, for many common general abdominal and gynecologic surgeries, which desires are addressed by the Senhance System.

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

The Senhance System is available for sale in Europe, the United States, Japan, Taiwan, 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, allowing for its sale and utilization throughout the Russian Federation.

We also enter into lease arrangements with certain qualified customers. For some lease arrangements, the customers are provided with the right to purchase the leased Senhance System during or at the end of the lease term (which we refer to as a Lease Buyout). In the first quarter of 2021, we completed one Lease Buyout of a Senhance System.

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 |
|--|--|---|--|
| Senhance System | October 2017 | January 2012 | Taiwan – April 2018 Japan – May 2019 Russian Federation – December 2020 |
| Indications for Use of Senhance System | | | |
| • Initial general surgery indications for laparoscopic colorectal and gynecologic surgery procedures | October 2017 | N/A | N/A |
| • Extended to cholecystectomy and inguinal hernia repair | May 2018 | N/A | N/A |
| • Extended to hiatal and paraesophageal hernia, sleeve gastrectomy, and sacrocolpopexy | March 2021 | N/A | 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 | 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 | N/A |
| Instruments and Other Products | | | |
| • Intelligent Surgical Unit, or ISU | Initial - March 2020 Expansion of augmented intelligence in August 2021 | January 2021 | Japan - December 2020 |
| • 5mm articulating instruments | July 2021 | September 2018 | N/A |
| • 3mm diameter instruments | October 2018 | April 2019 | Taiwan - November 2018 Japan - October 2019 |
| • Senhance ultrasonic system | January 2019 | September 2018 | Japan - October 2020 |
| • 3 and 5mm hooks | 5mm July 2019 3mm November 2019 | December 2019 | Japan - December 2020 |

On January 19, 2021, we announced that we received CE Mark for the ISU, allowing us to expand our augmented intelligence capabilities to all global areas accepting CE Marks. In addition, in August 2021, we received FDA clearance for expanded augmented intelligence features on the ISU. The ISU enables machine vision-driven control of the camera for a surgeon by responding to commands and recognizing certain objects and locations in the surgical fields and allows a surgeon to change the visualized field of view using the movement of their instruments. The newest ISU features expand upon these capabilities and introduce more advanced features including 3D measurement, digital tagging, image enhancement, and enhanced camera control based on real-time data from anatomical structures while performing surgery. We acquired the assets used in the development of the ISU as part of our October 2018 acquisition of the assets, intellectual property and highly experienced multidisciplinary personnel of Medical Surgical Technologies, Inc., or MST, an Israeli-based medical technology company.

On July 28, 2021, we announced that we received FDA clearance for 5mm diameter articulating instruments, offering better access to difficult-to-reach areas of the anatomy by providing two additional degrees of freedom. These instruments previously received CE Mark for use in the EU.

We also focused on expanding the indications for use of the Senhance System. As of March 2021, the Senhance System is FDA 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. 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.

2021 Market Development Activities

In 2021 we continued to focus 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 technical advancement of digital surgical tools to lead to the realization of Performance-Guided Surgery;
- 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.

2021 Senhance Surgical System Programs

We define the initiation of a Senhance Surgical program as entering into an agreement to purchase or lease, and subsequently utilize a Senhance Surgical System. Throughout 2021, we initiated ten Senhance System programs, one in the U.S., six in EMEA, and three in Asia. We initiated six Senhance System programs in the fourth quarter of 2021 alone.

Training Sites

In February 2021, we announced an agreement with the Amsterdam Skills Centre 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 Amsterdam Skills Centre 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 Advent Health Nicholson Center in Celebration, Florida, at LSU Health's University Medical Center New Orleans, and our office in Research Triangle Park North Carolina; two in Europe at Amsterdam Skills Center, and our office in Milan, Italy; and, one in Japan at Saitama Medical University International Medical Center in Tokyo.

Procedure Volumes

In 2021, surgeons performed over 2,100 procedures utilizing the Senhance System, representing a 45% increase over the previous year, despite the continued 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

Foundational sites are hospitals that are performing clinical procedures with the Senhance System at an annualized rate of greater than 100 procedures per year. The COVID-19 pandemic's impact on establishing sites, and training physicians, coupled with periodic suspension of elective surgeries by hospitals have impacted case volumes resulting in volatility in specific hospitals and regions. As we continue to emphasize the training and onboarding of new surgeon users and focus on increased utilization, we expect to see growth in foundational sites.

Performance-Guided Surgery (PGS)

PGS builds upon the foundation of Digital Laparoscopy by adding machine vision, augmented intelligence, and deep learning capabilities to help guide improved decision making, enrich collaboration, and enhance predictability for all surgeons, independent of training or experience, to shift the promise of consistently superior surgery into practice. Historical advances in surgery have largely focused on bringing tools and techniques into the OR to reduce the invasiveness of procedures and improve the execution of discrete tasks. Unlike many other industries, very little focus has been on improving the decision-making aspects of the surgical process, which is crucial in the high-pressure, highly variable situations which happen repeatedly during any surgery. PGS focuses on a holistic solution for the entire surgeon workflow to drive consistently superior outcomes. We believe PGS can deliver real-time clinical decision support to boost surgeon capabilities to perceive complex environments, make decisions, and perform the desired tasks with increased precision, safety, and efficiency to mitigate surgical errors and complications.

Senhance Connect

Senhance Connect is a mobile tool that allows surgeons in an operating room to connect with and communicate with other Senhance surgeons in other locations. The process allows for streaming of multiple camera views and an endoscopic view simultaneously, and allows for two-way screen sharing and annotation. This feature is part of our PGS ability to provide real-time digital collaboration capabilities to surgeons.

Clinical Validation

During 2021, there were 21 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. In particular, there were four milestone papers published in 2021:

- In April, a study was published comparing health economic outcomes of the Senhance System versus another robotic system, as well as traditional laparoscopy. According to the study, the Senhance System was less than half the median instrument cost compared to procedures performed on another robotic platform and was comparable to traditional laparoscopic-assisted vaginal hysterectomy costs for certain gynecologic procedures.

- In May, a study was published which analyzed the outcomes of over 800 Senhance System procedures across multiple specialties including hernia repairs, cholecystectomies, and prostatectomies based on data from the Company's real-world clinical data registry, TRUST. According to the study, Senhance System procedures are safe and reproducible and deliver promising clinical outcomes.
- In August, a study was published which analyzed the outcomes and experience of utilizing the Senhance System to perform a high volume of urologic procedures. According to the study, the Senhance System is a safe and feasible platform to perform multiple common urologic procedures, namely upper urinary tract and extraperitoneal radical prostatectomies.
- In September, a study was published which analyzed the outcomes of inguinal hernia repair procedures based on data from the Company's TRUST registry. According to the study, the Senhance System is a safe and doable platform to perform inguinal hernia repair procedures, and it can deliver high quality clinical outcomes related to patient recovery time, length of hospital stay, and postoperative pain.

Impact of COVID-19

The COVID-19 pandemic had a significant impact on us in 2021 and continues to have a significant impact on our operations, primarily due to the continued repeated 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. 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

In 2021, we engaged in a number of equity financing transactions to fund our operations and extend our cash reach to provide capital to progress our strategy. These financings included:

- *January 2021 Public Offering.* On January 29, 2021, we completed an underwritten public offering of 26,545,832 shares of our 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 \$73.4 million.
- *January 2021 Registered Direct Purchase Agreement.* On January 12, 2021, 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 \$28.6 million.
- *At-the-Market Offerings.* On October 9, 2020, we filed a prospectus supplement relating to an at-the-market offering, referred to as the "2020 ATM Offering", with Cantor Fitzgerald & Co, or Cantor, pursuant to which we could sell from time to time, at our option, up to an aggregate of \$40.0 million of shares of our common stock, through Cantor as sales agent, pursuant to a Controlled Equity Offering Sales Agreement dated August 12, 2019, referred to as the 2019 Sales Agreement. We terminated this agreement in January 2021.

On May 19, 2021, we entered into a Controlled Equity OfferingSM Sales Agreement with Cantor, Robert W. Baird & Co. Incorporated and Oppenheimer & Co. Inc., as our sales agents, relating to an at-the-market offering of up to an aggregate of \$100,000,000 of shares of our common stock, referred to as the "2021 ATM Offering".

Sales during the year ended December 31, 2021, under the 2020 and 2021 ATM Offerings are as follows (in thousands except for share and per share amounts):

| | Year Ended December 31, 2021 |
|-----------------------------------|---------------------------------|
| Total shares of common stock sold | 20,237,045 |
| Average price per share | \$ 1.53 |
| Gross proceeds | \$ 30,943 |
| Commission earned by Sales Agents | \$ 928 |
| Net proceeds | \$ 30,015 |

- *2021 Exercise of Warrants.* During 2021, certain holders of our Series B, C, and D warrants to purchase shares of our common stock exercised such warrants for aggregate proceeds to the Company of \$30.6 million.

Following such financing transactions, we had cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of \$135.8 million as of December 31, 2021, and we believe we have sufficient capital to fund our 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. We are uniquely focused on the laparoscopic surgical market as we believe it separates us from our competitors and allows surgeons to perform minimally invasive surgery in a method more comfortable for the patient than open surgery utilizing fully reusable tools, smaller instruments to broaden applicability of the laparoscopic method, including in pediatric cases, and to utilize the additional Senhance System technology such as the ISU.

Robotic and computer-controlled assistance have developed as technologies that offer the potential to improve upon many aspects of the laparoscopic surgical experience. According to DRG Global Market's Laparoscopic Surgical Robotic Devices (October 2020), the existing laparoscopic market for soft tissue abdominal surgery is 16 million procedures annually. 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, but more recently developed robotic approaches like the Senhance System have been applied to many other clinical applications, particularly in general surgery.

Despite recent advances and new entrants into the market, we believe there remain many limitations associated with current robotic-assisted surgery systems.

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 amplify the urgency for Performance-Guided Surgery include:

- Value-based care is shifting a greater responsibility for poor quality and inefficiency to hospitals and physicians;
- COVID-19 exposed the 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 in Note 3 of the Notes to the Consolidated Financial Statements 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, non-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 3DHD, 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:* The ISU enables machine vision capabilities providing the ability to recognize certain objects and locations in the surgical field. This capability enhances visualization and camera control over currently available surgical technologies, and provides the foundation for additional augmented intelligence capabilities, with a number of enhancements added and FDA-cleared in 2021. Additionally, the ISU improves surgical team collaboration by seamlessly sharing the surgeon's console view in real-time across the entire operating room. The most recently cleared augmented intelligence features available in the U.S. and Japan include 3D point-to-point measurement, advanced endoscopic control modalities, image enhancement, and intra-operative surgeon digital tagging. Further features may

include anatomical structure identification, further enhancing the digital laparoscopic experience with the Senhance System.

- *Haptic Feedback*: The Senhance System's haptic feedback feature heightens the surgeon's sensing of pressure/tension throughout the surgical procedure; haptics provides the surgeon with the ability to feel the tissue response of the body during a procedure.
- *Laparoscopic Motion*: Digital laparoscopy maintains familiar motions, tools, and techniques that are similar to the motion used during traditional laparoscopic surgeries.
- *Comfortable Ergonomics*: Ergonomic seating for the surgeon throughout the procedure helps to reduce fatigue and risk of musculoskeletal injuries.
- *E-Fulcrum*: A digital fulcrum, setting a dynamic virtual pivot point, helps to potentially minimize incision trauma.
- *Open-Platform Architecture*: The Senhance System 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.).
- *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, our 3mm diameter instruments, our 3mm and 5mm hooks and articulating instruments. The 3mm instruments enable the Senhance System to be used for microlaparoscopic surgeries, allowing for tiny incisions. We currently offer approximately 80 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.

In January 2020, we submitted a 510(k) submission to the FDA for our ISU, which is designed to enable machine vision capabilities on the Senhance System. The ISU was developed using the MST image analytics technology that we retained. On March 13, 2020, we announced that we had received FDA clearance for the ISU. On September 23, 2020, we announced the first surgical procedures successfully completed using the ISU. In January 2021, we received the CE Mark for the ISU and in September 2021 we received FDA clearance for additional augmented intelligence features of 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.
- 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. These additional indications helped to increase procedure volume to over 2,100 cases in 2021.

Products in Development

Instruments

In July 2021, we received FDA clearance for 5mm articulating instruments, which offer better access to difficult-to-reach areas of the anatomy. We are working on introducing other advanced instrumentation and functionality to the Senhance System.

Augmented Intelligence Assets with Global Use

In September 2021, we announced that we had received 510(k) clearance from the FDA for an expansion of machine vision capabilities on the previously cleared ISU. The initial features of the ISU enable machine vision-driven control of the camera for a surgeon by responding to commands and recognizing certain objects and locations in the surgical field and allows a surgeon to change the visualized field of view using the movement of their instruments. The newest ISU features expanded upon these capabilities and introduced more advanced features including: real-time 3D measurement, digital tagging, image enhancement, and

enhanced camera control based on real-time data from anatomical structures while performing surgery. In addition, we received a CE mark for the ISU in 2021, expanding its global use potential. We are currently working on additional enhancements to assist in Performance-Guided Surgery.

Business Strategy

Our strategy is to focus our resources on the market development of the Senhance System and related instruments as we work to accelerate adoption of Performance-Guided Surgery techniques to maximize the benefits of our technology and products.

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 3DHD 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 3mm instruments and 5mm articulating instruments for the Senhance System help to increase adoption of our products in the laparoscopic surgery market;
- leveraging haptic feedback, 3mm 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.

Sales and Marketing

We utilize distributors in jurisdictions where we do not sell directly. Our distribution agreements typically provide exclusivity in a specific territory or jurisdiction.

We are dependent on growing the number of hospital customers and increasing the number of customers with installed Senhance Systems. Throughout 2021, we initiated ten Senhance surgical programs, one in the U.S., six in EMEA, and three in Asia. We define the initiation of a Senhance Surgical program as entering into an agreement to purchase or lease, and subsequently utilizing a Senhance Surgical System. We also focused on growing the number of foundational sites using the Senhance System.

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, 2021, the Company's patent portfolio includes approximately 66 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 approximately 38 of our patents and patent applications that are exclusively licensed to us and the approximately 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 8 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, for the Company's convenience, 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 were new entrants in the market for robotic surgery in 2021, and some forward steps by a number of existing entrants, such as the CE Mark attained by Medtronic for its Hugo™ robot. We believe that our focus on the laparoscopic market and our Performance-Guided Surgery initiative help us to remain competitive in this growing field.

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., Titan Medical, Vicarious Surgical, Memic Innovative Surgery Ltd., Distalmotion SA, 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 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 post-market 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 2021, the Medical Device Directive was replaced by the updated European Medical Device Regulation, or 2017/745 (MDR), after a four-year transition period. 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.

Environmental, Social and Governance

Environmental

As a company, we are committed to encouraging and fostering sustainable practices to support the global environment. We comply with environmental regulations in each of our locations. We have a corporate goal of limiting the use of plastic with paper cups and recyclable materials and, prior to COVID, adopted a no plastic policy in our Milan office, which was interrupted due to the need for single-use packaging for health concerns during COVID. Our employees located in our European facilities are encouraged to travel by train rather than aircraft, and some employees benefit from local government incentives to use electric cars. We also put safety first in our locations. Our employees at our manufacturing facility in Italy follow mandatory safety training and take mandatory vision tests and a check-up by the occupational doctor every five years; we also have safety procedures which are drafted with assistance from a third-party safety consultant and updated twice a year.

Social

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, 2021, we had 167 employees, including 153 full-time employees, of whom 55 were in the R&D department, 15 were in Quality and Regulatory Affairs, 34 were in marketing and sales, 29 were in Corporate Administration, and 20 were in Customer Care. As of December 31, 2021, approximately 33% of the Company's workforce were female, and minorities represented approximately 24% of the Company's workforce. As of December 31, 2021, approximately 58% of the Company's employees were in the United States and 42% were outside of the United States. In 2021, our turnover rate was approximately 18% and we hired 48 full-time employees.

Diversity, Equity & Inclusion ("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. In 2021, we launched e-learning modules hosted by a third-party to provide our employees with education and training on DEI topics. We are also focused on incorporating DEI principles into our governance structure and believe having mix of backgrounds and experience in our Board composition is essential to understanding and reflecting the needs of our diverse stakeholders. Currently, two of eight board members self-identify as women, and three of our eight Board members self-identify as individuals from underrepresented communities (defined as an individual who self-identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, or Alaska Native, or who self-identifies as gay, lesbian, bisexual, or transgender).

COVID-19 Pandemic

Throughout the COVID-19 pandemic, employee safety is of top priority. Until August 2021, most of our employees globally worked from home since the beginning of the pandemic, except for those with a business need to engage in work onsite. Beginning in August 2021, we encouraged a return to the office on a hybrid basis, while monitoring the ongoing impact of the pandemic on our office locations. Ongoing safety measures remain in place at each of our locations including implementing pre-screening and social distancing requirements in addition to providing PPE. Our Global Prevention Team continues 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 2021, health and wellness was a key focus of the Company, especially in light of the ongoing pandemic and new variants. 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. To enhance our employees' satisfaction and retention, we offer ongoing training opportunities that support professional growth. We have an annual performance review process for all employees worldwide to review performance and inform compensation recommendations. 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.

Employee Engagement

We partner with Gallup, Inc., a global analytics and advice firm, to monitor and improve the engagement of our workforce. Gallup's Q12 survey measures employee engagement based on twelve key needs of employees. We utilize survey results to identify strengths and weaknesses and create action plans to improve engagement and ultimately team performance. In 2021, we saw an increase in our engagement score over the prior year. We continue to incorporate Gallup's programs into our overall People Strategy.

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 retention grants of restricted stock units and/or stock options, which we believe help align longer term employee incentives with our company performance. Ensuring fair and equitable pay is also an important commitment we make to our employees.

Governance

Our Board of Directors, through its Nominating and Corporate Governance Committee, evaluates the governance and management practices of the Company. We believe our corporate governance guidelines and structure provide our stockholders with a dedicated, qualified and skilled board of directors and management team. Our governance structure includes:

- annual elections of all board members;
- an independent Board chair and separation of the CEO/Chair role;
- diversity in skills, gender and ethnicity in our board and management team;
- the addition of two new board members in 2021 and transition of our Board chair; and
- the ability of stockholder to propose candidates for potential nomination to the board and proposals for consideration by stockholders at annual meetings.

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., Asensus International, Inc., Asensus Surgical Italia S.r.l., Asensus Surgical Europe S.à.r.l., Asensus Surgical Taiwan Ltd., Asensus Surgical Japan K.K., 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. 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, 2021, 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 \$785.4 million and our working capital was \$103.4 million as of December 31, 2021. We believe that cash and cash equivalents, short-term investments, and long-term investments, including proceeds from our capital raising transactions in 2021 and the warrant exercises are sufficient to fund our operations for more than 12 months.

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, travel restrictions, stay-at-home or shelter-in-place orders, or return-to-work on a hybrid basis. Our Senhance Systems are manufactured at a contract manufacturing facility in Milan. A variety of travel restrictions, caused delays in our product installation and training activities in 2021, particularly in the second quarter. Elective surgeries have also been curtailed a number of times during variant surges in 2021 in various parts of the globe. Although such procedures have recommenced in large part, the limits on elective procedures 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 continue to be negatively impacted or halted again in the future by a resurgence of COVID-19 cases in any of these jurisdictions.

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, including new variants; 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; the effect on our customers and customer demand for Senhance Systems and the ability to provide training services; disruptions or restrictions on our employees' ability to work and travel; and shortages of certain supplies and materials. 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, including emerging variant strains of the virus, 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. There is a risk that government actions will not be effective at containing further COVID-19 outbreaks, including from variants, and that government actions, including the orders and restrictions described above, that are intended to contain the spread of COVID-19 will have a devastating negative impact on the world economy at large, in which case the risks to our sales, operating results and financial condition described herein would be elevated significantly.

Our 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 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, 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, in the second quarter of 2018 in Asia and, through distributors in the Russian Federation in 2021. 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 2021 we initiated ten Senhance Systems programs. 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 in certain of these countries 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. With respect to future sales in the Russian Federation, we are monitoring geo-political events and assessing whether the implementation of sanctions may result in our inability to conduct future sales in the Russian Federation through our distributors or at all. Any such disruption in our sales efforts could have an adverse impact on our financial results. 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.

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., Titan Medical, Vicarious Surgical, Memic Innovative Surgery Ltd., Distalmotion SA, 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.

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., or MST, 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 and FDA clearance in the U.S. 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.

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 will 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.

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; the number of Senhance Systems sold vs. placed, our ability to maintain or reduce production costs, changes in production volume driven by demand for our products, changes in material, labor or other manufacturing-related costs, including increases in costs relating to global supply shortages and inflation, and the 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 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.

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.

Global supply shortages may prevent or restrict our ability to purchase adequate supplies of materials, parts and components at acceptable prices, which could result in delivery delays for our products or increases in our manufacturing costs.

A disruption or termination in the supply of components could result in our inability to meet demand for our products, which could harm our ability to generate revenues, lead to customer dissatisfaction, and damage our reputation and our brand. Furthermore, if we are required to change the manufacturer of a key component of our products, we may be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The time and processes associated with the verification of a new manufacturer could delay our ability to manufacture our products on schedule or within budget, which may have a material adverse impact on our business, financial condition, results of operations, or cash flows. In addition, our ability to meet customers’ demands depends, in part, on our ability to timely obtain an adequate delivery of quality materials, parts, and components from our suppliers. Any such supply shortage could adversely impact our business, financial condition, results of operations, or cash flows.

Labor shortages may disrupt our operations and result in delays in the manufacture and delivery of our products.

Increased labor shortages globally, including staff burnout and attrition, could also impact our ability to hire and retain personnel critical to our manufacturing, logistics, and commercial operations. We are also highly dependent on the principal members of our management and scientific staff. Attracting and retaining qualified personnel is critical to our success, and competition for them has become more intense. The loss of critical members of our team, or our inability to attract and retain qualified personnel, could significantly harm our operations, business, and ability to compete. In addition, hospitals are also experiencing staffing shortages and supply chain issues that could impact their ability to provide patient care.

The inflationary environment could materially adversely impact our business and results of operations.

Changes in economic conditions and supply chain constraints and steps taken by governments and central banks, particularly in response to the COVID-19 pandemic as well as other stimulus and spending programs, could lead to higher inflation than previously experienced or expected, which could, in turn, lead to an increase in costs. An inflationary environment could have a negative impact on our expenses, increase our labor costs and reduce our available cash flow.

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.

Natural disasters and the effects of climate change could disrupt our business and harm our financial condition.

The effects of climate change, weather or other events could adversely impact our supply chain, including our ability to manufacture our products, source materials or components or services from suppliers (including sole-source suppliers) that are needed for such manufacturing (including sterilization), or provide products to our customers, including events that impact key distributors. Natural disasters, including the impacts of climate change, hurricanes, tornadoes, windstorms, fires, earthquakes and floods and other extreme weather events, global health pandemics, war, terrorism, labor disruptions and international conflicts that could cause significant economic disruption and political and social instability, could result in decreased demand for our products, or adversely affect our manufacturing and distribution capabilities or cause interruptions in our supply chain.

Our operations, and the activities of our customers, vendors or distributors, could be disrupted by climate change. The physical changes caused by climate change may prompt changes in regulations or consumer preferences which in turn could have negative consequences for our and our customers' businesses. Potential physical risks from climate change may include altered distribution and intensity of rainfall, prolonged droughts or flooding, increased frequency of wildfires and other natural disasters, rising sea levels, and a rising heat index, any of which could cause negative impacts to our and our customers' businesses. If such events affect our customers' businesses, they may purchase fewer of our products, and our revenues may be negatively impacted.

There has been a broad range of proposed and promulgated state, national and international regulations aimed at reducing the effects of climate change. Such regulations could result in additional costs to maintain compliance and additional income or other taxes. Climate change regulations continue to evolve, and it is not possible to accurately estimate potential future compliance costs.

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, 2021, the market price of our common stock fluctuated from a high of \$6.32 per share to a low of \$0.29 per share. 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;
- the success of our Performance-Guided Surgery initiative;
- variations in our and our competitors' results of operations;
- developments in surgical robotics;
- 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.

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.

Our products are subject to international regulatory processes and approval or certification requirements. If we do not obtain and maintain the necessary international regulatory approvals or certifications, we will not be able to sell our products in other countries.

To be able to sell our products in other countries, we must obtain regulatory approvals or certifications and comply with the regulations of those countries, which may differ substantially from those of the U.S. These regulations, including the requirements for approvals or certifications and the time required for regulatory review, and vary from country to country. Obtaining and maintaining foreign regulatory approvals or certifications is complex, and timing to obtain clearances or certifications in those countries varies; therefore, we cannot be certain that we will receive regulatory approvals or certifications in any other country in which we plan to market our products or obtain such approvals or certifications on a favorable schedule. The time required to obtain marketing authorization in other countries might differ from that required to obtain FDA authorization. If we fail to obtain or maintain regulatory approval or certification in any other country in which we plan to market our products, our ability to generate revenue will be harmed. Regulatory authorization of a product in one country does not ensure regulatory authorization in another, but a failure or delay in obtaining marketing authorization in one country may negatively impact the regulatory process in others.

One of the most significant moving targets related to the regulatory landscape is in the EU; more specifically, the medical devices regulation has recently evolved. Regulation (EU) 2017/745 on medical devices became applicable in the European Union on May 26, 2021. The Medical Device Regulation (MDR) changes the European legal framework for medical devices and introduces new principal and supportive responsibilities for the European Medicines Agency (EMA) and for national competent authorities in the assessment of certain categories of products. Our products in EU countries must now comply with extensive safety and quality regulations detailed in the MDR.

The MDR, which replaced 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. European Economic Area (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.

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.

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.

Disruptions at the FDA and other government agencies or notified bodies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent products from being developed, cleared, certified, approved, or commercialized in a timely manner or at all, which may adversely affect our business.

The delivery of healthcare by hospitals, health systems, and physicians depends on a number of government agencies and services. Further prolonged government shutdowns or restrictions could impact inspections, regulatory review and certifications, grants, or approvals or could cause other situations that could impede their ability to effectively deliver healthcare, including attempts to reduce payments and other reimbursements to hospitals by federal healthcare programs. These situations could adversely affect our customers' ability to perform procedures with our devices and/or their decisions to purchase additional products from us.

In addition, the review and clearance, approval, or certification of new products can be affected by a variety of factors globally, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. In addition, government funding of other government agencies that fund research and development activities is subject to unpredictable and ever-changing political processes. Disruptions at the FDA and other agencies

or notified bodies for any of these or other reasons may cause significant regulatory delays and, therefore, delay our efforts to seek clearances, approvals, or certifications from the FDA, foreign authorities, and notified bodies and adversely affect business travel and import and export of products, all of which could have a material adverse effect on our business, financial condition, results of operations, or cash flows. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, in early 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020 and temporarily postponed routine surveillance inspections of domestic manufacturing facilities. In mid-2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. In 2021, the FDA resumed standard inspectional operations of domestic facilities and announced its intention to resume certain prioritized inspections of foreign manufacturing facilities, including surveillance and application-related inspections, starting in February 2022. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA, other regulatory authorities, or notified bodies from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact their ability to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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.

We are subject to an evolving set of complex laws and regulations relating to privacy, data protection and information collection matters.

There are numerous state, federal, and foreign laws, regulations, decisions, and directives regarding privacy and the collection, storage, transmission, use, processing, disclosure, and protection of different types of personal data and personal information and other customer or other data, the scope of which is continually evolving and subject to differing interpretations. We also must comply with the policies, procedures and business requirements of our customers relating to data privacy and security, which can vary based upon the customer, the customer's industry or location, and the product the customer selects, and which may be more restrictive than the privacy and security measures required by law or regulation. In particular, the European Union and many countries in Europe have stringent privacy laws and regulations, which may impact our ability to profitably operate in certain European countries or to offer products that meet the needs of customers subject to European Union privacy laws and regulations.

For example, the General Data Protection Regulation (the "GDPR") in effect across the EEA, imposes several stringent requirements for controllers and processors of personal data, including imposing strict standards when obtaining consent from individuals to process their personal data, requiring detailed disclosures to individuals, providing individual data rights, imposing short time lines for data breach notifications, limiting retention periods and secondary use of information, imposing certain requirements pertaining to health data, as well as additional obligations when we contract third-party processors to process personal data. The GDPR provides that EEA Member States may make their own further laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to use and share personal data or could cause our costs to increase and harm our business and financial condition. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EEA member states may result in fines of up to 4% of the total worldwide annual turnover of the preceding financial year and other administrative penalties. Compliance with the new data protection rules imposed by GDPR may be onerous and adversely affect our business, financial condition, and results of operations.

Likewise, the California Consumer Privacy Act, or the CCPA, is a state law that gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information and how their personal information is used and imposes compliance obligations on many organizations doing business in California that collect information about California residents. The definition of personal information is very broad and may impact our ability to profitably operate across the United States given that our customers' employees may be resident in California or to offer products that meet the needs of customers subject to California privacy laws and regulations. The CCPA also allows for significant fines by the state attorney general as well as a private right of action for individuals in connection with certain security breaches. The enactment of the CCPA is prompting a wave of similar legislative developments in other US states and creating the potential for a patchwork of

overlapping but different state laws. These developments are increasing our compliance burden and our risk, including risks of regulatory fines, litigation and associated reputational harm.

The costs of compliance with, and other burdens imposed by, our customers' own requirements and the privacy and security laws and regulations that are applicable to our customers' businesses may limit the use and adoption of our products and reduce overall demand. Non-compliance with our customers' specific requirements may lead to termination of contracts with these customers or liabilities to the customers; non-compliance with applicable laws and regulations may lead to significant fines, penalties or liabilities. Furthermore, privacy concerns may cause our customers' workers to resist providing the personal data necessary to allow our customers to use our products effectively. If a customer experiences a significant data security breach involving our products, our customers could lose confidence in our ability to protect the personal information of their employees, customers and suppliers, which could cause our customers to discontinue use of our products. The loss of confidence from a significant data security breach involving our software products could hurt our reputation, cause sales and marketing challenges to existing and new customers, cause loss of market share or exacerbate competitive pressures, result in an increase in our development costs to address any potential vulnerabilities in our software products, and may result in reduced demand and revenue. Even the perception of privacy concerns, whether or not valid, may inhibit market adoption of our products in certain industries.

Domestic and international legislative and regulatory initiatives and our customers' privacy policies and practices may adversely affect our and our customers' ability to process, handle, store, use and transmit demographic and personal information from their employees, customers and suppliers, which could reduce demand for our products.

In addition to government activity, privacy advocacy groups and the technology and other industries are considering various new, additional or different self-regulatory standards that may place additional burdens on our software products. Complying with these varying requirements could cause us to incur substantial costs or require it to change our business practices in a manner adverse to our business. Any failure, or perceived failure, on our part to comply with any regulatory requirements or international privacy or consumer protection-related laws and regulations could result in proceedings or actions against it by governmental entities or others, subject it to significant penalties or fines and negative publicity and adversely affect us.

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. Any failure, breach or unauthorized access to our or third-party systems could result in the loss of confidential, sensitive or proprietary information, interruptions in service or production or otherwise our ability to conduct business operations and could result in potential reductions in revenue and profits, damage to its reputation or liability. 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. Further, as regulatory focus on privacy and data security issues continues to increase and worldwide laws and regulations concerning the protection of information become more complex, the potential risks and costs of compliance to the company's business will intensify.

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 11,733 square feet, for a seven-year and three month term ending on December 31, 2028, under a lease that commenced on October 1, 2021.

Our Israeli research and development facilities are located at Ha Kadima 9, Fibernet Building, 4th Floor, Yokne'am Illit, Israel. We lease these facilities, which consist of 8,471 square feet, for a five-year term ending on June 30, 2026, under a lease that commenced on July 1, 2021.

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

Market Information

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 when we changed our name from TransEnterix Surgical, Inc. to Asensus Surgical, Inc. In June 2021, we were added to the Russell 2000 and the Russell Microcap Indexes.

Holders

As of February 25, 2022, there were approximately 59 record holders of our common stock (counting all shares held in single nominee registration as one stockholder).

Dividends

We have never declared or paid any cash dividends on our common stock. We intend to retain earnings for use in the operation and expansion of our business.

Recent Sales of Unregistered Securities and Use of Proceeds.

None.

Issuer Purchases of Equity Securities

The following table summarizes the Company's purchases of its common stock for the quarter ended December 31, 2021:

| Period | Issuer Purchases of Equity Securities | | | |
|-----------------------|---|------------------------------------|--|---|
| | Total Number of Shares Purchased | Average Price Paid per Share | Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs | Maximum Number of Shares that May Yet be Purchased Under the Plan or Programs |
| October 1 - 31, 2021 | - | - | - | - |
| November 1 - 30, 2021 | 1,365 | \$1.74 | - | - |
| December 1 - 31, 2021 | - | - | - | - |
| Total | 1,365 | \$1.74 | - | - |

These amounts consist of 1,365 shares we acquired from employees associated with the withholding of shares to pay certain withholding taxes upon the vesting of stock-based compensation in accordance with the terms of our equity compensation plan that were previously approved by our stockholders and disclosed in our proxy statements filed with the Securities and Exchange Commission. We purchased these shares at their fair market value, as determined by reference to the closing price of our common stock on the vesting date.

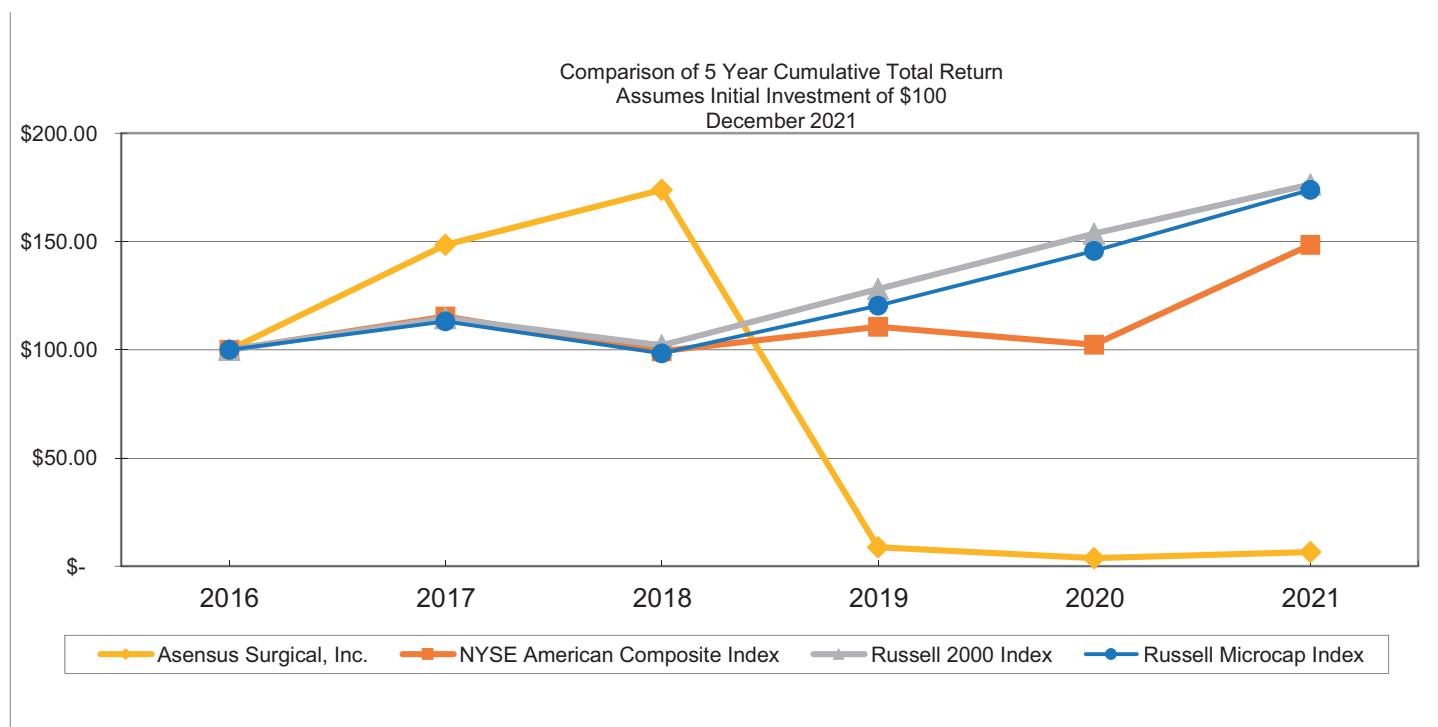
Stock Performance Graph

This graph is not "soliciting material" or deemed "filed" with the SEC for purposes of Section 18 of the Exchange Act of 1934., or otherwise subject to liabilities under the Section, and shall not be deemed incorporated by reference into any filings of Asensus Surgical, Inc. under the Securities Act of 1933, as amended, whether made before or after the date hereof and irrespective of any general incorporate language in any such filing.

The graph set forth below compares the cumulative total stockholder return on our common stock between December 31, 2016, and December 31, 2021, with the cumulative total return of (i) the NYSE American Composite Index, (ii) the Russell 2000 Index, and (iii) the Russell Microcap Index over the same period. This graph assumes an investment of \$100.00 on December 31, 2016 in our common stock, the NYSE American Composite Index, the Russell 2000 Index, and the Russell Microcap Index and assumes the re-investment of dividends, if any.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.

COMPARISON OF CUMULATIVE TOTAL RETURN AMONG ASENSUS SURGICAL, INC., NYSE AMERICAN COMPOSITE, RUSSELL 2000 INDEX, AND RUSSELL MICROCAP INDEX



| Company/Market | COMPARISON OF CUMULATIVE TOTAL RETURN | | | | | |
|-------------------------------|---------------------------------------|-----------|-----------|-----------|-----------|-----------|
| | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 |
| Asensus Surgical, Inc. | \$ 100.00 | \$ 148.46 | \$ 173.85 | \$ 8.70 | \$ 3.70 | \$ 6.57 |
| NYSE American Composite Index | \$ 100.00 | \$ 115.32 | \$ 99.32 | \$ 110.60 | \$ 102.29 | \$ 148.49 |
| Russell 2000 Index | \$ 100.00 | \$ 114.65 | \$ 102.02 | \$ 128.06 | \$ 153.62 | \$ 176.39 |
| Russell Microcap Index | \$ 100.00 | \$ 113.17 | \$ 98.36 | \$ 120.43 | \$ 145.67 | \$ 173.84 |

ITEM 6. RESERVED

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 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™, or 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. 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 3mm microlaparoscopic instruments, 5mm articulating 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 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.

We also enter into lease arrangements with certain qualified customers. For some lease arrangements, the customers are provided with the right to purchase the leased Senhance System during or at the end of the lease term ("Lease Buyout"). In the first quarter of 2021, we completed one Lease Buyout of a Senhance System.

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 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, but we also believe it will ultimately help reduce the cognitive load of the surgeons.
- Post-operative – 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 to establish a new standard of analytics to improve not only the skills of all surgeons but move 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 3mm instruments will prove to be an effective tool in surgery with smaller patients.

On July 28, 2021, the Company announced that it received FDA clearance for 5mm diameter articulating instruments, offering better access to difficult-to-reach areas of the anatomy by providing two additional degrees of freedom. These instruments have previously received CE Mark for use in the EU.

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, 2021, we had an accumulated deficit of \$785.4 million.

We operate in one business segment.

Financing Transactions

During late 2020 and 2021, 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:

- *October 2020 At-the-Market Offering.* On October 9, 2020, the Company filed a prospectus supplement relating to an at-the-market offering with Cantor Fitzgerald & Co., or 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, referred to as the "2020 ATM Offering". The Company terminated this agreement in January 2021.
- *January 2021 Public Offering.* On January 29, 2021, the Company completed an underwritten public offering of 26,545,832 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 \$73.4 million.
- *January 2021 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 \$28.6 million.

2021 At-the-Market Offering. On May 19, 2021, we entered into a Controlled Equity OfferingSM Sales Agreement with Cantor, Robert W. Baird & Co. Incorporated and Oppenheimer & Co. Inc., as our sales agents, relating to an at-the-market offering of up to an aggregate of \$100,000,000 of shares of our common stock, referred to as the "2021 ATM Offering".

Sales during the year ended December 31, 2021, under the 2020 and 2021 ATM Offerings are as follows (in thousands except for share and per share amounts):

| | Year Ended December 31, 2021 |
|-----------------------------------|---|
| Total shares of common stock sold | 20,237,045 |
| Average price per share | \$ 1.53 |
| Gross proceeds | \$ 30,943 |
| Commission earned by Sales Agents | \$ 928 |
| Net proceeds | \$ 30,015 |

- *2021 Exercise of Warrants.* During 2021, certain holders of our Series B, C and D warrants to purchase shares of our common stock exercised such warrants for aggregate proceeds to the Company of \$30.6 million.

Paycheck Protection Program

During 2020, the Company received an unsecured non-recourse loan of \$2.8 million under the Paycheck Protection Program (PPP) provisions of the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act). The Company accounted for the PPP promissory note as debt within notes payable on the consolidated balance sheet. As of December 31, 2020, \$1.6 million of the promissory note was classified as long-term and \$1.2 million was classified as current. On June 10, 2021, the Company received notification from the Small Business Administration that the principal amount of \$2.8 million and related interest had been forgiven. Gain on extinguishment of debt of \$2.8 million was recognized for the year ended December 31, 2021 on the consolidated statement of operations and comprehensive loss.

Results of Operations for the Years Ended December 31, 2021 and 2020

Revenue

In 2021, our revenue consisted of the sale of two Senhance Systems, one Lease Buyout, ongoing Senhance System leasing payments, sales of instruments and accessories, and services for Senhance Systems sold or placed in Europe, Asia and the U.S. In 2020, our revenue consisted of Senhance System leasing payments, and sales of instruments, accessories, and services for Senhance Systems sold in Europe, Asia and the U.S. in prior periods.

Product, instrument, and accessory revenue for the year ended December 31, 2021 increased to \$6.7 million compared to \$1.6 million for the year ended December 31, 2020. The \$5.1 million increase was derived primarily from the sale of two Senhance Systems and a Lease Buyout in 2021, versus 2020 revenue driven by system leasing arrangements, as well as instruments and accessories sales. Services revenue for the year ended December 31, 2021 decreased to \$1.5 million from \$1.6 million for the year ended December 31, 2020 due to the timing of the service contracts and 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 incurred internally to produce the products. Depreciation expense related to leased systems is included in the cost of revenue. Shipping and handling costs incurred by the Company are included in the cost of revenue. We expense all inventory obsolescence provisions 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 decline 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, 2021 increased to \$8.0 million as compared to \$2.3 million for the year ended December 31, 2020. This \$5.7 million increase over the prior year period was primarily the result of increased materials cost of \$6.2 million, which is driven by increased system placements in the current year. The change also includes a decrease in the inventory reserve of \$0.5 million. The decrease in the inventory reserve was driven by the sale of previously reserved inventory. Also contributing to the increase were increased facility costs of \$0.1 million and increased freight costs of \$0.1 million offset by decreased personnel costs of \$0.6 million and decreased supplies cost of \$0.1 million.

Service cost for the year ended December 31, 2021 increased to \$3.1 million as compared to \$2.9 million for the year ended December 31, 2020. This \$0.2 million increase over the prior year period was primarily related to \$0.3 million in increased supplies and \$0.1 million in increased consulting costs offset by \$0.1 million in reduced personnel costs, and \$0.1 million in reduced facilities 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, 2021 increased 16% to \$19.3 million as compared to \$16.6 million for the year ended December 31, 2020. The \$2.7 million increase primarily relates to increased personnel costs of \$2.0 million, increased supplies costs of \$0.3 million, increased consulting costs of \$0.3 million and increased facility costs of \$0.1 million.

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 increase moderately as we refocus our resources and efforts on market development activities.

Sales and marketing expenses for the year ended December 31, 2021 increased 2% to \$13.4 million compared to \$13.1 million for the year ended December 31, 2020. The \$0.3 million increase was primarily related to increased consulting costs of \$0.2 million, increased software costs of \$0.2 million, increased travel costs of \$0.1 million, increased supplies expense of \$0.1 million, and increased other costs of \$0.2 million offset by decreased depreciation expense of \$0.4 million and decreased personnel costs of \$0.1 million.

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. We expect general and administrative costs to remain flat in future periods.

General and administrative expenses for the year ended December 31, 2021 increased 37% to \$19.3 million compared to \$14.1 million for the year ended December 31, 2020. The \$5.2 million increase was primarily due to increased personnel costs of \$4.0 million, which is primarily driven by an increase in employee headcount and a \$1.6 million increase in stock compensation expense. The change is also driven by increased shareholder meeting costs of \$0.6 million, increased supplies expense of \$0.2 million, increased product costs of \$0.1 million, increased depreciation expense of \$0.1 million, and increased other costs of \$0.3 million, offset by decreased facilities costs of \$0.1 million.

Amortization of Intangible Assets

Amortization of intangible assets for the year ended December 31, 2021 increased to \$11.3 million compared to \$10.8 million for the year ended December 31, 2020. The \$0.5 million increase was primarily the result of a higher Euro to Dollar exchange rate.

Change in Fair Value of Contingent Consideration

The change in fair value of contingent consideration in connection with the Senhance Acquisition described in the Product Overview section above was a \$1.6 million decrease for the year ended December 31, 2021 compared to an increase of \$2.9 million for the year ended December 31, 2020. The \$4.5 million decrease was primarily due to changes in the Company's forecast of future product revenue.

Other Income (Expense)

Other income (expense) for the year ended December 31, 2021 primarily related to the \$2.8 million gain on extinguishment of debt from the PPP loan forgiveness and \$1.3 million refund for the Employee Retention Tax Credit (ERTC), offset by a \$2.0 million increase in the fair value of warrant liabilities recorded during the year.

Income Tax (Expense) Benefit

Income tax expense of \$0.2 million in the year ended December 31, 2021 consisted primarily of current income taxes related to profitable foreign jurisdictions in Japan, Israel, and the Netherlands.

Income tax benefit of \$1.5 million in the year ended December 31, 2020, consisted 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 Senhance Acquisition.

Results of Operations for the Years Ended December 31, 2020 and 2019

Revenue

In 2020, our revenue consisted of Senhance System leasing payments, and sales of 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 was 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

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 is driven by fewer system placements compared to the prior period. This change 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 \$0.2 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

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 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 \$7.6 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 tradeshowes 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.

General and administrative expenses for the year ended December 31, 2020 decreased 25% to \$14.1 million compared to \$18.8 million for the year ended December 31, 2019. The \$4.7 million decrease was primarily due to decreased personnel costs of \$2.3 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 \$0.5 million offset by increased facilities costs of \$0.4 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 net gain from the sale of AutoLap assets was \$16.0 million for the year ended December 31, 2019. 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 sheets as of December 31, 2021 and 2020. 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 \$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, revenue volatility, and an estimated discount rate associated with the risks of the expected cash flows attributable to the milestone.

Other Income (Expense)

Other income (expense) for the year ended December 31, 2020 primarily related to a \$0.3 million increase in the fair value of warrant liabilities recorded for the year. Other income (expense) for the year ended December 31, 2019 primarily related to \$3.6 million in interest expense related to notes payable obligations outstanding during the year, a \$2.2 million decrease in the change in the fair value of warrant liabilities recorded for the year, and a \$1.0 million loss on extinguishment of debt.

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 Senhance Acquisition. 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 \$785.4 million as of December 31, 2021 and working capital of \$103.4 million as of December 31, 2021.

The Company has raised additional capital through equity offerings, including raising net proceeds of \$73.4 million in the January 2021 public offering, \$28.6 million in the January 2021 registered direct offering, \$57.2 million in the 2019, 2020, and 2021 ATM Offerings, \$13.5 million in the March 2020 public offering, an additional \$13.6 million in net proceeds in the July 2020 public offering (see Note 17 to the Company’s consolidated financial statements included in this Annual Report), aggregate proceeds to the Company of \$33.7 million for exercises of Series B, C and D warrants in 2020 and 2021, and \$2.8 million related to a non-recourse loan under the PPP provisions of the CARES Act that was forgiven as of December 31, 2021. 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.

As of December 31, 2021, the Company had cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of \$135.8 million. While the Company believes that its existing cash, cash equivalents, short-term investments and long-term investments as of December 31, 2021 will be sufficient to sustain operations for at least the next 12 months from the issuance of these consolidated financial statements, the Company believes it will need to obtain additional financing in the future to proceed with its business plan. Management's plan to obtain additional resources for the Company may include additional sales of equity under the 2021 ATM Offering or otherwise, 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 or be able to secure additional funding when needed on terms acceptable to the Company, or at all. For a discussion of our recent equity financings, see "Financing Transactions" above in this Management's Discussion and Analysis and Results of Operations.

Trends and Uncertainties

Our industry is highly competitive, subject to change and significantly affected by new product introductions and other activities by competitors. Many of these competitors have significantly greater financial and human resources than we do, have established reputations with our target customers, and more established worldwide distribution channels. There were new entrants in the market for robotic surgery in 2021, and some forward steps by existing competitors, such as the CE Mark attained by Medtronic for its Hugo robot. Several competitors have launched devices that enable reduced incision or single incision laparoscopic surgery with or without robotic assistance. We believe that our focus on the laparoscopic market and our Performance-Guided Surgery initiative will help us to remain competitive in this growing field.

Our strategy is 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. We are currently focused on increasing utilization of the existing Senhance Systems by increasing the number of procedures conducted using the Senhance System quarter over quarter. We are also focused on increasing the number of placements of the Senhance System, not necessarily through sales, but through leasing arrangements. 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 near-term meaningful increase in our business or financial condition.

We will need additional new products and product enhancements to deliver the opportunities of Performance-Guided Surgery. Such new products and product enhancements are subject to regulatory clearances or approvals, and our ability to provide training and implement the use of such new products.

The global spread of COVID-19 and the various attempts to contain it continue to create significant volatility, uncertainty, and economic disruption. Elective surgeries have also been curtailed a number of times during variant surges in 2021 in various parts of the globe. Although such elective surgeries have recommenced in large part, the limits on elective procedures 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 continue to be negatively impacted or halted again in the future by a resurgence of COVID-19 cases in any of the jurisdictions we operate in.

Changes in economic conditions and supply chain constraints and steps taken by governments and central banks, particularly in response to the COVID-19 pandemic as well as other stimulus and spending programs, could lead to higher inflation than previously experienced or expected, increased labor shortages, our ability to hire and retain personnel, which could, in turn, lead to an increase in costs. An inflationary environment could have a negative impact on our expenses, increase our labor costs and reduce our available cash flow.

Consolidated Cash Flow Data

| | Year Ended December 31, | | |
|---|-------------------------|-----------|-----------|
| | 2021 | 2020 | 2019 |
| | in millions | | |
| Net cash (used in) provided by | | | |
| Operating activities | \$ (40.7) | \$ (46.7) | \$ (73.5) |
| Investing activities | (119.7) | (0.0) | 67.6 |
| Financing activities | 161.7 | 53.4 | (5.6) |
| Effect of exchange rate changes on cash and cash equivalents | 0.4 | 0.3 | 0.4 |
| Net increase (decrease) in cash, cash equivalents and restricted cash | \$ 1.7 | \$ 7.0 | \$ (11.1) |

Operating Activities

For the year ended December 31, 2021, net cash used in operating activities of \$40.7 million consisted of a net loss of \$62.5 million and cash provided by working capital of \$0.4 million, offset by non-cash items of \$21.4 million. The non-cash items primarily consisted of \$11.3 million of net amortization of intangible assets, \$9.4 million of stock-based compensation expense, \$2.9 million of depreciation, \$2.8 million gain on extinguishment of debt, \$2.0 million change in fair value of warrant liabilities, \$1.6 million change in fair value of contingent consideration, \$0.5 million change in inventory reserves, \$0.4 million of accretion of discounts and amortization of premiums on investments, net, \$0.2 million deferred tax expense and \$0.1 million bad debt expense. The decrease in cash from changes in working capital included a \$4.5 million increase in operating lease liabilities, a \$4.3 million increase in operating lease right-of-use assets, a \$0.6 million increase in inventories net of transfers to property and equipment, a \$1.6 million increase in accounts payable, a \$1.3 million increase in tax credit receivable, a \$0.9 million increase in other current and long-term assets, a \$0.5 million decrease in accrued expenses, a \$0.2 million decrease in accounts receivable, a \$0.2 million decrease in deferred revenue, and a \$0.1 million decrease in prepaid expenses.

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 \$7.7 million, offset by non-cash items of \$20.3 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, \$3.0 million change in inventory reserves, \$2.9 million change in fair value of contingent consideration, \$2.9 million of depreciation, \$1.5 million deferred tax benefit, and \$0.3 million change in fair value of warrant liabilities. The decrease in cash from changes in working capital included \$4.2 million increase in inventories, \$2.2 million decrease in accrued expenses, \$1.8 million decrease in accounts payable, \$1.2 million decrease in operating lease liabilities, \$1.1 million decrease in operating lease right-of-use assets, \$0.8 million decrease in prepaid expenses, \$0.4 million increase in accounts receivable, \$0.4 million decrease in other current and long term assets, \$0.1 million decrease in other long term liabilities, 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, \$10.3 million of net amortization of intangible assets, \$1.5 million amortization of debt discount and debt issuance costs, \$0.3 million net amortization of discounts and premiums on investments, \$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 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 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, \$6.1 million decrease in accounts receivable, \$5.4 million other current and long-term assets, \$2.5 million decrease in operating lease liabilities, \$2.5 million decrease in prepaid expenses, \$2.4 million other long-term liabilities, \$2.3 million decrease in operating lease right-of-use assets, \$1.0 million decrease in deferred revenue, \$0.7 million decrease in accounts payable. The decrease in cash from changes in working capital was primarily driven by an increase in manufacturing activities combined with decreased Senhance System sales for the year ended December 31, 2019.

Investing Activities

For the year ended December 31, 2021, net cash used in investing activities was \$119.7 million. This amount primarily consists of \$122.3 million in purchases of available-for-sale investments, \$1.4 million in purchases of property and equipment, offset by \$4.0 million proceeds from maturities of available-for-sale securities.

For the year ended December 31, 2020, net cash used in investing activities was not significant.

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 available-for-sale investments and \$16.0 million in proceeds related to the sale of the AutoLap assets, offset by \$12.9 million purchase of available-for-sale investments and \$0.4 million purchases of property and equipment.

Financing Activities

For the year ended December 31, 2021, net cash provided by financing activities was \$161.7 million. The net change primarily related to \$131.9 million in proceeds from the issuance of shares of our common stock in equity financings, net of issuance costs, \$30.9 million in proceeds from the exercise of stock options and warrants, partially offset by \$1.1 million in taxes paid related to the net share settlement of vesting of restricted stock units.

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 net proceeds from the issuance of common stock, preferred stock, and warrants under the March 2020 Public Offering, \$33.8 million in net proceeds from the issuance 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 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 cannot assure you that additional financing will not be required in the future to support our operations. We intend to use financing opportunities strategically to continue to strengthen our financial position.

Cash and cash equivalents held by our foreign subsidiaries totaled \$4.8 million at December 31, 2021, 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.

Off-Balance Sheet Arrangements

As of December 31, 2021, 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 consolidated financial statements and notes thereto appearing in Item 8 of this Annual Report. The preparation of these consolidated 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 consolidated 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, contingent consideration, warrant liabilities, stock-based compensation, inventory, revenue recognition and income taxes.

Identifiable Intangible Assets

Identifiable intangible assets consist of purchased patent rights recorded at cost and developed technology acquired as part of 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.

Contingent Consideration

Contingent consideration is recorded as a liability and measured at fair value using a Monte-Carlo simulation utilizing significant unobservable inputs including the probability of achieving each of the potential milestones, revenue volatility, and an estimated discount rate associated with the risks of the expected cash flows attributable to the achievement of 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 consolidated 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. All remaining outstanding Series B Warrants were exercised in the first quarter 2021.

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 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.

Inventories

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

The Company's revenue consists of product revenue resulting from the sale and lease of Senhance Systems, Senhance 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 Senhance System sale arrangements generally include a five-year service period;

the first year of service is generally free and included in the Senhance System sale arrangement and the remaining four years are generally included at a stated service price.

The Company's Senhance 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 Senhance System sale arrangements may include a combination of the following performance obligations: system(s), system components, instruments, accessories, and system services.

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 may not be 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 when or 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 Senhance Systems and Senhance System components sold directly to end customers (including those arising from System purchases under lease rights to purchase), 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 lease buyouts, where the customer has already acknowledged installation of the system, transfer of control occurs when we receive an executed contract for the lease buyout of the Senhance System. For Senhance Systems sold through distributors, for which distributors are responsible for installation, revenue is recognized generally at the time of shipment. The Company's Senhance System arrangements generally do not provide a right of return. The Senhance 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.

We enter into lease arrangements for our Senhance Systems 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 instruments, accessories, and services. For some lease arrangements, the customers are provided with the right to purchase the leased Senhance 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 Senhance System. In determining whether a transaction should be classified as a sales-type, operating, or direct financing lease, we consider 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 Senhance System, (3) whether the lease term is for the major part of the remaining economic life of the leased Senhance System, (4) whether the lease grants the lessee an option to purchase the leased Senhance System that the lessee is reasonably certain to exercise, and (5) whether the underlying Senhance 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, 2021 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 Senhance System usage and is presented as product revenue.

We invoice our 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. 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.

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 and 2021, no GILTI tax has been recorded.

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 exposed to changes in foreign currency exchange rates. Operations outside of the United States accounted for 87% and 73% of revenue for 2021 and 2020, respectively, and are concentrated principally in Europe. We translate the revenue and expenses of our foreign operations using average exchange rates prevailing during the period. The effect of a 10% change in the average foreign currency exchange rates among the U.S. dollar versus the Euro for the year ended December 31, 2021, would result in revenue changing by \$0.8 million. This change would be material to our cash flows and our results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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Report of Independent Registered Public Accounting Firm

Shareholders 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, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) and our report dated February 28, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate 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 critical audit matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Inventories Valuation

Inventories totaled approximately \$15.7 million at December 31, 2021, including approximately \$7.1 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 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 as well as the Company's assumptions with respect to expected sale and lease terms of future arrangements related to the Senhance Systems.

Contingent Consideration Valuation

As described in Notes 2 and 6 of the Company's consolidated financial statements, the Company has recorded a contingent consideration liability of approximately \$2.4 million related to the Senhance acquisition. Contingent consideration is recorded as the estimated fair value of potential milestone payments to be made related to the acquisition. Contingent consideration is measured using a Monte-Carlo simulation utilizing significant unobservable inputs including the probability of achieving each of the potential milestones, future Euro-to-USD exchange rates, revenue volatility and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones.

We have identified management's estimation of the contingent consideration liability as a critical audit matter. Due to the Company's limited sales history, the inherent uncertainty involved in estimating long-range forecasts, and the complexity of the Monte-Carlo simulation utilized by management auditing the contingent consideration liability required increased auditor effort including the use of valuation specialists.

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

- Evaluating the reasonableness of management's forecast of future revenues by comparing against historical operating results, relevant market data, analyst expectations for the Company and discussions with the Company's research and development personnel knowledgeable about changes in the Company's product life cycles.
- Utilizing professionals with specialized knowledge and skills in valuation to assist in evaluating the valuation methodology selected by management as well as assessing the reasonableness of key inputs including the discount rate and revenue volatility.

/s/ BDO USA, LLP

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

Raleigh, North Carolina
February 28, 2022

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited Asensus Surgical Inc.'s (the "Company's") internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated February 28, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ BDO USA, LLP

Raleigh, North Carolina
February 28, 2022

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

| | <u>December 31, 2021</u> | <u>December 31, 2020</u> |
|--|--------------------------|--------------------------|
| Assets | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 18,129 | \$ 16,363 |
| Short-term investments, available-for-sale | 80,262 | - |
| Accounts receivable, net | 749 | 1,115 |
| Inventories | 8,634 | 10,034 |
| Prepaid expenses | 3,255 | 3,535 |
| Employee retention tax credit receivable | 1,311 | - |
| Other current assets | 957 | 2,966 |
| Total Current Assets | 113,297 | 34,013 |
| Restricted cash | 1,154 | 1,166 |
| Long-term investments, available-for-sale | 37,435 | - |
| Inventories, net of current portion | 7,074 | 8,813 |
| Property and equipment, net | 10,971 | 10,342 |
| Intellectual property, net | 9,892 | 22,267 |
| Net deferred tax assets | 288 | 307 |
| Operating lease right-of-use assets, net | 5,348 | 1,164 |
| Other long-term assets | 1,014 | 186 |
| Total Assets | \$ 186,473 | \$ 78,258 |
| Liabilities and Stockholders' Equity | | |
| Current Liabilities: | | |
| Accounts payable | \$ 3,448 | \$ 1,965 |
| Accrued expenses | 5,176 | 5,615 |
| Operating lease liabilities - current portion | 683 | 686 |
| Deferred revenue | 543 | 789 |
| Notes payable - current portion, net of debt discount | - | 1,228 |
| Total Current Liabilities | 9,850 | 10,283 |
| Long-Term Liabilities: | | |
| Contingent consideration | 2,371 | 3,936 |
| Noncurrent operating lease liabilities | 5,006 | 628 |
| Notes payable, less current portion | - | 1,587 |
| Warrant liabilities | - | 255 |
| Total Liabilities | 17,227 | 16,689 |
| Commitments and Contingencies (Note 20) | | |
| Stockholders' Equity: | | |
| Common stock \$0.001 par value, 750,000,000 shares authorized at December 31, 2021 and December 31, 2020; 235,218,552 and 116,231,072 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively | 235 | 116 |
| Preferred stock, \$0.01 par value, 25,000,000 shares authorized, no shares issued and outstanding at December 31, 2021 and December 31, 2020 | - | - |
| Additional paid-in capital | 954,649 | 781,397 |
| Accumulated deficit | (785,374) | (722,912) |
| Accumulated other comprehensive income | (264) | 2,968 |
| Total Stockholders' Equity | 169,246 | 61,569 |
| Total Liabilities and Stockholders' Equity | \$ 186,473 | \$ 78,258 |

See accompanying notes to consolidated financial statements.

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

| | Year ended December 31, | | |
|---|----------------------------|-------------|--------------|
| | 2021 | 2020 | 2019 |
| Revenue: | | | |
| Product | \$ 6,712 | \$ 1,612 | \$ 7,104 |
| Service | 1,520 | 1,563 | 1,427 |
| Total revenue | 8,232 | 3,175 | 8,531 |
| Cost of revenue: | | | |
| Product | 7,974 | 2,254 | 16,439 |
| Service | 3,122 | 2,912 | 4,292 |
| Total cost of revenue | 11,096 | 5,166 | 20,731 |
| Gross loss | (2,864) | (1,991) | (12,200) |
| Operating Expenses: | | | |
| Research and development | 19,348 | 16,621 | 22,468 |
| Sales and marketing | 13,395 | 13,064 | 28,014 |
| General and administrative | 19,323 | 14,137 | 18,758 |
| Amortization of intangible assets | 11,254 | 10,801 | 10,301 |
| Change in fair value of contingent consideration | (1,565) | 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 | 61,755 | 58,398 | 142,375 |
| Operating Loss | (64,619) | (60,389) | (154,575) |
| Other Income (Expense) | | | |
| Gain (loss) on extinguishment of debt | 2,847 | - | (1,006) |
| Change in fair value of warrant liabilities | (1,981) | (336) | 2,248 |
| Interest income | 590 | 35 | 582 |
| Interest expense | (370) | (19) | (3,607) |
| Employee retention tax credit | 1,311 | - | - |
| Other expense, net | (15) | (119) | (967) |
| Total Other Income (Expense), net | 2,382 | (439) | (2,750) |
| Loss before income taxes | (62,237) | (60,828) | (157,325) |
| Income tax (expense) benefit | (225) | 1,516 | 3,124 |
| Net loss | (62,462) | (59,312) | (154,201) |
| 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 | (62,462) | (60,023) | (154,201) |
| Comprehensive loss: | | | |
| Net loss | (62,462) | (59,312) | (154,201) |
| Foreign currency translation (loss) gain | (2,985) | 4,338 | (2,708) |
| Unrealized loss on available-for-sale investments | (247) | - | - |
| Comprehensive loss | \$ (65,694) | \$ (54,974) | \$ (156,909) |
| Net loss per common share attributable to common stockholders - basic and diluted | \$ (0.28) | \$ (0.85) | \$ (8.69) |
| Weighted average number of shares used in computing net loss per common share - basic and diluted | 226,960 | 70,809 | 17,737 |

See accompanying notes to consolidated financial statements.

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

| | Common Stock | | Preferred Stock | | Treasury Stock | | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|--|--------------|--------|-----------------|--------|----------------|--------|-------------------------------|------------------------|---|-------------------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | | | | |
| Balance, December 31, 2018 | 16,642 | \$ 17 | - | \$ - | - | \$ - | \$ 676,572 | \$ (509,406) | \$ 1,338 | \$ 168,521 |
| Stock-based compensation | - | - | - | - | - | - | 11,508 | - | - | 11,508 |
| Issuance of common stock, net of issuance costs | 3,571 | - | - | - | - | - | 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 | - | - | - | - | - | - | (7) | 7 | - | - |
| Other comprehensive loss | - | - | - | - | - | - | - | - | (2,708) | (2,708) |
| Net loss | - | - | - | - | - | - | - | (154,201) | - | (154,201) |
| Balance, December 31, 2019 | 20,691 | \$ 21 | - | \$ - | - | \$ - | \$ 720,484 | \$ (663,600) | \$ (1,370) | \$ 55,535 |
| Stock-based compensation | - | - | - | - | - | - | 7,911 | - | - | 7,911 |
| Issuance of common stock, preferred stock and warrants under 2020 financing, net of issuance costs | 14,122 | - | 7,937 | - | - | 79 | 13,384 | - | - | 13,477 |
| Issuance of common stock, net of issuance costs | 66,241 | - | - | - | - | - | 33,780 | - | - | 33,846 |
| Conversion of preferred stock to common stock | 7,937 | - | (7,937) | - | - | (79) | 71 | - | - | - |
| Exchange of shares for Series B Warrants | 2,041 | - | - | - | - | - | 2,468 | - | - | 2,470 |
| Exercise of stock options and warrants | 4,913 | - | - | - | - | - | 3,335 | - | - | 3,340 |
| Award of restricted stock units | 286 | - | - | - | - | - | (36) | - | - | (36) |
| Return of common stock to pay withholding taxes on restricted stock | - | - | - | - | 28 | - | - | - | - | - |
| Cancellation of treasury stock | - | - | - | - | (28) | - | - | - | - | - |
| Other comprehensive income | - | - | - | - | - | - | - | - | 4,338 | 4,338 |
| Net loss | - | - | - | - | - | - | - | (59,312) | - | (59,312) |
| Balance, December 31, 2020 | 116,231 | \$ 116 | - | \$ - | - | \$ - | \$ 781,397 | \$ (722,912) | \$ 2,968 | \$ 61,569 |
| Stock-based compensation | - | - | - | - | - | - | 9,429 | - | - | 9,429 |
| Issuance of common stock, net of issuance costs | 71,787 | - | - | - | - | - | 131,857 | - | - | 131,929 |
| Exercise of stock options and warrants | 45,630 | - | - | - | - | - | 33,029 | - | - | 33,075 |
| Award of restricted stock units | 1,571 | - | - | - | - | - | - | - | - | 1 |
| Return of common stock to pay withholding taxes on restricted stock | - | - | - | - | 320 | - | (1,063) | - | - | (1,063) |
| Cancellation of treasury stock | - | - | - | - | (320) | - | - | - | - | - |
| Other comprehensive loss | - | - | - | - | - | - | - | - | (3,232) | (3,232) |
| Net loss | - | - | - | - | - | - | - | (62,462) | - | (62,462) |
| Balance, December 31, 2021 | 235,219 | \$ 235 | - | \$ - | - | \$ - | \$ 954,649 | \$ (785,374) | \$ (264) | \$ 169,246 |

See accompanying notes to consolidated financial statements.

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

| | Year Ended December 31, | | |
|--|-------------------------|-------------|--------------|
| | 2021 | 2020 | 2019 |
| Operating Activities: | | | |
| Net loss | \$ (62,462) | \$ (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 | 2,857 | 2,898 | 2,166 |
| Amortization of intangible assets | 11,254 | 10,801 | 10,301 |
| Amortization of debt discount and debt issuance costs | - | - | 1,513 |
| Amortization of discounts and premiums on investments, net | 409 | - | (327) |
| Stock-based compensation | 9,429 | 7,911 | 11,508 |
| Interest expense on deferred consideration - MST acquisition | - | - | 756 |
| (Gain) loss on extinguishment of debt | (2,847) | - | 1,006 |
| Deferred tax expense (benefit) | 225 | (1,516) | (3,124) |
| Bad debt expense | 144 | - | 1,634 |
| Change in inventory reserves | (492) | (3,034) | 8,931 |
| Change in fair value of warrant liabilities | 1,981 | 336 | (2,248) |
| Change in fair value of contingent consideration | (1,565) | 2,924 | (9,553) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | 174 | (447) | 6,083 |
| Inventories | (611) | (4,164) | (16,404) |
| Operating lease right-of-use assets | (4,254) | 1,106 | 2,271 |
| Prepaid expenses | 146 | 824 | 2,541 |
| Employee retention tax credit receivable | (1,311) | - | - |
| Other current and long-term assets | 902 | 366 | (5,441) |
| Accounts payable | 1,614 | (1,758) | (668) |
| Accrued expenses | (475) | (2,219) | (168) |
| Deferred revenue | (229) | (105) | (959) |
| Operating lease liabilities | 4,452 | (1,203) | (2,515) |
| Other long-term liabilities | - | (83) | 2,401 |
| Net cash and cash equivalents used in operating activities | (40,659) | (46,675) | (73,484) |
| Investing Activities: | | | |
| Proceeds from sale of AutoLap assets | - | - | 15,965 |
| Purchase of available-for-sale investments | (122,330) | - | (12,883) |
| Proceeds from maturities of available-for-sale investments | 4,030 | - | 65,000 |
| Purchase of property and equipment | (1,368) | (3) | (437) |
| Net cash and cash equivalents used in investing activities | (119,668) | (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 | 131,929 | 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 | (1,063) | (36) | (499) |
| Payment of contingent consideration | - | (74) | - |
| Proceeds from exercise of stock options and warrants | 30,839 | 3,340 | 538 |
| Net cash and cash equivalents provided by financing activities | 161,705 | 53,370 | (5,609) |
| Effect of exchange rate changes on cash and cash equivalents | 376 | 270 | 364 |
| Net increase in cash, cash equivalents and restricted cash | 1,754 | 6,962 | (11,084) |
| Cash, cash equivalents and restricted cash, beginning of period | 17,529 | 10,567 | 21,651 |
| Cash, cash equivalents and restricted cash, end of period | \$ 19,283 | \$ 17,529 | \$ 10,567 |

See accompanying notes to consolidated financial statements.

| | Year Ended December 31, | | |
|--|-------------------------|----------|----------|
| | 2021 | 2020 | 2019 |
| Supplemental Disclosure for Cash Flow Information: | | | |
| Interest paid | \$ - | \$ - | \$ 2,187 |
| Cash paid for taxes | \$ 170 | \$ 82 | \$ 75 |
| Supplemental Schedule of Non-cash Investing and Financing Activities: | | | |
| Transfer of inventories to property and equipment | \$ 3,244 | \$ 8,113 | \$ 486 |
| Right-of-use assets recognized related to new lease obligations | \$ 5,119 | \$ - | \$ - |
| Reclass of warrant liability to common stock and additional paid-in capital | \$ 2,236 | \$ - | \$ - |
| 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

Asensus Surgical, Inc. (formerly known as TransEnterix, 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 3mm microlaparoscopic instruments, 5mm articulating 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 has received its registration certificate by the Russian medical device regulatory agency, Roszdravnadzor, allowing for its sale and utilization throughout the Russian Federation.

In 2020, the Company obtained regulatory clearance for the Senhance ultrasonic system in Taiwan and Japan. On February 12, 2020, the Company expanded its claims in the EU 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 3mm diameter instruments, will prove to be an effective tool in surgery with smaller patients.

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, the Company announced the first surgical procedures successfully completed using the ISU. On September 1, 2021, the Company announced that it received FDA clearance for an expansion of machine vision capabilities. On January 19, 2021, the Company announced that it received CE Mark for the ISU. Lastly, on July 28, 2021, the Company announced that it received FDA clearance for 5mm diameter articulating instruments, offering better access to difficult-to-reach areas of the anatomy by providing two additional degrees of freedom. These instruments have previously received CE Mark for use in the EU.

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.

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 inter-company accounts and transactions have been eliminated in consolidation.

Reclassifications

Certain amounts reported previously have been reclassified to conform to the current year presentation, with no effect on stockholders' equity or net loss as previously reported. These reclassifications relate to the (gain) loss on extinguishment of debt which was historically included in interest expense on the consolidated statements of operations for the year ended December 31, 2019.

Liquidity

The Company had an accumulated deficit of \$785.4 million and working capital of \$103.4 million as of December 31, 2021. The Company has not established sufficient sales revenues to cover its operating costs and believes it may require additional capital in the future 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.

In 2021, the Company raised additional capital through equity offerings, including raising net proceeds of \$73.4 million in a January 2021 public offering, \$28.6 million in a January 2021 registered direct offering, and \$27.3 million in an at-the-market offering launched in 2020 (the "2020 ATM Offering"). Additionally, in 2021, the Company launched the 2021 ATM Offering and raised proceeds, net of legal costs and commissions, of \$2.8 million under this offering during the year ended December 31, 2021. Also, certain holders of our Series B, Series C, and D warrants to purchase shares of our common stock exercised such warrants in 2021 for aggregate proceeds to the Company of \$30.6 million.

As of December 31, 2021, the Company had cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of \$135.8 million.

While the Company believes that its existing cash, cash equivalents, and short-term investments as of December 31, 2021 will be sufficient to sustain operations for at least the next 12 months from the issuance of these consolidated financial statements, the Company believes it may need to obtain additional financing in the future to proceed with its business plan. Management's plan to obtain additional resources for the Company may include additional sales of equity under the 2021 ATM Offering or otherwise, 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 and be able to secure additional funding when needed on terms acceptable to the Company, or at all.

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, including new variants of the virus; 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 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 company; competition in the market for robotic surgical devices; and its ability to identify and pursue development of additional products.

The COVID-19 pandemic had a significant impact on the Company in 2021 and continues to have a significant impact on its operations, primarily due to the continued repeated 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. The Company's

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. This has significantly impacted the Company's ability to implement its market development activities to place 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.

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 consolidated 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 long-term assets, fair value estimates related to contingent consideration, warrant liabilities, stock compensation expense, revenue recognition, accounts receivable reserves, short-term and long-term investments, excess and obsolete inventory reserves, inventory classification between current and non-current, measurement of lease liabilities and corresponding right-of-use ("ROU") assets, and deferred tax asset valuation allowances.

Principles of Consolidation and Foreign Currency Considerations

The accompanying consolidated financial statements include the accounts of the Company and its direct and indirect wholly owned subsidiaries, Asensus Surgical US, Inc., Asensus International, Inc., Asensus Surgical Italia S.r.l., Asensus Surgical Europe S.à.r.l., Asensus Surgical Taiwan Ltd., Asensus Surgical Japan K.K., Asensus Surgical Israel Ltd., Asensus Surgical Netherlands B.V., and Asensus Surgical Canada, Inc. All inter-company accounts and transactions have been eliminated in consolidation.

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, 2021, 2020, and 2019 were not significant.

Cash and Cash Equivalents, Restricted Cash, and Investments

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 as of December 31, 2021 and 2020 includes \$1.2 million and \$1.2 million, respectively, in cash accounts held as collateral primarily under the terms of an office operating lease, credit cards, and automobile leases.

The Company's investments as of December 31, 2021 consisted of commercial paper and corporate bonds and were classified as available-for-sale. Investments classified as available-for-sale are measured at fair value, and net unrealized gains and losses are recorded as a component of accumulated other comprehensive income (loss) on the consolidated balance sheets until realized. Realized gains and losses on sales of investment securities are determined based on the specific-identification method and are recorded in interest income, net. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity computed under the effective interest method. Such amortization and accretion is included in interest expense, net. The Company held no investments as of December 31, 2020. The Company recognized an immaterial amount of gross realized losses for the year ending December 31, 2021. There were no gross realized gains for the year ended December 31, 2021. There were no gross realized gain or losses recorded for the years ended December 31, 2020 and 2019. The Company reclassified an immaterial amount of unrealized losses from accumulated other comprehensive income (loss) for the year ended December 31, 2021 with no related reclassification for the years ended December 31, 2020 and 2019. Investments with remaining maturities at date of

purchase greater than 90 days and remaining maturities as of the reporting period less than one year are classified as short-term investments. Investments with remaining maturities greater than one year are classified as long-term investments.

Concentrations and Credit Risk

The Company's principal financial instruments subject to potential concentration of credit risk are cash and cash equivalents, and investments, including amounts held in money market funds, commercial paper, and corporate bonds. 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. Investments are stated at their estimated fair values, based on quoted market prices for the same or similar instruments. The counterparties to the agreements relating to the Company's investments consist of various major corporations, financial institutions, and government agencies of high credit standing.

The Company's accounts receivable are derived from sales and leases 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 \$0.1 million, \$0 million, and \$1.6 million in bad debt charges during the years ended December 31, 2021, 2020 and 2019, respectively. The Company had three customers who constituted 61% of the Company's net accounts receivable as of December 31, 2021. The Company had seven customers who constituted 68% of the Company's net accounts receivable at December 31, 2020. The Company had two customers who accounted for 52% of revenue in 2021, 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 \$1.7 million and \$1.8 million as of December 31, 2021 and December 31, 2020, 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

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 in-process research and development ("IPR&D") assets related to (i) the Senhance System acquired in 2015 and reclassified in 2017 and (ii) the MST acquisition 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, 2021, 2020 and 2019.

Indefinite-Lived Intangible Assets

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 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 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.

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, and purchased software which are recorded at cost less accumulated depreciation. Depreciation is recorded using the straight-line method over the estimated useful lives of the assets as follows:

| | Years |
|---|------------------------------------|
| 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 |
| Purchased Software | 5 |

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, 2021, 2020, and 2019.

Operating Leases

We have operating leases for our corporate office buildings, vehicles, and machinery and equipment. At inception, we determine whether an agreement represents a lease and, at commencement, we evaluate each lease agreement to determine whether the lease constitutes an operating or financing lease.

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. Non-lease components consist of common area maintenance payments for most real estate leases, which are determined based on costs incurred by the lessor. 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.

Adoption of ASU No. 2016-02 did not have a material impact on the Company's cash flows from operations or the Company's operating results. The most significant impact was the recognition of operating lease right-of-use assets and operating lease liabilities on our balance sheet. Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, we utilize the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms.

Employee Retention Tax Credit Receivable

The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") included an Employee Retention Tax Credit ("ERTC") provision designed to encourage employers to keep employees on their payroll. The ERTC is a refundable tax credit against certain payroll taxes paid by employers for eligible wages. We assessed the government assistance in accordance with Topic 958-605, Not for Profit Entities-Revenue Recognition, and concluded it represents a conditional non-exchange transaction that is recognized when the conditions have been substantially met. During the year ended December 31, 2021, we submitted an ERTC refund for \$1.3 million and recorded the amount into Other Income (Expense) on the consolidated statements of operations and comprehensive loss. The Company believes the relevant conditions of the employee retention credit provision of the CARES Act have been substantially met and that it will receive the credit.

Notes Payable – Payroll Protection Program

The Company's policy is to account for forgivable loans received through the U.S. Small Business Administration (the "SBA") under the CARES Act Payroll Protection Program ("PPP"), as debt in accordance with ASC 470, Debt, and other related accounting pronouncements. The forgiveness of debt, in whole or part, is recognized once the debt is extinguished, which occurs when the Company is legally released from the liability by the SBA. Any portion of debt forgiven, adjusted for accrued interest forgiven and unamortized debt issuance costs, is recorded as a gain on extinguishment of debt, and presented in the consolidated statements of operations and comprehensive loss. On June 10, 2021, the Company received notification from the SBA that the principal amount of its PPP loan of \$2.8 million and related interest had been forgiven.

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 Monte-Carlo simulation utilizing significant unobservable inputs including the probability of achieving each of the potential milestones, future Euro-to-USD exchange rates, revenue volatility 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.

On September 21, 2015, the Company completed the strategic acquisition, through its wholly owned subsidiary TransEnterix International, from Sofar S.p.A., an Italian company ("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, as amended in 2016, as of December 31, 2021, the Company has accrued \$2.4 million of estimated fair value of remaining contingent consideration related to a milestone 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 or 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.

Warrant Liabilities

The Company's Series B Warrants (see Note 16) were measured at fair value using a simulation model which took 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. The warrant liability was revalued at each reporting period and changes in fair value were 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. All remaining outstanding Series B Warrants were exercised in the first quarter 2021.

Revenue Recognition

The Company's revenue consists of product revenue resulting from the sale and lease of Senhance Systems, Senhance 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 Senhance System sale arrangements generally include a five-year service period; the first year of service is generally free and included in the Senhance System sale arrangement and the remaining four years are generally included at a stated service price.

The Company's Senhance 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 Senhance System sale arrangements may include a combination of the following performance obligations: system(s), system components, instruments, accessories, and system services.

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 when or 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 Senhance Systems and Senhance System components sold directly to end customers (including those arising from Senhance System purchases under lease rights to purchase), 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 lease buyouts, where the customer has already acknowledged installation of the system, transfer of control occurs when the Company receives an executed contract for the lease buyout of the Senhance System. For Senhance Systems sold through distributors, for which distributors are responsible for installation, revenue is recognized generally at the time of shipment. The Company's Senhance System arrangements generally do not provide a right of return. The Senhance 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:

| | Years Ended December 31, | | |
|--------------------------------|--------------------------|----------|----------|
| | 2021 | 2020 | 2019 |
| | (in thousands) | | |
| U.S. | | | |
| Systems | \$ 380 | \$ 282 | \$ 90 |
| Instruments and accessories | 270 | 187 | 108 |
| Services | 383 | 380 | 338 |
| Total U.S. revenue | 1,033 | 849 | 536 |
| Outside of U.S. ("OUS") | | | |
| Systems | 4,363 | 490 | 5,459 |
| Instruments and accessories | 1,699 | 653 | 1,447 |
| Services | 1,137 | 1,183 | 1,089 |
| Total OUS revenue | 7,199 | 2,326 | 7,995 |
| Total | | | |
| Systems | 4,743 | 772 | 5,549 |
| Instruments and accessories | 1,969 | 840 | 1,555 |
| Services | 1,520 | 1,563 | 1,427 |
| Total revenue | \$ 8,232 | \$ 3,175 | \$ 8,531 |

The Company recognizes sales by geographic area based on the country in which the customer is based. Operating lease revenue from Senhance System leasing is included as Systems revenues in the above table and was approximately \$1.3 million, \$0.7 million, and \$0 million in the years ended December 31, 2021, 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 \$3.0 million, \$3.1 million, and \$3.7 million as of December 31, 2021, 2020, and 2019, respectively. The amounts as of December 31, 2021 are expected to be recognized as revenue over one to five years.

The Company invoices its customers based on the billing schedules in its sales arrangements. Payments are generally due 30 to 60 days from the date of invoice. 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 \$0.1 million as of December 31, 2021 and 2020, 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, 2021, 2020 and 2019 that was included in the deferred revenue balance at the beginning of each reporting period was \$0.6 million, \$0.6 million and \$1.0 million, respectively.

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 instruments, accessories, and services. For some lease arrangements, the customers are provided with the right to purchase the leased Senhance 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 Senhance System.

In determining whether a transaction should be classified as a sales-type, operating, or direct financing 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 Senhance 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 Senhance System that the lessee is reasonably certain to exercise, and (5) whether the underlying Senhance 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, 2021 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 Senhance System usage and is presented as product revenue. Revenue related to lease elements from operating lease arrangements was approximately \$1.3 million, \$0.7 million, \$0 million for the years ended December 31, 2021, 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. Depreciation expense related to leased systems is included in the cost of revenue. Shipping and handling costs incurred by the Company are included in the cost of revenue. We expense all inventory obsolescence provisions as cost of revenue.

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 recognizes expenses for share-based awards exchanged for services rendered equal to 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 stock options. The volatility assumption used in the Black-Scholes-Merton model is based on 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. For awards with performance conditions, we begin recognizing compensation expense when it becomes probable that the performance condition will be attained.

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 \$9.4 million, \$7.9 million, and \$11.5 million for the years ended December 31, 2021, 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.

Revision of Previously Disclosed Amounts

During the course of preparing the Company's consolidated financial statements as of and for the year ended December 31, 2021, the Company completed an Internal Revenue Code Section 382 and 383 analysis of its historical net operating loss and tax credit carryforward amounts. As a result, a portion of the prior year net operating loss and tax credit carryforwards were determined to be limited. See Note 11—Income Taxes, for further details.

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 77% and 27% of the Company's total consolidated assets are located within the U.S. as of December 31, 2021 and 2020, respectively. The remaining assets are mostly located in Europe and are primarily related to the Company's facility in Italy, and include intellectual property, other current assets, property and equipment, cash, accounts receivable, other long-term assets and inventory of \$43.2 million and \$56.8 million as of December 31, 2021 and 2020, respectively. Total assets outside of the United States amounted to 23% and 73% of total consolidated assets at December 31, 2021 and 2020, respectively. Long-lived assets in the U.S. were 63% and 11%, Switzerland were 22% and 41%, and Italy were 13% and 48%, as of December 31, 2021 and 2020, respectively.

The Company recognizes sales by geographic area based on the country in which the customer is based. For the years ended December 31, 2021, 2020 and 2019, 13%, 27% and 6%, respectively, of net revenue was generated in the United States; while 62%, 53% and 39%, respectively, was generated in Europe; and 25%, 20%, and 55%, respectively, was generated in Asia. For the year ended December 31, 2021, 47% of net revenue was generated in Germany, 22% was generated in Japan, and 13% was generated in the United States. For the year ended December 31, 2020, 28% of net revenue was generated in Germany, 27% was generated in the United States, 10% was generated in Japan, and 10% was generated in Taiwan. For the year ended December 31, 2019, 53% of net revenue was generated in Taiwan, and 23% was generated in Germany.

Impact of Recently Issued Accounting Standards

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. The Company adopted ASU 2019-12 effective January 1, 2021; the adoption did not result in 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, 2021, 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. 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. Following the Amendment, 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 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, 2021 and 2020 at their estimated fair value.

4. Cash, Cash Equivalents, and Restricted Cash

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

| | December 31, 2021 | December 31, 2020 |
|---------------------------------|----------------------|----------------------|
| | (in thousands) | |
| Cash | \$ 8,343 | \$ 6,679 |
| Money Market | 5,287 | 9,684 |
| Commerical Paper | 4,499 | - |
| Total cash and cash equivalents | \$ 18,129 | \$ 16,363 |
| Restricted Cash | 1,154 | 1,166 |
| Total | \$ 19,283 | \$ 17,529 |

Restricted cash at December 31, 2021 and 2020 includes \$1.2 million and \$1.2 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. Investments, available-for-sale

The aggregate fair values of investment securities along with unrealized gains and losses determined on an individual investment security basis and included in other comprehensive income are as follows:

| December 31, 2021 (in thousands) | | | | | | |
|-------------------------------------|-------------------|--------------------|--------------------|------------|---------------------------|--------------------------|
| | Amortized Cost | Unrealized Gain | Unrealized Loss | Fair Value | Short-term investments | Long-term investments |
| Commerical Paper | \$ 50,705 | \$ - | \$ (46) | \$ 50,659 | \$ 50,660 | \$ - |
| Corporate Bonds | 67,239 | 1 | (202) | 67,038 | 29,602 | 37,435 |
| Total Investments | \$ 117,944 | \$ 1 | \$ (248) | \$ 117,697 | \$ 80,262 | \$ 37,435 |

The following table summarizes the contractual maturities of the Company's available-for-sale investments, as of December 31, 2021:

| | Amortized Cost | Fair Value |
|------------------------------|-------------------|------------|
| Mature in less than one year | \$ 80,336 | \$ 80,262 |
| Mature in one to two years | 37,608 | 37,435 |
| Total | \$ 117,944 | \$ 117,697 |

Actual maturities may differ from contractual maturities because certain borrowers have the right to call or prepay certain obligations. There were no sales of investments or gross realized gains for the years ended December 31, 2021, 2020 and 2019, respectively. The Company recorded an immaterial amount of gross realized losses for the year ended December 31, 2021 related to the maturity of investments.

6. 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, 2021 and 2020.

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 revenue volatility, 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.

The carrying values of accounts receivable, other current assets, accounts payable, and certain accrued expenses as of December 31, 2021 and 2020 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, 2021 and 2020, 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, 2021

(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 ⁽¹⁾ | \$ 18,129 | \$ - | \$ - | \$ 18,129 |
| Restricted cash | 1,154 | - | - | 1,154 |
| Short-term investments | - | 80,262 | - | 80,262 |
| Long-term investments | - | 37,435 | - | 37,435 |
| Total assets measured at fair value | \$ 19,283 | \$ 117,697 | \$ - | \$ 136,980 |
| Liabilities measured at fair value | | | | |
| Contingent consideration | \$ - | \$ - | \$ 2,371 | \$ 2,371 |
| Total liabilities measured at fair value | \$ - | \$ - | \$ 2,371 | \$ 2,371 |

⁽¹⁾ Includes investments that are readily convertible to cash with original maturities of 90 days or less.

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 | \$ 17,529 | \$ - | \$ - | \$ 17,529 |
| Liabilities measured at fair value | | | | |
| Contingent consideration | \$ - | \$ - | \$ 3,936 | \$ 3,936 |
| Warrant liabilities | - | - | 255 | 255 |
| Total liabilities measured at fair value | \$ - | \$ - | \$ 4,191 | \$ 4,191 |

The Company's financial liabilities consisted of contingent consideration payable to Sofar related to the Senhance Acquisition (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 a Monte-Carlo simulation utilizing significant unobservable inputs including the probability of achieving each of the potential milestones, future Euro-to-USD exchange rates, revenue volatility and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones. The decrease in fair value of the contingent consideration of \$1.6 million for the year ended December 31, 2021 was primarily due to changes in the Company's forecast of future revenue. The increase in fair value of the contingent consideration of \$2.9 million for the year ended December 31, 2020 was primarily due to lower discount rate, stronger Euro versus the U.S. dollar, and the passage of time. The decrease in the fair value of the contingent consideration of \$9.6 million for the year ended December 31, 2019 was primarily due to the change in the Company's forecast of future revenue. 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 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, 2021 and 2020:

| | Valuation Methodology | Significant Unobservable Input | December 31, | |
|--------------------------|--------------------------------------|--------------------------------|--------------|-------|
| | | | 2021 | 2020 |
| Contingent consideration | Probability weighted income approach | Milestone dates | 2031 | 2025 |
| | | Discount rate | 9.5% | 9.5% |
| | | Revenue volatility | 39.0% | 71.0% |

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 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. All of the Series A Warrants were exercised prior to the expiration date of October 31, 2017. On February 24, 2020, the Company entered into a Series B Warrants Exchange Agreement (the "Exchange Agreement") with certain holders of its unexercised 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 final remeasurement upon exercise of the Series B warrants was recorded during the first quarter of 2021 and all outstanding Series B Warrants were exercised.

The change in fair value of all outstanding Series B warrants for the years ended December 31, 2021 and 2020 was an increase of \$2.0 million and \$0.3 million, respectively, was included in the Company's consolidated statements of operations and comprehensive loss and was primarily due to an increase in share price, a lower risk free rate, increased volatility, and the passage of time. The change in the fair value of all outstanding Series B warrants for the year ended December 31, 2019, was a decrease of \$2.2 million. The following table presents the inputs and valuation methodologies used for the Company's fair value of the Series B warrants:

| Series B Warrants | December 31, 2021 | December 31, 2020 | December 31, 2019 |
|-----------------------|----------------------|----------------------|----------------------|
| Valuation methodology | Black-Scholes-Merton | Black-Scholes-Merton | Monte Carlo |
| Term (years) | 1.22 | 1.32 | 2.32 |
| Risk free rate | 0.07% | 0.10% | 1.59% |
| Dividends | - | - | - |
| Volatility | 174.00% | 150.97% | 109.80% |
| Share price | \$ 4.21 | \$ 0.63 | \$ 1.47 |

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, 2021, 2020 and 2019:

| | Fair Value Measurement at Reporting Date (Level 3) | |
|---------------------------------------|---|---------------------------------|
| | (in thousands) | |
| | Series B 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 |
| Exercise of warrants | \$ (2,236) | \$ - |
| Change in fair value | 1,981 | \$ (1,565) |
| Balance at December 31, 2021 | \$ - | \$ 2,371 |
| Current portion | \$ - | \$ - |
| Long-term portion | - | 2,371 |
| Balance at December 31, 2021 | \$ - | \$ 2,371 |

7. Accounts Receivable, Net

The following table presents the components of accounts receivable:

| | December 31, 2021 | December 31, 2020 |
|--------------------------------------|--------------------------|--------------------------|
| | (In thousands) | |
| Gross accounts receivable | \$ 2,426 | \$ 2,917 |
| Allowance for uncollectible accounts | (1,677) | (1,802) |
| Total accounts receivable, net | \$ 749 | \$ 1,115 |

The Company recorded \$0.1 million, \$0 million, and \$1.6 million in bad debt expense during the years ended December 31, 2021, 2020 and 2019, respectively.

8. Inventories

The components of inventories are as follows:

| December 31, 2021 | | | |
|--------------------------|--------------------------------------|------------------------|------------------------------------|
| (in thousands) | | | |
| | Gross Carrying Amount | Reserve Balance | Net Carrying Amount |
| Finished goods | \$ 10,566 | \$ (2,987) | \$ 7,579 |
| Raw materials | 10,824 | (2,695) | 8,129 |
| Total inventories | <u>\$ 21,390</u> | <u>\$ (5,682)</u> | <u>\$ 15,708</u> |
| Current Portion | \$ 9,931 | \$ (1,297) | \$ 8,634 |
| Long-term portion | 11,459 | (4,385) | 7,074 |
| Total inventories | <u>\$ 21,390</u> | <u>\$ (5,682)</u> | <u>\$ 15,708</u> |

| December 31, 2020 | | | |
|--------------------------|--------------------------------------|------------------------|------------------------------------|
| (in thousands) | | | |
| | Gross Carrying Amount | Reserve Balance | Net Carrying Amount |
| Finished goods | \$ 13,858 | \$ (3,109) | \$ 10,749 |
| Raw materials | 11,163 | (3,065) | 8,098 |
| Total inventories | <u>\$ 25,021</u> | <u>\$ (6,174)</u> | <u>\$ 18,847</u> |
| Current Portion | \$ 11,444 | \$ (1,410) | \$ 10,034 |
| Long-term portion | 13,577 | (4,764) | 8,813 |
| Total inventories | <u>\$ 25,021</u> | <u>\$ (6,174)</u> | <u>\$ 18,847</u> |

The Company records an inventory reserve for estimated excess and obsolete inventory based upon historical consumption and assumptions about future demand for its products. 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. The decrease in the inventory reserve balance was \$0.5 million and \$3.0 million for the twelve months ended December 31, 2021 and 2020, respectively.

9. Property and Equipment

Property and equipment consisted of the following:

| | December 31, 2021 | December 31, 2020 |
|---|------------------------------|------------------------------|
| | (In thousands) | |
| Machinery, manufacturing, and demonstration equipment | \$ 8,289 | \$ 9,909 |
| Operating lease assets - Senhance System leasing | 10,143 | 8,906 |
| Computer equipment | 325 | 2,297 |
| Furniture | 644 | 640 |
| Leasehold improvements | 1,259 | 2,309 |
| Total property and equipment | <u>20,660</u> | <u>24,061</u> |
| Accumulated depreciation and amortization | <u>(9,689)</u> | <u>(13,719)</u> |
| Property and equipment, net | <u>\$ 10,971</u> | <u>\$ 10,342</u> |

Depreciation expense was approximately \$2.9 million, \$2.9 million and \$2.2 million for the years ended December 31, 2021, 2020, 2019, respectively.

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

Goodwill

Goodwill consisted of \$93.8 million that was recorded in connection with the 2013 merger transaction with SafeStitch Medical, Inc., or the Merger, goodwill of \$38.3 million that was recorded in connection with the Senhance Acquisition, as described in Note 3, and goodwill of \$9.6 million that was recorded in connection with the MST Acquisition, as described in Note 3, before impairment of \$61.7 million that was recorded in 2016. 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 | \$ — |

The Company performed an annual impairment test of goodwill at December 31 of each year, 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 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, 2020 and 2019 is as follows:

| | In-Process Research and Development |
|--|--|
| | (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 | \$ — |

Intellectual Property

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.

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, 2021 and 2020 are as follows:

| December 31, 2021 | | | | |
|----------------------------------|--------------------------------------|-------------------------------------|--|------------------------------------|
| (in thousands) | | | | |
| | Gross Carrying Amount | Accumulated Amortization | Foreign Currency Translation Impact | Net Carrying Amount |
| Developed technology | \$ 68,838 | \$ (58,912) | \$ (262) | \$ 9,664 |
| Technology and patents purchased | 400 | (199) | 27 | 228 |
| Total intellectual property | <u>\$ 69,238</u> | <u>\$ (59,111)</u> | <u>\$ (235)</u> | <u>\$ 9,892</u> |

| December 31, 2020 | | | | |
|----------------------------------|--------------------------------------|-------------------------------------|--|------------------------------------|
| (in thousands) | | | | |
| | Gross Carrying Amount | Accumulated Amortization | Foreign Currency Translation Impact | Net Carrying Amount |
| Developed technology | \$ 68,838 | \$ (51,734) | \$ 4,872 | \$ 21,976 |
| Technology and patents purchased | 400 | (168) | 59 | 291 |
| Total intellectual property | <u>\$ 69,238</u> | <u>\$ (51,902)</u> | <u>\$ 4,931</u> | <u>\$ 22,267</u> |

The weighted average remaining useful life of the developed technology and technology and patents purchased was 1.6 years and 5.3 years, respectively as of December 31, 2021.

The estimated future amortization expense of intangible assets as of December 31, 2021 is as follows:

| | Year ending December 31, 2021 |
|------------|--|
| | (In thousands) |
| 2022 | 8,218 |
| 2023 | 400 |
| 2024 | 400 |
| 2025 | 400 |
| 2026 | 400 |
| Thereafter | 74 |
| Total | <u>\$ 9,892</u> |

11. Income Taxes

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

| | 2021 | 2020 | 2019 |
|------------------------------------|---------------|-------------------|-------------------|
| Current income taxes | | | |
| Federal | \$ - | \$ - | \$ - |
| State | - | - | - |
| Foreign | 232 | 169 | 100 |
| Deferred income taxes | | | |
| Federal | - | - | - |
| State | - | - | - |
| Foreign | (7) | (1,685) | (3,224) |
| Total income tax expense (benefit) | <u>\$ 225</u> | <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):

| | 2021 | 2020 | 2019 |
|---|--------------------|--------------------|---------------------|
| United States | \$ (32,094) | \$ (34,398) | \$ (91,935) |
| Foreign | (30,143) | (26,430) | (65,390) |
| Total loss from operations before taxes | <u>\$ (62,237)</u> | <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):

| | 2021 | 2020 |
|--|---------------|---------------|
| Deferred Tax assets: | | |
| Stock-based compensation | \$ 2,440 | \$ 4,253 |
| Accrued expenses and other | 2,423 | 906 |
| Research credit carryforward | 564 | - |
| Fixed Assets | 101 | 385 |
| Capitalized start-up costs and other intangibles | 1,109 | 2,686 |
| Net operating loss carryforwards | 75,237 | 63,786 |
| | 81,874 | 72,016 |
| Valuation Allowance | (78,294) | (67,312) |
| Net deferred tax asset | 3,580 | 4,704 |
| Deferred tax liabilities | | |
| Fixed assets and other | (1,176) | (1,590) |
| Purchase accounting intangibles | (2,116) | (2,807) |
| Net deferred tax liability | (3,292) | (4,397) |
| Net deferred tax asset (liability) | <u>\$ 288</u> | <u>\$ 307</u> |

During the current year, the Company completed an assessment of the available net operating loss and tax credit carryforwards under Section 382 and Section 383 of the Internal Revenue Code, respectively. The Company determined that it underwent multiple ownership changes throughout its history as defined under Section 382, including most recently in 2020. As a result of the identified ownership changes, the portion of net operating loss and tax credits carryforwards attributable to the pre-ownership change periods are subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code. The Company has adjusted its net operating loss and tax credit carryforwards to address the impact of the 382 ownership changes. This resulted in a reduction of available Federal and State NOLs of \$253 million and \$204 million, respectively. The write down of the NOLs reduced the net operating loss carryforward line as previously disclosed for the year ended December 31, 2020 by \$58.4 million, with a corresponding decrease in the valuation allowance. The Company also reduced its research credit carryforwards for the year ended December 31, 2020 by \$7.2 million with a corresponding decrease in the valuation allowance. The \$7.2 million reduction was net of the related unrecognized tax benefit in the amount of \$1.6 million.

Since the limitation affected the prior period, the Company has determined that its December 31, 2020 tax footnote presentation overstated the gross deferred tax asset and corresponding valuation allowance by \$65.6 million. However, there was no net impact to the net deferred tax asset and tax expense as the decrease in the net operating loss carryforward was offset completely by a corresponding adjustment to the Company's overall valuation allowance. For comparative purposes, the Company's prior year tax footnote has been revised to reflect the adjustment to the net operating losses and valuation allowance. The change had no effect on the previously reported balance sheets, statements of operations and comprehensive loss, cash flows and stockholders' equity.

At December 31, 2021 and 2020, the Company has provided a full valuation allowance against its net deferred assets in the U.S., Canada, Italy, Luxembourg, Switzerland, and Taiwan tax jurisdictions, since realization of these benefits is not more likely than not. The valuation allowance increased approximately \$11.0 million from the prior year. At December 31, 2021, the Company had U.S. federal net operating loss carryforwards of \$397.2 million, of which \$253 million are expected to expire unused under the limitations imposed by Internal Revenue Code Section 382 (as discussed above). Of the total amount of Federal NOLs (notwithstanding the 382 limitation), \$254.5 million begin to expire in 2027, while the remaining \$142.7 million carry forward indefinitely. At December 31, 2021, the Company had U.S. state net operating loss carryforwards of \$309.2 million, of which \$204 million are expected to expire unused under the state tax law equivalents of Internal Revenue Code Section 382. Of this amount (notwithstanding the 382 limitations), \$299.9 million of state NOLs begin to expire in 2022, while the remaining \$9.3 million carry forward indefinitely. At December 31, 2021, the Company had federal research credit carryforwards in the amount of \$9.4 million. These carryforwards begin to expire in 2027. However, under the limitations of Internal Revenue Code Section 383, it is expected that \$8.8 million of this carryforward will expire unused. 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.

At December 31, 2021, the Company had foreign operating loss carryforwards in Italy of approximately \$25.2 million, which can be carried forward indefinitely; foreign operating loss carryforwards in Luxembourg of approximately \$96.6 million, which will begin to expire in 2034; foreign operating loss carryforwards in Switzerland of approximately \$90.6 million, which begin to expire in 2023, and foreign operating loss carryforwards in Canada of approximately \$0.5 million, which begin to expire in 2040.

The Company has evaluated its tax positions to consider whether it has any unrecognized tax benefits. As of December 31, 2021, the Company had gross unrecognized tax benefits of approximately \$0.1 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.

Note that the Company removed \$1.6 million of the unrecognized tax benefits associated with R&D credit carryforwards that it expects to expire unused due to Section 383 limitations. This adjustment is reflected in the table below as of December 31, 2020.

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

| | 2021 | 2020 | 2019 |
|--|---------------|-------------|-----------------|
| Beginning balance | \$ - | \$ 1,512 | \$ 1,363 |
| Gross increases for tax positions related to current periods | 141 | 108 | 149 |
| Gross decreases related to 382 limitations | - | (1,620) | - |
| Ending balance | <u>\$ 141</u> | <u>\$ -</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, 2021 and 2020, 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 2018, although carryforward attributes that were generated prior to 2018 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:

| | 2021 | | 2020 | | 2019 | |
|---|---------------|----------------------------|-------------------|----------------------------|-------------------|----------------------------|
| | Amount | Percent of Pretax Earnings | Amount | Percent of Pretax Earnings | Amount | Percent of Pretax Earnings |
| United States federal tax at statutory rate | \$ (13,070) | 21.0% | \$ (12,774) | 21.0% | \$ (33,038) | 21.0% |
| State taxes (net of deferred benefit) | (2,205) | 3.5% | (1,768) | 2.9% | (4,778) | 3.0% |
| Nondeductible expenses | (440) | 0.7% | 719 | (1.2%) | 709 | (0.5%) |
| Change in fair market value of contingent consideration | (397) | 0.6% | 717 | (1.2%) | (2,342) | 1.5% |
| Warrant remeasurment and financing costs | 502 | (0.8%) | 82 | (0.1%) | (551) | 0.4% |
| Research & Development | (705) | 1.1% | (542) | 0.9% | (743) | 0.5% |
| Change in unrecognized tax benefits | 141 | (0.2%) | (1,512) | 2.5% | 149 | (0.1%) |
| Foreign tax rate differential | 1,911 | (3.1%) | 1,589 | -2.6% | 2,590 | (1.6%) |
| Goodwill and investment impairments | - | - | - | - | (6,638) | 4.2% |
| Adjustment for 382 Limitations | - | - | 67,255 | (110.6%) | - | 0.0% |
| True-up to Stock Compensation - Cancellations | 2,832 | (4.6%) | - | - | - | 0.0% |
| Change in enacted tax rates and other, net | 731 | (1.0%) | 533 | (0.9%) | (253) | 0.2% |
| Change in valuation allowance | 10,925 | (17.6%) | (55,815) | 91.8% | 41,771 | 26.6% |
| Income tax expense (benefit) | <u>\$ 225</u> | <u>(0.4%)</u> | <u>\$ (1,516)</u> | <u>2.5%</u> | <u>\$ (3,124)</u> | <u>2.0%</u> |

12. Operating Leases

We determine if an arrangement is a lease or service contract at inception. Where an arrangement is a lease, we determine if it is an operating lease or a finance lease. Subsequently, if the arrangement is modified, we reevaluate our classification. We have entered into operating leases for corporate office buildings, vehicles, and machinery and equipment. Some of our lease agreements have renewal options, tenant improvement allowances, rent escalation clauses, and assignment and subletting clauses. While our operating leases range from one year to ten years, some may include options to extend the lease generally between one year and six years, and some may include options to terminate the leases within one year.

Operating lease liabilities presented on the consolidated balance sheets 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.

Operating lease costs for the year ended December 31, 2021, 2020 and 2019 were \$1.8 million, \$2.0 million and \$2.1 million, respectively. Total cash paid for operating leases during the year ended December 31, 2021, 2020 and 2019 was \$1.5 million, \$1.5 million and \$1.7 million, respectively, and is included in with cash flows from operating activities with the consolidated statement of cash flows.

Supplemental balance sheet information, as of December 31, 2021 and 2020, related to operating leases was as follows:

| | December 31, | |
|---------------------------------------|--------------|-----------|
| | 2021 | 2020 |
| Weighted-average remaining lease term | 7.8 years | 1.8 years |
| Weighted-average discount rate | 7.8% | 8.2% |

Maturities of operating lease obligations were as follows (in thousands):

| Fiscal Year | |
|--|-----------------|
| 2022 | \$ 994 |
| 2023 | 1,008 |
| 2024 | 918 |
| 2025 | 920 |
| 2026 | 854 |
| Thereafter | 3,004 |
| Total minimum lease payments | \$ 7,698 |
| Less: Amount of lease payments representing interest | (2,009) |
| Present value of future minimum lease payments | <u>\$ 5,689</u> |

During 2021 we entered into three building leases; the first with a 125-month term beginning in the first quarter of 2021; the second with a 60-month term beginning in the second month of the quarter; and the third with an 87-month term beginning in the fourth quarter of 2021. The total lease commitment for these three operating leases is approximately \$7.1 million.

13. Accrued Expenses

The following table presents the components of accrued expenses:

| | December 31, 2021 | December 31, 2020 |
|------------------------------|----------------------|----------------------|
| | (In thousands) | |
| Compensation and benefits | \$ 3,682 | \$ 4,541 |
| Consulting and other vendors | 128 | 66 |
| Other | 124 | 177 |
| Royalties | 247 | 147 |
| Legal and professional fees | 503 | 314 |
| Taxes and other assessments | 492 | 351 |
| Interest | — | 19 |
| Total | <u>\$ 5,176</u> | <u>\$ 5,615</u> |

14. Notes Payable

Paycheck Protection Program

On April 27, 2020, the Company received an unsecured non-recourse loan of \$2.8 million under the Paycheck Protection Program (“PPP”) provisions of the CARES Act. The Company accounted for the PPP promissory note as debt within notes payable on the consolidated balance sheet. As of December 31, 2020, \$1.6 million of the promissory note was classified as long-term and \$1.2 million was classified as current.

On June 10, 2021, the Company received notification from the SBA that the principal amount of \$2.8 million and related interest had been forgiven. Gain on extinguishment of debt of \$2.8 million was recognized for the year ended December 31, 2021 on the consolidated statement of operations and comprehensive loss. There were no related amounts recorded for the year ended December, 31, 2020 and 2019, respectively.

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 Amendments were treated as a debt modification for accounting purposes.

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

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 on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2019.

15. Stock-Based Compensation

Overview

On July 22, 2021, at the 2021 Annual Meeting of Stockholders, stockholders voted to approve the Company's Amended and Restated Incentive Compensation Plan (the "Plan") to increase the number of shares reserved for issuance under the Plan by 22,000,000 shares. As of December 31, 2021, there were 32,072,308 shares authorized for issuance, and 20,553,294 shares available for future issuance under the Plan. To date all equity awards under the Plan have consisted of nonqualified stock options, incentive stock options, and restricted stock units.

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.

During the years ended December 31, 2021, 2020 and 2019, the Company recognized approximately \$9.4 million, \$7.9 million, and \$11.5 million, respectively, of stock-based compensation expense, including stock options and restricted stock units.

Stock Options

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 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, | | |
|--------------------------|-------------------------|--------------|---------------|
| | 2021 | 2020 | 2019 |
| Expected dividend yield | 0% | 0% | 0% |
| Expected volatility | 118% - 139% | 82% - 126% | 81% - 92% |
| Risk-free interest rate | 0.33% - 1.11% | 0.2% - 1.69% | 1.39% - 2.66% |
| Expected life (in years) | 3.8 - 4.5 | 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, 2021:

| | Number of Shares | Weighted- Average Exercise Price | Weighted-Average Remaining Contractual Term (Years) |
|--|---------------------|--|--|
| Options outstanding at December 31, 2020 | 4,361,872 | \$ 10.49 | 6.05 |
| Granted | 1,490,266 | 4.06 | |
| Forfeited | (285,391) | 8.10 | |
| Cancelled | (610,287) | 30.32 | |
| Exercised | (315,800) | 0.67 | |
| Options outstanding at December 31, 2021 | 4,640,660 | \$ 6.64 | 5.66 |

The following table summarizes information about stock options outstanding at December 31, 2021:

| | Number of Shares | Weighted- Average Exercise Price | Weighted-Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value (Millions) |
|---|---------------------|--|--|--|
| Exercisable at December 31, 2021 | 1,887,155 | \$ 11.50 | 5.40 | \$ 0.7 |
| Vested or expected to vest at December 31, 2021 | 4,498,953 | \$ 6.75 | 5.65 | \$ 1.4 |

The Company granted 1,490,266, 3,005,964, and 623,272 options to employees and non-employees during the years ended December 31, 2021, 2020, and 2019, respectively, with a weighted-average grant date fair value of \$2.40, \$0.53, and \$21.23, respectively.

As of December 31, 2021, the Company had future employee stock-based compensation expense of approximately \$4.0 million related to unvested stock options, which is expected to be recognized over an estimated weighted-average period of 1.5 years.

Restricted Stock Units

During 2021, 2020, and 2019, the Company issued Restricted Stock Units (“RSUs”) to certain employees which vest over two years and three years. The RSUs vest on defined vesting dates and in certain circumstances subject to certain performance criteria, 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, including performance restricted stock units, for the years ended December 31, 2021, 2020, and 2019:

| | Number of Restricted Stock Units Outstanding | Weighted- Average Grant Date Fair Value |
|----------------------------|--|---|
| 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 | (313,508) | 19.38 |
| Forfeited | (245,402) | 6.54 |
| Unvested December 31, 2020 | 2,997,399 | \$ 1.41 |
| Granted | 3,133,753 | 2.77 |
| Vested | (1,891,869) | 1.63 |
| Forfeited | (400,253) | 1.86 |
| Unvested December 31, 2021 | 3,839,030 | \$ 2.36 |

As of December 31, 2021, 2020, and 2019, the Company recorded approximately \$4.8 million, \$1.7 million, and \$3.2 million, respectively, in compensation expense for the RSUs. As of December 31, 2021, the unrecognized stock-based compensation expense related to unvested RSUs was approximately \$4.3 million, which is expected to be recognized over a weighted average period of approximately 1.3 years.

Performance Restricted Stock Units

In 2021 and 2020, the Company granted performance-based restricted stock units with vesting terms based on our attainment of certain operational targets by October 1, 2023 and October 1, 2022, respectively. The number of shares earnable under the 2021 and 2020 awards were based on achieving designated corporate goals. As of December 31, 2021 and 2020, the Company recorded approximately \$0.9 million and \$0.1 million, respectively, in compensation expense for these performance-based restricted stock units.

16. Warrants

On August 14, 2015, in connection with an amendment to a then-existing loan agreement with Silicon Valley Bank 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, 2021, 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. 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 were exercisable 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, and were liability classified. All Series B Warrants have been exercised as of December 31, 2021.

On February 24, 2020, the Company entered into a Series B Warrants Exchange Agreement (the "Exchange Agreement") with certain holders of its unexercised 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. As of December 31, 2021, 25,306,942 Series C Warrants and 24,354,263 Series D Warrants have been exercised. The remaining Series C warrants expired on March 10, 2021.

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, 2021, 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. None of these warrants were exercised during the years ended December 31, 2021, 2020 or 2019.

| | Number of Warrant Shares | Weighted- Average Exercise Price | Weighted- Average Remaining Contractual Life (in years) | Weighted- Average Fair Value |
|----------------------------------|-----------------------------|--|---|------------------------------------|
| Outstanding at December 31, 2018 | 333,034 | 13.39 | 3.70 | 3.38 |
| Exercised | (15,385) | 13.00 | - | - |
| Reserve for future issuance | 1,753,523 | 1.39 | 2.20 | 1.22 |
| Outstanding at December 31, 2019 | 2,071,172 | \$ 2.05 | 2.40 | \$ 1.34 |
| Granted | 50,735,292 | 0.68 | 2.40 | 0.19 |
| Exercised | (4,911,764) | 0.68 | - | - |
| Exchanged | (2,040,757) | 1.24 | - | - |
| Reserve for future issuance | 644,966 | 0.35 | 1.30 | 0.45 |
| Unvested December 31, 2020 | 46,498,909 | \$ 0.71 | 2.40 | \$ 0.20 |
| Exercised | (45,317,101) | 0.68 | - | - |
| Expired | (61,508) | 1.35 | - | - |
| Outstanding at December 31, 2021 | 1,120,300 | \$ 1.94 | 3.00 | \$ 0.55 |

The aggregate intrinsic value of the common stock warrants in the above table was \$0.4 million, \$0.2 million, and \$0.2 million at December 31, 2021, 2020, and 2019, respectively. The aggregate intrinsic value is before applicable income taxes and is calculated based on the difference between the exercise price of the warrants and the estimated fair market value of the applicable stock as of the respective dates.

17. Equity Offerings

At-the-Market Offerings

On August 12, 2019, the Company entered 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. 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 (the “2020 ATM Offering”). The Company terminated this agreement in January 2021.

On May 19, 2021, the Company entered into a Controlled Equity Offering Sales Agreement (the “2021 Sales Agreement”) with Cantor, Robert W. Baird & Co. Incorporated (“Baird”) and Oppenheimer & Co. Inc. (“Oppenheimer”). The Company commenced an at-the-market offering (the “2021 ATM Offering”) pursuant to which the Company could sell from time to time, at its option, up to an aggregate of \$100.0 million shares of the Company’s common stock.

The following table summarizes the total sales under the 2019, 2020, and 2021 ATM Offerings during the years ended December 31, 2021, 2020 and 2019, respectively (in thousands except for share and per share amounts):

| | December 31, | | |
|-----------------------------------|--------------|------------|-----------|
| | 2021 | 2020 | 2019 |
| Total shares of common stock sold | 20,237,045 | 23,008,639 | 1,374,685 |
| Average price per share | \$ 1.53 | \$ 0.90 | \$ 5.23 |
| Gross proceeds | \$ 30,943 | \$ 20,822 | \$ 7,193 |
| Commissions | \$ 928 | \$ 625 | \$ 212 |
| Net proceeds | \$ 30,015 | \$ 20,197 | \$ 6,981 |

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. 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.

All of the shares of Series A Preferred Stock were converted to 7.9 million shares of 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. Approximately 4.9 million Series C Warrants were exercised during the year ended December 31, 2020, generating net proceeds of \$3.3 million.

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.

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 \$28.6 million.

On January 29, 2021, the Company completed an underwritten public offering of 26,545,832 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, for aggregate gross proceeds of \$79.6 million and net proceeds of approximately \$73.4 million.

During the year ended December 31, 2021, the Company issued 45,317,101 shares of common stock upon the exercise of Series B, C, and D warrants for aggregate proceeds of \$30.6 million.

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. 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 during the year ended December 31, 2019. The option to purchase additional shares of common stock was not exercised.

18. 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. In computing diluted net loss per share for the years ended December 31, 2021, 2020, and 2019, no adjustments have been made to the weighted average outstanding common shares 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:

| | December 31, 2021 | December 31, 2020 | December 31, 2019 |
|----------------------------------|----------------------|----------------------|----------------------|
| Stock options | 4,640,660 | 4,361,872 | 1,830,958 |
| Stock warrants | 1,120,300 | 46,498,909 | 2,071,172 |
| Nonvested restricted stock units | 3,839,030 | 2,959,099 | 443,927 |
| Total | 9,599,990 | 53,819,880 | 4,346,057 |

19. 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:

| | Restructuring Liability (In thousands) |
|--------------------------------------|--|
| Balance at December 31, 2019 | \$ 882 |
| Amount charged to operating expenses | 851 |
| Cash payments | (1,733) |
| Balance at December 31, 2020 | \$ — |

20. Commitments and Contingencies

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, 2021, 2020 and 2019.

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. The Company has placed orders with various suppliers for the purchase of certain tooling, supplies and contract engineering and research services. Commitments under these agreements amount to approximately \$2.3 million in 2022, \$0.1 million in 2023, and \$0.2 million in 2024 when the agreements terminate.

21. Related Person Transactions

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 \$186,000, \$110,000, and \$12,000 for the years ended December 31, 2021, 2020 and 2019, respectively.

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, 2021. 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, 2021, 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, 2021, 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, 2021, our internal control over financial reporting was effective.

The Company's independent registered public accounting firm, BDO USA, LLP, audited the effectiveness of the Company's internal control over financial reporting as of December 31, 2021. BDO USA, LLP's report on the effectiveness of the Company's internal control over financial reporting as of December 31, 2021 is set forth herein.

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, 2021 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.

ITEM 9.C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

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 May 2, 2022.

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 May 2, 2022.

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 May 2, 2022.

Securities Authorized for Issuance Under Equity Compensation Plans.

The Company currently has one equity compensation plan under which it makes awards, the Asensus Surgical, 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 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 |
| 7 | Increase the number of shares reserved for issuance under the Plan to 32,072,307 shares. | July 22, 2021 |

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, 2021:

| Plan Category | Number of securities to be issued upon exercise of outstanding options and other equity awards (1) | Weighted average exercise price of outstanding options | Number of securities remaining available for future issuance (2) |
|--|---|---|---|
| Equity compensation plans approved by security holders | 8,298,442 | 6.85 | 20,755,273 |
| Equity compensation plans not approved by security holders (3) | 186,058 | 0.49 | 0 |
| Total | 8,484,500 | | 20,755,273 |

(1) Includes 4,488,795 shares underlying outstanding stock options awarded under the Plan and 3,809,647 restricted stock units awarded under the Plan.

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

(3) Represents 3,000 shares underlying outstanding stock options awarded prior to the Merger under the 2006 Plan and assumed in the Merger and 183,000 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 May 2, 2022.

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 May 2, 2022.

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 : | |
| Reports of Independent Registered Public Accounting Firm | 46 |
| Consolidated Balance Sheets as of December 31, 2021 and 2020 | 49 |
| Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2021, 2020 and 2019 | 50 |
| Consolidated Statements of Stockholders' Equity for the years ended December 31, 2021, 2020 and 2019 | 51 |
| Consolidated Statements of Cash Flows for the years ended December 31, 2021, 2020 and 2019 | 52 |

(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 | 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). |
| 2.1(a) | 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). |
| 3.1.1 | 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). |
| 3.1.2 | 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). |
| 3.2 | 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). |
| 4.1 | Specimen Certificate for Common Stock of Asensus Surgical, Inc. (incorporated by reference to Exhibit 4.1 to our Annual Report on Form 10-K for the year ended December 31, 2020). |
| 4.2 | 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). |
| 4.3 | 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). |
| 4.4 | 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). |
| 4.5 | 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). |
| 4.6 | 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). |
| 4.7 | Form of Warrant Agency Agreement by and between the Registrant and Continental Stock Transfer & 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). |

| | |
|-------------|---|
| 4.8 | Description of Listed Securities (filed as Exhibit 4.8 to our Annual Report on Form 10-K, filed with the SEC on March 11, 2021 and incorporated herein by reference). |
| 10.1 + | 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). |
| 10.2+ | Employment Agreement, dated August 14, 2020, by and between Asensus 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). |
| 10.2.1+ | Amendment to Employment Agreement, dated September 16, 2020, by and between Asensus 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). |
| 10.3 + | 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). |
| 10.4 + | Asensus Surgical Amended and Restated Incentive Compensation Plan, as amended and restated July 22, 2021 (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on July 23, 2021). |
| 10.4.1 + * | Form of Employee Stock Option Award Notice |
| 10.4.2 + * | Form of Employee Restricted Stock Unit/Performance Restricted Stock Unit Award Notice |
| 10.4.3 + | Form of Non-Employee Director Stock Option Agreement pursuant to the Plan (filed as Exhibit 10.4.5 to our Annual Report on Form 10-K, filed with the SEC on March 11, 2021 and incorporated herein by reference). |
| 10.4.4 + | Form of Non-Employee Director Restricted Stock Unit Agreement pursuant to the Plan (filed as Exhibit 10.4.6 to our Annual Report on Form 10-K, filed with the SEC on March 11, 2021 and incorporated herein by reference). |
| 10.4.5 + | Form of Non-Employee Director Other Stock Award Agreement (filed as Exhibit 10.4.5 to our Annual Report on Form 10-K, filed with the SEC on March 11, 2021 and incorporated herein by reference). |
| 10.4.6 + | Form of Non-Employee Director Stock Option Grant in Lieu of Cash Retainer (filed as Exhibit 10.4.7 to our Annual Report on Form 10-K, filed with the SEC on March 11, 2021 and incorporated herein by reference). |
| 10.5+ * | Non-Qualified Deferred Compensation Plan, adopted December 8, 2021 |
| 10.6 ++ | 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). |
| 10.6.1 +++* | Amendment to License Contract between the European Union and Asensus Surgical Italia S.r.l., effective July 2, 2021 |
| 10.6 | 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). |
| 10.7 | 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). |
| 10.7.1 | 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). |
| 10.7.2 | 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). |
| 10.8 + | Asensus Surgical Non-Employee Director Compensation Plan effective July 1, 2021 (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on April 30, 2021). |
| 10.9 | Form of Series B Warrants Exchange Agreement dated February 28, 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). |
| 10.10 | 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). |

| | |
|-----------|--|
| 10.11 | 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). |
| 21.1 * | Subsidiaries of the Registrant. |
| 23.1 * | Consent of BDO USA, LLP. |
| 31.1 * | Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a). |
| 31.2 * | Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a). |
| 32.1 * | Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 * | Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 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, 2021, 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. |
| +++ | Portions of this exhibit have been omitted because the information is not material and would likely cause competitive harm if publicly disclosed. |
| * | 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.

February 28, 2022

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.

| Signature | Title(s) | Date |
|---|--|-------------------|
| <u>/s/ Anthony Fernando</u> Anthony Fernando | President, Chief Executive Officer and a Director (principal executive officer) | February 28, 2022 |
| <u>/s/ Shameze Rampertab</u> Shameze Rampertab | Executive Vice President and Chief Financial Officer (principal financial officer and principal accounting officer) | February 28, 2022 |
| <u>/s/ David B. Milne</u> David B. Milne | Chairman of the Board and a Director | February 28, 2022 |
| <u>/s/ Andrea Biffi</u> Andrea Biffi | Director | February 28, 2022 |
| <u>/s/ Jane H. Hsiao</u> Jane H. Hsiao, Ph.D. | Director | February 28, 2022 |
| <u>/s/ Kevin Hobert</u> Kevin Hobert | Director | February 28, 2022 |
| <u>/s/ Elizabeth Kwo, M.D.</u> Elizabeth Kwo, M.D. | Director | February 28, 2022 |
| <u>/s/ Richard C. Pfenniger, Jr.</u> Richard C. Pfenniger, Jr. | Director | February 28, 2022 |
| <u>/s/ William N. Starling, Jr.</u> William N. Starling, Jr. | Director | February 28, 2022 |

Asensus Surgical, Inc. Board of Directors
As of April 18, 2022

David B. Milne – Chairman (1)(2)(3)
Retired Private Equity Executive

Andrea Biffi
CEO, SOFAR, S.p.A.

Kevin Hobert (2)
CEO, Breg, Inc.

Elizabeth Kwo, M.D. (3)
Chief Medical Officer, Everly Health

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)
Retired Healthcare Executive

William N. Starling (1)(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 18, 2022

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*

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

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

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, 2021 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.

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, 2021, filed with the SEC on February 28, 2022.