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, 2022

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	**11-2962080**
(State or other jurisdiction of incorporation or organization)	**(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	☐	Accelerated filer	☐
Non-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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b) ☐

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, 2022, 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 $93.1 million.

The number of shares outstanding of the registrant's common stock as of February 24, 2023 was 239,279,746.

Documents Incorporated By Reference: Part III of this Annual Report on Form 10-K is incorporated by reference to our proxy statement to be filed in respect of our 2023 Annual Meeting of Stockholders

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

DECEMBER 31, 2022

Table of Contents

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 continue as a going concern within one year from the date that these financial statements are issued as a result of anticipated capital needs, in conjunction with past recurring losses and an accumulated deficit;
- our ability to successfully develop, clinically test and commercialize new products and services;
- our ability to successfully finalize collaboration agreements;
- our ability to successfully implement our Performance-Guided Surgery™ strategy and grow our business as a result;
- our ability to successfully grow the sales and distribution of our products;
- our ability to increase use of our products by existing and new customers;
- competition from existing and new market entrants;
- our ability to identify and pursue development of additional products;
- the timing and outcome of the regulatory review process for our products and product candidates;
- 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 healthcare 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

Introduction

We are a medical device company that is digitizing the interface between the surgeon and patient to reimagine surgery and pioneer a new era of surgery that we refer to as, Performance-Guided Surgery™ (PGS), by unlocking clinical intelligence to enable surgeons to deliver consistently superior outcomes to patients and establish a new standard of surgery. Built upon the foundation of laparoscopic minimally invasive surgery, that remains the gold standard of surgery today, with the Senhance Surgical System, combined with the Intelligent Surgical Unit™ (ISU™), the Company is pioneering this new standard of surgery, PGS, to increase surgeon control and reduce surgical variability. With the addition of machine vision, Augmented Intelligence, and deep learning capabilities throughout the surgical experience delivered via the ISU, we intend to holistically address the current clinical, surgeon performance (fatigue and ergonomics), and the economic shortcomings that drive surgical outcomes in a value-based healthcare environment.

Our mission is focused on leveraging robotic technologies, in combination with real time computer vision and machine learning capabilities, or Augmented Intelligence, 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, as well as reduce cognitive and physical fatigue for 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 Performance-Guided Surgery, and believe that it is the missing element in surgery today.

Recent Developments

On February 21, 2023, we held an investor day to describe our focus on developing a next generation robotic system we call the LUNA™ Surgical System and the ongoing developments in our Performance-Guided Surgery platform. Performance-Guided Surgery is comprised of three strategic pillars:

- enhanced robotic precision and manipulation capabilities, via the Senhance System today and, when developed and approved, the LUNA System;
- expanded intra-operative Augmented Intelligence clinical decision support guidance for the surgeon via the ISU; and
- integration of cloud and big data to harness best practices across pre-, intra- and post-operative settings, and make it available to surgeons around the world via the Asensus Cloud.

In the LUNA System we are developing a “best in class” robot that will use 3mm and 5mm instruments (as contrasted with current systems available that use 8mm instruments), TrueWrist™ fully wristed 5mm instruments, monopolar and bipolar electrosurgery capabilities, rapid instrument exchange with our proprietary instrument drive system, an open platform with a smaller footprint in the OR, as compared to the Senhance System, up to four-arm configuration with enhanced manipulation and dexterity, a surgeon console with 4K-3D capabilities without the need to wear 3D glasses, and unconstrained handles with improved digital features while retaining haptic feedback.

The LUNA System will continue our tradition of providing instruments that are reusable and can be re-sterilized and re-processed, and, with improvements in manufacturing, are expected to have lower costs per procedure.

We also clarified our focus areas for our future development efforts with the ISU, including:

- an analytical feature set, which includes intra-operative surgical planning that will allow surgeons to map out and plan for specific surgical actions intraoperatively using the ISU’s Augmented Intelligence;
- a safety feature set, which includes real-time notifications that will enable the identification and marking of potential hazards during the operation, and optionally restrict access to these structures or areas by simultaneously controlling the robotic arm; and
- a training and education set, allowing multiple team members to work together in real-time by annotating, highlighting and drawing on a shared visual display of the surgical field to communicate and provide expert support in real-time.

The Asensus Cloud is being designed to assist in pre-operative surgical planning, post-surgical performance analytics and best practices guidance, and enable the extraction and aggregation of insights from surgical data. We believe that the collection and analysis of surgical data transformed into insights, and when shared with our physicians, will enhance surgical planning, surgeon education and training, and promote better patient outcomes.

We anticipate that, although we have been working on aspects of the LUNA System for four years, we will spend the rest of 2023 refining and finalizing the design builds, and conducting testing on the ISU enhancements for standalone use. We anticipate reaching design freeze on the LUNA System in the first quarter of 2024 and making regulatory notices and submissions by the end of 2024. For the ISU enhancements and standalone configuration, we anticipate making regulatory notices and submissions in the first quarter of 2024 and beginning commercial activities by mid-2024. We anticipate a commercial pilot launch of the LUNA System in the second half of 2025.

On February 16, 2023, we announced that we had entered into a memorandum of understanding with KARL STORZ VentureONE Pte. Ltd, a wholly owned subsidiary of KARL STORZ SE & Co. KG (KARL STORZ), a global leader in the medical technologies industry. Under the definitive agreements to be developed:

- KARL STORZ will market and sell the ISU as a standalone device together with their IMAGE1 S™ imaging system and OR 1™ integrated OR offering;
- KARL STORZ and Asensus will work on an ISU product that will integrate with KARL STORZ' laparoscopic vision systems; and
- KARL STORZ and Asensus will collaborate on developing next-generation instrumentation to be used with their respective surgical product offerings.

KARL STORZ will, under the definitive agreements once negotiated, be assisting in the development of the instrument and machine vision portions of our LUNA System development program.

Performance-Guided Surgery - current

Historical advances in surgery have largely focused on incremental advancements in surgical tools and techniques targeted at reducing the invasiveness of procedures. When we introduced the Senhance digital laparoscopy platform, our intention was to help surgeons minimize surgical variability in a cost-effective manner while also helping to offset the increasing physical and cognitive demands on surgeons. The next logical step in the progression is looking for ways to deliver real-time Augmented Intelligence and actionable analytics which we believe will take us from digital laparoscopy to Performance-Guided Surgery.

Performance-Guided Surgery builds upon our foundation of digital laparoscopy by adding Augmented Intelligence enabled by our machine vision, 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 leverages our capabilities across robotics, Augmented Intelligence and cloud/big data and is executed across all 3 phases of surgery, including:

- Pre-operative - in what we call "intelligent preparation," our machine learning models will take data from procedures done utilizing our current Senhance System with the ISU, such as tracking surgical motion and team interaction, to create a large and constantly expanding database of surgeries and their outcomes to enable surgeons to best inform their surgical approach and setup.
- Intra-operative – we believe the Senhance System provides "perceptive real-time guidance" for intra-operative tasks, allowing surgeons performing a procedure with the Senhance System and ISU to execute multiple tasks while benefitting from the collective knowledge of other successful Senhance-based procedures delivered through Augmented Intelligence in real time. 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, enabling more sustained peak performance over time and reducing risk of burn-out.
- Post-operative – finally, by tapping into the vast amount of data captured during procedures, surgeons and operating room staff will have access to "performance analytics" with actionable assessments of their performance giving them the information needed to constantly and consistently improve. We intend to establish a new standard of descriptive, diagnostic, predictive and prescriptive analytics to improve not only the skills of surgeons but move towards accessible best-practice-sharing that bridges the global surgeon community.

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

- empower surgeons with improved precision, ergonomics, dexterity, visualization, perceptive real-time guidance and surgical decision support;
- offer high patient satisfaction and enable a more predictable 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.

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 are a data driven company that expects to continue to invest in research and development, market development, and generation and analysis of clinical evidence 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.

2022 Market Development Activities

In 2022 we continued to focus our resources and efforts on market development activities to increase awareness of:

- our growing body of real-world clinical data through the utilization of our TRUST™ registry
- the expanded global ISU machine vision capabilities
- the digitization of high volume procedures using the Senhance System
- the collection of surgical data on the Asensus Cloud
- the benefits of the use of the Senhance System in laparoscopic surgery;
- the technical advancement of digital surgical tools to lead to the realization of Performance-Guided Surgery;
- the indications for use, including pediatric indications for use in CE Mark territories; and
- the overall cost efficiency of the Senhance System.

We are a healthcare driven organization, focused on building a strong and collaborative surgeon community to develop collaborations to collect data to inform the Augmented Intelligence engine of our robotic applications for our robotic and ISU product offerings and elevate surgical practice and training. We are focusing on markets with high utilization of laparoscopic techniques, including Japan, Western Europe and the United States. Our focus in 2022 was 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 value of the Senhance System in laparoscopic procedures. We are not focusing on revenue targets, especially in the United States.

2022 Senhance Surgical System Programs
We define the initiation of a Senhance Surgical program as entering into an agreement to purchase or lease, and subsequently utilizing a Senhance System. Throughout 2022, we initiated nine Senhance System programs, four in Germany, three in Japan and two in the CIS region. We initiated five Senhance System programs in the fourth quarter of 2022 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 serves surgeons and staff throughout Europe with basic and advanced training on the Senhance System. The Amsterdam Skills Centre also provides 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 Sciences Center, New Orleans, and our office in Research Triangle Park North Carolina; two in Europe at Amsterdam Skills Centre, and our office in Milan, Italy; and one in Asia at our office in Tokyo, Japan.

Procedure Volumes
In 2022, surgeons performed 3,137 procedures utilizing the Senhance System, representing a 29% 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, bariatric and pediatric surgical procedures. Beginning with reporting the results for the year ended December 31, 2022, we have re-analyzed our data and are reporting the surgical procedures performed using the Senhance System, rather than surgical cases, where multiple procedures may take place in a single surgical setting or surgical case. For the comparable period in 2021, surgeons performed 2,434 surgical procedures, within the 2,106 surgical cases previously reported.

Clinical Validation

During 2022, there were 16 peer-reviewed clinical papers published providing further support for 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 with the device. In particular, there was a milestone paper published in October 2022 describing comparable intra-operative and short-term post-operative complications outcomes between DaVinci robots and the Senhance Surgical System, with significantly lower procedure costs with use of the Senhance Surgical System when accounting for operative time, estimated blood loss and other equipment usage.

Impact of COVID-19

The COVID-19 pandemic continued to have a significant impact on our operations in 2022, primarily due to the continued repeated temporary cessation of elective surgical procedures in many markets, implementation of time limitations for certain surgeries by certain hospitals, 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 Surgical 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.

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 upon 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 ergonomic for surgeons to adopt. Our Senhance System is designed to mimic 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 which provide improved patient outcomes compared to open surgery, while utilizing fully reusable tools, smaller instruments to broaden applicability of the laparoscopic method, including in pediatric cases, and the additional Senhance System technology such as the ISU with its Augmented Intelligence capabilities.

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 (September 2022), the existing laparoscopic market for soft tissue abdominal surgery is up to 19 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 continue to expand the Senhance System capabilities adding new Augmented Intelligence and decision support capabilities. In addition, we believe our focus on expanding surgical data to include pre- and post-operative intelligence will help in surgical planning, review and overall evaluation.

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 the Senhance digital laparoscopy platform, our intention was to help surgeons minimize surgical variability in a cost-effective manner. The next step in our progress is looking for ways to deliver superior outcomes, which we believe can be enabled by 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. We are also addressing the need for clinically relevant data and analysis through our PGS offerings.

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.

The Senhance System addresses 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, the Commonwealth of Independent States, or CIS, 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, and surgeries in direct contact with central nervous systems.
- In the United States, we have 510(k) clearance from the U.S. Food and Drug Administration (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 124 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).

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 including 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 and surgeries in direct contact with central nervous systems	Japan – regulatory approval and reimbursement for 98 laparoscopic procedures – July 2019 Additional 26 laparoscopic procedures approved for reimbursement in Japan during 2022
● Pediatric indications	Applied for during third quarter 2022	February 2020	N/A
● Inelligent Surgical Unit, or ISU	Initial - March 2020 Expansion of Augmented Intelligence in August 2021	January 2021 Expansion of Augmented Intelligence in January 2023	Japan - December 2020
Instruments and Other Products			
● 5mm articulating instruments	July 2021	September 2018	Japan - October 2022
● 3mm diameter instruments	October 2018	July 2017	Taiwan - November 2018 Japan - October 2019
● Senhance ultrasonic system	January 2019	September 2018	Japan - October 2020
● 3mm and 5mm hooks	5mm July 2019 3mm November 2019	December 2019	Japan - December 2020

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 including 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.

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, and surgeries in direct contact with central nervous systems.

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. Exceptions to this are ultrasonic disposals and articulating instruments.
- *Enhanced Vision, Eye-Tracking Camera Control*: The Senhance System is compatible with 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 previously available surgical technologies, and provides the foundation for additional Augmented Intelligence capabilities, with a number of enhancements added and FDA-cleared in 2021 and CE Marked in early 2023. 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., Japan and the EU include 3D point-to-point measurement, advanced endoscopic control modalities, image enhancement, and intra-operative surgeon digital tagging.
- *Articulating Instruments*: These instruments improve accessibility and reach around critical structures, providing two additional degrees of freedom, when working in deep anatomical spaces. They optimize efficiency for the surgeon.
- *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.
- *Improved 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 OR 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.

ISU and Digital Solutions

Our ISU is a real-time intra-operative surgical image analytics platform that leverages Augmented Intelligence to help reduce surgical variability and provides tools to reduce a surgeon's cognitive fatigue. It is currently used to enable machine vision capabilities on the Senhance System and collect clinical data related to surgical procedures. The ISU was developed using image analytics technology that we acquired 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 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. 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 the CE Mark.

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. In September 2021 we received FDA clearance for additional Augmented Intelligence features of the ISU, and received CE Mark for such additional features in January 2023. The newest ISU features expand upon these capabilities and introduce additional advanced features including 3D measurement, digital tagging, image enhancement, and enhanced camera control based on real-time data while performing surgery. The regulatory review of such expanded capabilities, which included a review of the Senhance System platform, made Senhance one of the first robotic surgical systems to be approved through the new, more rigorous EU Medical Device Regulation, or MDR, process.

We are continuing to advance the utility of the ISU for the Senhance System while also adding such capabilities to the standalone ISU and the LUNA System.

Our digital solutions are the features, products and platforms that are enabled by data, generated through the digitization of the interface between the surgeon and the patient, and deployed via software. Our digital solutions are a foundational component of our PGS strategy enabling the delivery of insights in pre-operative and post-operative settings, while continuously enhancing our real-time, intra-operative Augmented Intelligence offerings. Given the criticality of this part of our business, in 2022 we reorganized our R&D structure to establish a dedicated engineering team focused on digital solutions and established an additional cross-functional team to advance efforts in data collection, connectivity, needs definition and solution development. Currently, commercially available digital solutions are largely deployed via the ISU in the form of Augmented Intelligence applications including automatic camera control, digital tagging, and digital measurement. To develop these and future digital solutions, we designed and deployed the Asensus Cloud, which has been architected to efficiently manage unique surgical data automatically transferred via connected ISUs and additional sources. The Asensus Cloud provides a secure, scalable, and efficient platform for data storage, data use and computing in machine learning model development, business model innovation and future analytics delivery via portals and dashboards. We believe these analytics solutions will address numerous challenges in the pre-operative planning and post-operative assessment phases of surgery, enhancing training as well as continuing education, to help advance Performance-Guided Surgery and promote consistently superior outcomes.

Senhance Connect
Senhance Connect is a telesurgical platform 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 operating room camera views and an endoscopic view simultaneously, and allows for two-way screen sharing and annotation. This product is part of our PGS, enabling the ability to provide real-time digital collaboration capabilities to surgeons enabling best practice sharing and surgical proctoring to a wider audience. Additionally, this expands surgeon flexibility and is more cost effective, enabling broader global access to clinical excellence.

Clinical Registry (TRUST)
We believe TRUST is the largest multi-specialty robotic-assisted laparoscopic registry in the industry. In 2022, we continued to leverage the growing body of real-world clinical data through the utilization of our TRUST clinical registry, which is aimed at providing a research tool that enables physicians to monitor safety, efficacy, and feasibility of robotic assisted surgical interventions in a variety of abdominal, thoracic, urologic and gynecologic surgical cases using the Senhance System. In 2022, we continued to drive enrollment as well as support peer-reviewed publications through this registry.

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.

Our articulating instruments were commercially launched in the U.S. and Japan in the fourth quarter of 2022.

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.

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 a notice 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 which allows for hiatal and paraesophageal hernia, and sleeve gastrectomy procedures. These additional indications helped to increase procedure volume in 2022.
- We submitted a 510(k) notice to the FDA for expanding the indications for use of the Senhance System to pediatric patients.

Business Strategy

Our strategy is to focus on the realization of Performance-Guided Surgery through the continued collection of surgical data via the ISU and Asensus Cloud leveraging the Senhance System and by other means of non-robotic laparoscopic surgery, while completing the design and development of the LUNA System and its capabilities. We anticipate that the definitive agreements with KARL STORZ will lead to an increase the sales of our ISU standalone configuration and also grant us greater access to surgical video and surgical data via non-robotic laparoscopic surgical towers. We believe that:

- the LUNA System, if successfully developed and approved for use, will dramatically improve our ability to offer digital solutions to surgeons to promote better patient outcomes;
- the ISU and Asensus Cloud will enable the structured acquisition, processing and analysis of surgical video and data and glean insights to better inform our Augmented Intelligence engines to help reduce surgical variability and drive consistently superior outcomes for patients;
- 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 our robotic surgery products, surgeons can benefit from the haptic feedback for better connection to the patient, enhanced three-dimensional, high definition, or 3DHD, vision, and open console design to better connect the surgeon with the operating room; and
- patients will continue to benefit from minimally invasive options, offering better overall patient outcomes than other MIS surgical techniques.

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, improved 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.

Our strategy is to focus our resources on the market development of digital surgery to create a new and unique market segment for Performance-Guided Surgery using the standalone ISU and the LUNA System in the future and the Senhance System, the ISU and currently offered instruments to generate procedural data to inform and elevate practice in real time.

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, 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;
- the addition of advanced energy instruments, 3mm instruments and 5mm articulating instruments for the Senhance System will 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;
- a standalone ISU will enable much broader access to Augmented Intelligence solutions, providing better surgeon experience and clinical outcomes in laparoscopic procedures, compared to if all ISUs needed to be part of a robotic system; and
- the enablement of image analytics technology, Augmented Intelligence and machine vision capabilities, enabled by the ISU, will help accelerate and drive meaningful adoption of our robotic systems 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 2022, we initiated nine Senhance surgical programs, four in Germany, three in Japan and two in the CIS region. We define the initiation of a Senhance Surgical program as entering into an agreement to purchase or lease, and subsequently utilizing a 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, 2022, the Company's patent portfolio includes approximately 75 issued or allowed United States patents, over 100 patents issued outside the United States, and more than 130 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, the LUNA System, the ISU or other features, instruments, or components for robotic-assisted surgery. Our patents and applications that we acquired from MST relate to image analytics, our digital solutions 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 2022 and 2021, and some forward steps by a number of existing entrants, such as the CE Mark attained by Medtronic for its Hugo™ robot, and the enrollment of the first patient in its U.S. clinical trial. 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: Medtronic plc, Intuitive Surgical Inc., Vicarious Surgical, Inc., Momentis Surgical, Distalmotion SA, and CMR Surgical Ltd. We are aware that more entrants anticipate introducing additional robotic-based instruments in the next few years.

There are also a number of existing and emerging competitors in the digital surgery space. Some well-established players have and are expanding their digital offerings, such as Medtronic's post acquisition of Digital Surgery with their Touch Surgery offerings and Intuitive Surgical with their My Intuitive app. Several smaller companies that are exclusively focused on digital surgery solutions are currently in, or are expected to enter in the near future, the market including, but not limited to Theator Surgical, Activ Surgical and CareSyntax.

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 real-time 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 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 in 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 have heightened regulatory requirements, typically including clearance of a 510(k) notice prior to marketing; and (iii) Class III devices are new, high-risk devices, and frequently are permanently implantable or help sustain life, and generally require approval of a Pre-Market Approval application, or PMA, by the FDA.

Our current products are subject to premarket notification and clearance under section 510(k) of the FDCA, and the 510(k) process is normally used for products of the type that we are developing and propose to market and sell. To obtain 510(k) clearance, we must submit to the FDA a premarket notification (510(k) notice) demonstrating that the proposed device is “substantially equivalent” to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to PMA, generally either a Class I or Class II device. A 510(k) notice 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 are required to support the 510(k) notice, these data must be gathered in compliance with the investigational device exemption, or IDE, regulations for investigations performed in the United States.

If the FDA agrees that the device is substantially equivalent to a predicate device, it will grant 510(k) clearance, which permits the company to commercially distribute the device for its intended use. If the FDA determines that the device is “not substantially equivalent” to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the “de novo” process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. Review times for de novo requests vary widely, and may take in excess of one year.

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 a 510(k) review process 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; if clearance is not granted, 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 de novo process escribed above or PMA process described below.

A new device that is high-risk and not substantially equivalent to a predicate device must obtain approval of a PMA prior to commercial distribution in the U.S. These devices are normally Class III devices. Before a company can market a product in the United States that is subject to PMA approval, it typically must collect clinical data to support the intended use of the device, and must comply with IDE regulations in connection with any human clinical investigation of the device conducted in the United States. Prior express FDA approval of an IDE application is required if the device is a significant risk device (as opposed to a “non-significant risk”, or NSR, device), which is typically the case for Class III devices. The FDA must subsequently 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 and are required to pass a manufacturing facility inspection in accordance with the current “good manufacturing practices” standards prior to obtaining marketing approval. The FDA will approve the PMA application if it determines that the data and information in the PMA constitute valid scientific evidence and finds that 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.

The Company believes the Senhance System and many related products are Class II devices as evidenced by our cleared 510(k) notices. 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) clearance. 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 legally-marketed Class II devices. If that were to occur, the Company would be required to undertake either the de novo reclassification process or the even more complex and costly PMA process. 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 510(k) clearance. 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, including changes to the intended use/indications for use, without first submitting a PMA Supplement application and obtaining FDA approval for that supplement. In some instances, the FDA may require clinical trials to support a PMA Supplement. A manufacturer of a device cleared through the 510(k) process must submit an additional premarket notification if it intends to modify the device in a manner 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, or that represents a major change in the intended use.

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 and promotional activities;
- Medical Device Reporting 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
- in some cases, 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 and listed the products that we currently commercialize in the U.S. 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 (21 CFR Part 820), 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 an initial four-year transition period, which has been extended to a seven-year period. 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. To date, the Senhance System (with the ISU included) and articulating instruments have been certified under the MDR process 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. The transition extensions are until 2027 for class IIb devices and 2028 for class IIa devices under the following conditions: (1) devices do not present any unacceptable risk to health and safety, (2) devices have not undergone significant changes in design or intended purpose, and (3) the manufacturers have already undertaken the necessary steps to launch the certification process under the MDR, such as adaptation of their quality management system to the MDR and submission to a notified body. Some of our legacy devices in class IIb and IIa still require MDR transition (instruments and ultrasonic). Full 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.

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 healthcare 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. These laws include the following:

- The U.S. Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving anything of value to induce (or in return for) the referral of business, including the purchase of a particular medical device reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between medical device manufacturers on one hand and purchasers on the other. A violation of the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. The government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly and practices that involve remuneration to those who purchase medical devices, including certain discounts, or engaging such individuals as consultants, speakers or advisors, may be subject to scrutiny if they do not fit squarely within the exception or safe harbor.

- The federal civil False Claims Act, or FCA, which prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of federal funds, or knowingly making, or causing to be made, a false statement material to a false claim. Actions under the False Claims Act may be brought by private individuals known as qui tam relators in the name of the government and relators may share in any monetary recovery.

- The Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively “HIPAA”) prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. We may obtain health information from third parties that are subject to privacy and security requirements under HIPAA and we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

- The majority of states also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

- The U.S. Physician Payment Sunshine Act, or Sunshine Act, requires tracking of payments and transfers of value to physicians and teaching hospitals and ownership interests held by physicians and their families, and reporting to the federal government and public disclosure of these data. As of last year, manufacturers must also report transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. 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 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 healthcare 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.

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.

Health Care Reform

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. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

For example, in March 2010, the Patient Protection and Affordable Care Act was enacted. The ACA is a sweeping measure generally designed to expand access to affordable health insurance, control healthcare spending, and improve healthcare quality. Several provisions of the ACA specifically affect the medical equipment industry. Among other things, the ACA established enhanced Medicare and Medicaid program integrity provisions, including expanded documentation requirements, and new disclosure requirements regarding manufacturer payments to physicians and teaching hospitals, along with broader expansion of federal fraud and abuse authorities. It is unclear how efforts to modify or invalidate the ACA or its implementing regulations, or portions thereof, will affect our business. Additional legislative changes, regulatory changes, and judicial challenges related to the ACA remain possible. We cannot predict what effect further changes related to the ACA would have on our business.

Other legislative changes have been proposed since the ACA was enacted such as the Budget Control Act of 2011 which, among other things and in concert with subsequent legislation, resulted in reductions in payments to Medicare providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect into 2031. Sequestration is currently set at 2% and will increase to 2.25% for the first half of fiscal year 2030, to 3% for the second half of fiscal year 2030, and to 4% for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031. As long as these cuts remain in effect, they could adversely impact payment for the procedures performed with our products.

We expect there will continue to be reforms to healthcare legislation, regulation, and policy guidance at the federal and state level. Any such reform could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of existing products or to successfully commercialize product candidates.

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.

Additionally, the General Data Protection Regulation (the GDPR) in effect across the EEA, imposes many 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.

Global laws are increasingly restricting and regulating the cross-border transfer of personal data, which may require us to undertake additional obligations in order to receive personal data from overseas customers or transfer such data, including to our vendors. For example, the GDPR restricts the ability of companies to transfer personal data from the EEA to the United States and other countries, which may adversely affect our ability to transfer or receive personal data or otherwise may cause us to incur significant costs to undertake data transfer impact assessments and implement lawful data transfer mechanisms.

In addition, we are utilizing distributors and sales agents in various territories throughout Europe, the Middle East, Africa, and the CIS, 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, 2022, we had 197 employees, including 183 full-time employees, of whom 71 were in the R&D Department, 16 were in Quality and Regulatory Affairs, 38 were in Marketing and Sales, 32 were in Corporate Administration, and 26 were in Customer Care. As of December 31, 2022, approximately 32% of the Company's workforce were female, and minorities represented approximately 19% of the Company's workforce. As of December 31, 2022, approximately 57% of the Company's employees were in the United States and 43% were outside of the United States. In 2022, our turnover rate was approximately 15% and we hired 53 full-time employees. We believe the improvement in our turnover rate, from 18% in 2021, is primarily attributed to our increased hiring in 2022 and the implementation of our DEI programs discussed below.

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 DEI resources for our employees, kicked off a DEI committee and partnered with a DEI alliance to further evolve our DEI efforts. In 2022, we held biweekly meetings of the DEI committee, attended the Raleigh Chamber 'Diversity, Equity & Inclusivity Conference in July, shared information on our social media pages about relevant events and holidays, and held various education events including DEI focused movie watch parties with follow-up discussion groups. 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, one of eight board members self-identifies as a woman, and two 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. During 2022, our employees returned to the office three days per week. 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 2022, 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 2022, we continued to see an improvement 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; and
- the ability of stockholders 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 26, 2022, 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 $860.9 million and our working capital was $76.5 million as of December 31, 2022. 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.

Our recurring operating losses and negative cash flows raise substantial doubt about our ability to continue as a going concern. We will need additional financing to execute our business plan and fund our operations.
Since inception, we have experienced recurring operating losses and negative cash flows and we expect to continue to generate operating losses and consume significant cash resources in the foreseeable future, particularly as we increase our research and development spending as we develop and seek regulatory approval for the LUNA System and enhancements to our digital surgery and Performance-Guided Surgery product offerings. Management has concluded that substantial doubt exists about our ability to continue as a going concern as a result of anticipated capital needs in conjunction with past recurring losses and an accumulated deficit. Our independent registered public accounting firm also included an explanatory paragraph in its report on our consolidated financial statements as of and for the year ended December 31, 2022 with respect to this uncertainty. We believe that our existing cash, cash equivalents, short-term investments and long-term investments, together with cash received from product, service, and lease sales will be sufficient to meet our anticipated cash needs into the first quarter of 2024. We will need additional financing to implement our next generation products strategy. We believe we have cash on hand to sustain our operations into the first quarter of 2024, and also believe we will need to raise capital in order to implement the LUNA System program. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and we may have a more difficult time obtaining financing.

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.

In order to compete successfully within the surgical robotics industry, we need to continue to evolve our robotic surgery products, including the innovations associated with assets we acquired. Failure to develop, obtain 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 our robotic surgery products, including the innovations associated with the assets we acquired from MST in 2018. Our focus currently is on harnessing the image technology acquired in the MST acquisition to advance the intelligence of our products through the ISU to provide meaningful real-time Augmented Intelligence to surgeons. We have developed and received CE Mark in Europe and FDA clearance in the U.S. for articulating instruments. 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 to successfully commercialize such innovations, such failure could have a material adverse effect on our business and financial position.

We are also focused on commercializing our ISU as a vital part of our Performance-Guided Surgery initiative. If we are not successful in commercializing the ISU, our business could be materially adversely affected. Companies such as us rely on innovation and new product development to attract and retain customers. Such development efforts take time, are expensive, and there is no certainty that we will be successful in commercializing the ISU, developing the LUNA System, or receiving regulatory clearances and approvals, on a timely basis, if at all. If we are not successful in our development efforts, such failure will have a material adverse effect on our business and financial position.

We may not be successful in realizing benefits from our collaboration agreements.
We are collaborating with Google on further developing the Asensus Cloud as a key component of our LUNA System product offerings, and have signed an MOU with KARL STORZ to increase sales of our ISU and to develop instruments and other technologies with them. We may not be successful in completing the definitive agreements with KARL STORZ or realizing the benefits of these collaborative programs. If we are not successful, our reputation and our operations and financial condition may be harmed.

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 2022. Elective surgeries have also been curtailed a number of times during variant surges in 2022 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 surgical 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.

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. In addition, we are now more focused on developing the LUNA System than focusing on continued commercial success with the Senhance System.

We cannot assure you that we will be successful in continuing to grow utilization of the Senhance System and the ISU year over year.
While we believe Performance-Guided Surgery and our other tools available to assist the laparoscopic surgeon perform successful surgeries, it is time-consuming to educate and train physicians and educate hospitals on the benefits of use of the Senhance System with the ISU. If we cannot continue to grow our procedure volume year over year, our business and financial condition will be adversely affected.

We have de-emphasized sales of the Senhance System, which occurs now only in areas in which our distributors and certain areas in Europe and Japan.

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. We cannot assure you that these lease arrangements will lead to longer term placements or result in sales of our Senhance System.

We use distributors and sales agents in a number of geographic locations where we do not have sales personnel. 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 and digital surgery industries are 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 Medtronic plc, Intuitive Surgical Inc., Vicarious Surgical, Inc., Momentis Surgical, Distalmotion SA, and CMR Surgical Ltd., Activ Surgical, Inc., Theator Surgical, CareSyntax Inc. 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 for 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; 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 healthcare 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 and digital surgery environments will become more intense because of increased consolidation by companies in the healthcare industry looking to achieve cost reductions. Such consolidation may have an adverse effect on our business operations.

Use of our Senhance System requires training for surgeons, and inadequate training may lead to negative patient outcomes, which could harm our business, financial condition, and results of operations.
The successful use of our Senhance System depends in part on the training and skill of the surgeon performing the procedure and his or her comfort level with the use of a robotic device. We provide training and proctoring, as well as Senhance Connect, that allows us to provide real-time guidance as desired. We cannot be certain that all of the surgeons that use our Senhance System have received and completed sufficient training. If a surgeon uses our Senhance System incorrectly, or without adhering to or completing all relevant training, their patients could be negatively affected. Adverse safety outcomes that arise from improper or incorrect use of our Senhance System may limit adoption of our Senhance System, which could harm our sales, business, financial condition, and results of operations.

We will require substantial additional funding to advance our current plans.
We are focused on our development efforts for our products, including the LUNA System and enhanced digital solutions, and commercialization of the Senhance System, ISU and other products, as well as market development for our products and other research and development activities. We expect increased research and development spend associated with the development of the LUNA System, next generation versions of the ISU and enhanced digital solutions, putting additional pressure on funding requirements as we advance through regulatory processes and commercialization, if our R&D efforts are successful. 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.

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.

We are subject to risk as a result of our international manufacturing operations.
Because most of our products are manufactured at third-party facilities located in Europe, Israel and Singapore, our operations are subject to risk inherent in doing business internationally. Such risks include the adverse effects on operations from corruption, war, international terrorism, civil disturbances, political instability, government activities such as border taxes and renegotiation of treaties, deprivation of contract and property rights and currency valuation changes. Countries may adopt other measures, such as controls on imports or exports of goods, technology, or data, that could adversely impact the Company’s operations and supply chain and limit the Company’s ability to offer our products and services as designed. These measures could require us to take various actions, including changing suppliers and restructuring business relationships. Changing our operations in accordance with new or changed trade restrictions can be expensive, time-consuming, disruptive to our operations and distracting to management. Such restrictions can be announced with little or no advance notice, and we may not be able to effectively mitigate all adverse impacts from such measures. Any of these events could increase the cost of our products and services, or otherwise have a materially adverse impact on our or our suppliers’ businesses and results of operations.

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

Our global operations expose us to additional risks and challenges associated with conducting business internationally.
The international nature of our business, particularly in Europe, Israel, Asia and the Russian Federation, may expose us to risks inherent in conducting foreign operations. These risks include: challenges associated with managing geographically diverse operations, which require an effective organizational structure and appropriate business processes, procedures and controls; the high cost of doing business in foreign jurisdictions, including compliance with international and U.S. laws and regulations that apply to our international operations; currency exchange and interest rate fluctuations and the resulting effect on our revenue and expenses, and the cost and risk of entering into hedging transactions, if we chose to do so in the future; changes in a specific country's or region's political or economic environment; trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments; potentially adverse tax consequences; complexities and difficulties in obtaining protection and enforcing our intellectual property; compliance with additional regulations and government authorities in a highly regulated business; difficulties associated with staffing and managing foreign operations, including differing labor relations; and general economic and political conditions outside of the U.S.

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

We 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, 2022, the market price of our common stock fluctuated from a high of $6.95 per share to a low of $0.28 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;
- variations in our and our competitors' results of operations;
- 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.

We are currently a smaller reporting company, which may limit our ability to raise sufficient capital to advance our LUNA System and Performance-Guided Surgery development efforts.
Our stock price was below $1.00 per share during much of 2022. If our stock price continues to remain under a $1.00 per share for an extended period, we will be subject to the SEC's "baby shelf" rules, which may limit the amount of capital we can raise over a twelve month period under a Form S-3 registration statement. Such rules may make our capital financing transactions more difficult or expensive.

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 stockholders to lose some or all of their 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.

Certain software being developed for the LUNA System and the ISU may include third-party open source software. Any failure to comply with the terms of one or more open source software licenses could adversely affect our business, subject us to litigation, or create potential liability.
Certain software being developed for the LUNA System and for the ISU may include third-party open source software and we expect to continue to incorporate open source software in the future. The use of open source software involves a number of risks, many of which cannot be eliminated and could negatively affect our business. For example, we cannot ensure that we have effectively monitored our use of open source software or that we are in compliance with the terms of the applicable open source licenses or our current policies and procedures. There have been claims against companies that use open source software asserting that the use of such open source software infringes the claimants' intellectual property rights. As a result, we could be subject to suits by third parties claiming infringement on such third parties' intellectual property rights. Litigation could be costly for us to defend, have a negative effect on our business, financial condition and results of operations, or require us to devote additional research and development resources to modify our computational drug discovery platform.

Use of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties, controls on the origin of the software or other contractual protections regarding infringement claims or the quality of the code, including with respect to security vulnerabilities. In addition, certain open source licenses require that source code for software programs that interact with such open source software be made available to the public at no cost and that any modifications or derivative works to such open source software continue to be licensed under the same terms as the open source software license. The terms of various open source licenses have not been interpreted by courts in the relevant jurisdictions, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to market our solutions. By the terms of certain open source licenses, if portions of our proprietary software are determined to be subject to an open source license or if we combine our proprietary software with open source software in a certain manner, we could be required to release the source code of our proprietary software and to make our proprietary software available under open source licenses, each of which could reduce or eliminate the effectiveness of our computational discovery efforts. We may also face claims alleging noncompliance with open source license terms or misappropriation or other violation of open source technology. Any of these events could create liability for us and damage our reputation, which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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 intended 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 oversight. 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, all manufacturing facilities are subject to routine 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 our products, manufacturers or manufacturing process; adverse inspectional observations (Form 483), Warning Letters, 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 or CE marked 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, PMA approval or de novo authorization or review by the Notified Body for CE marked devices. The FDA or Notified Body requires every manufacturer to make this determination in the first instance, but the FDA/Notified Body may review such determinations. The FDA/Notified Body may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA/Notified Body disagrees with our determinations for any future changes, or prior changes to previously marketed products, 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 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) notice for modifications to 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 future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce new products that will be accepted by the market in a timely manner. There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products on a timely basis, if at all, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.
When a 510(k) notice, de novo request, or PMA is submitted for a new product or for a change to an existing product, there is no guarantee that it will receive FDA authorization. Failure to receive clearance or approval for our new products or indications for use would have an adverse effect on our ability to expand our business. For example, the FDA review process is ongoing for our 510(k) notice to expand the Senhance System indications to pediatric use. If we do not receive clearance for this expanded indication, we will not be able to market the device for pediatric procedures in the U.S. until such clearance is obtained.

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, 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 MDR, which replaced the MDD in May 2021 after a four-year transition period, which has now been extended to a seven-year transition period for some class IIb and class IIa, 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 the 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 regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death, serious health threat 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 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.

Our employees, consultants, third-party vendors and collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.
We are exposed to the risk of employee, consultant, third-party vendor or collaborator fraud or other misconduct. Misconduct by our employees, consultants, third-party vendors or collaborators could include, among other things, intentional failures to comply with FDA, EU or other regulations, provide accurate information to the FDA or other regulators, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. It is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us.

U.S. legislative, FDA regulatory reforms or global 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. We anticipate that future regulatory requirements may focus on artificial intelligence or clinical decision support products, such as our ISU, which may subject our products to additional regulations.

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, global health concerns, 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.

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 further described under "Business" above. Some such laws, including privacy laws, may include private rights of action and can lead to class action litigation. 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 rights 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. Around the world, the privacy and data protection legal landscape is rapidly changing, which may require us to adjust aspects of our operations or expend significant time and resources to come into compliance with new laws or regulatory obligations. 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 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.

Global laws are increasingly restricting and regulating the cross-border transfer of personal data, which may require us to undertake additional obligations in order to receive personal data from overseas customers or transfer such data, including to our vendors. For example, the GDPR restricts the ability of companies to transfer personal data from the EEA to the United States and other countries, which may adversely affect our ability to transfer or receive personal data or otherwise may cause us to incur significant costs to undertake data transfer impact assessments and implement lawful data transfer mechanisms. Some available lawful transfer mechanisms are under scrutiny and in flux, such as the European Commission's Standard Contractual Clauses, or the Model Clauses and the recently invalidated Privacy Shield Frameworks. The Model Clauses may continue to be subject to scrutiny as a result of the European Court of Justice's judgement in July 2020, though they remain the most common authorized procedure to transfer personal data out of the EU. The European Commission and U.S. regulators are expected to revive a version of the EU-US Privacy Shield Framework, which may ease the burden of these cross-border transfers. Still, any approved transfer framework likely will face scrutiny and lawsuits from privacy advocacy groups, which may result in the invalidation of a transfer mechanism on which we or our customers rely, which may impede our ability to transfer or receive data from the EEA. Our continued monitoring of and reactions to these legal developments can affect our customer base, business operations, and costs of doing business abroad. Other countries are implementing data localization requirements or restrictions or obstacles on the cross-border transfers of personal data, such as requiring express consent, notification to local authorities, or assessments and contractual amendments similar to the GDPR requirements.

In addition to the laws specifically discussed, numerous other federal and state laws and regulations govern privacy and security, including state data breach notification laws, state health information and/or genetic privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act, new state consumer protection laws), many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, time consuming, and requires a flexible privacy framework and substantial resources. Compliance efforts will likely be an increasing and substantial cost in the future. Federal regulators, state attorneys general, and plaintiffs' attorneys have been and will likely continue to be active in this space.

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.

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.

Significant disruptions of our information technology systems or data security incidents could harm our reputation, cause us to modify our business practices, and otherwise adversely affect our business and subject us to liability.

We are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store, process, and transmit sensitive corporate, personal, and other information, including intellectual property, proprietary business information, customer data, and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity, and availability of such information. Our obligations under applicable laws, regulations, contracts, industry standards, self-certifications, and other documentation may include maintaining the confidentiality, integrity, and availability of personal information in our possession or control, maintaining reasonable and appropriate security safeguards as part of an information security program. These obligations create potential legal liability to regulators, our business partners, our customers, and other relevant stakeholders, and also impact the attractiveness of our products and services to existing and potential customers.

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, hacking 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.

Although we have implemented remote working protocols for some employees and offer work-issued devices to employees, the actions of our employees while working remotely may have a greater effect on the security of our systems and the data we process, including by increasing the risk of compromise to our systems, intellectual property, or data arising from employees' combined personal and private use of devices, accessing our systems or data using wireless networks that we do not control, or the ability to transmit or store company-controlled data outside of our secured network. These risks have been heightened by the dramatic increase in the numbers of our employees who have been and are continuing to work from home.

We maintain insurance policies to cover certain losses relating to our information technology systems. However, there may be exceptions to our insurance coverage such that our insurance policies may not cover some or all aspects of a security incident. Insurance policies will also not protect against the reputational harms caused by a major security incident. Even where an incident is covered by our insurance, the insurance limits may not cover the costs of complete remediation and redress that we may be faced with in the wake of a security incident. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

In addition, any actual or perceived failure by us, our vendors, or our business partners to comply with our privacy, confidentiality, or data security-related legal or other obligations to customers or other third parties, or any further security incidents or other unauthorized access events that result in the unauthorized access, release, or transfer of sensitive information (which could include personal data), may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including current and potential partners, to lose trust in us (including existing or potential customers' perceiving our products or services as less desirable), or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations, which could materially and adversely affect our business and prospects. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages.

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.

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 Gotenyama Trust Tower 12F, 4 Chome-7-35 Kitashinagawa, Shinagawa City, Toyko 140-0001, Japan. We lease this facility, which consists of 911 square feet, for a three-year term ending on August 31, 2025, under a lease that commenced on September 1, 2022.

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.

Holders

As of February 24, 2023, there were approximately 63 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

None.

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

We are a medical device company that is digitizing the interface between the surgeon and patient to pioneer a new era of Performance-Guided Surgery™ by unlocking clinical intelligence for surgeons to enable consistently superior outcomes and a new standard of surgery. This builds upon the foundation of digital laparoscopy (our combination of more advanced tools and robotic functionality) with the Senhance® Surgical System powered by the Intelligent Surgical Unit™ (ISU™) to increase surgeon control and reduce surgical variability. With the addition of Augmented Intelligence, enabled by our machine vision, and deep learning capabilities leveraged throughout the surgical experience, we intend to holistically address the clinical, cognitive and economic shortcomings to allow surgeons to deliver consistently superior surgical outcomes and realize the benefits of 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 (to the extent lawful), 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 124 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").

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 procedures done utilizing our current Senhance System with the ISU, such as tracking surgical motion and team interaction, to create a large and constantly expanding database of surgeries and their outcomes to enable surgeons to best inform their surgical approach and setup.
- Intra-operative – we believe the Senhance System provides "perceptive real-time guidance" for intra-operative tasks, allowing surgeons performing a procedure with the Senhance System and ISU to execute multiple tasks while benefitting from the collective knowledge of other successful Senhance-based procedures delivered through Augmented Intelligence in real time. 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, enabling more sustained peak performance over time and reducing risk of burn-out.

- Post-operative – finally, by tapping into the vast amount of data captured during procedures, surgeons and operating room staff will have access to "performance analytics" with actionable assessments of their performance giving them the information needed to constantly and consistently improve. We intend to establish a new standard of descriptive, diagnostic, predictive and prescriptive analytics to improve not only the skills of surgeons but move towards best-practice-sharing that bridges the global surgeon community.

We received FDA clearance in March 2020 for our 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 2022 we received FDA clearance for advanced features of the ISU, and received CE Mark for such enhancements in January 2023.

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, 2022, we had an accumulated deficit of $860.9 million, and there is substantial doubt about our ability to continue as a going concern. We operate in one business segment.

Recent Financing Transactions

At-the -Market Offerings

On March 18, 2022, the Company entered a Controlled Equity Offering Sales Agreement (the "2022 Sales Agreement"), with Cantor Fitzgerald & Co., and Oppenheimer & Co. Inc. The Company commenced an at-the-market offering (the "2022 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. No sales of common stock were made under the 2022 ATM Offering during the year ended December 31, 2022.

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, 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 Offering℠ 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
Commisssion 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, 2022 and 2021

Revenue
Both in 2022 and 2021, our revenue consisted of the sale of two Senhance Systems, ongoing System leasing payments, sales of instruments and accessories, and services revenue for Systems sold or placed in Europe, Asia, and the U.S. in prior periods.

Product revenue for the year ended December 31, 2022 decreased to $4.3 million compared to $5.4 million for the year ended December 31, 2021. The $1.1 million decrease was primarily the result of a Lease Buyout in the prior period.

Service revenue for the year ended December 31, 2022 decreased to $1.4 million compared to $1.5 million for the year ended December 31, 2021.

Lease revenue for the year ended December 31, 2022 and 2021 remained consistent at approximately $1.4 million.

Cost of Revenue
Cost of revenue consists of contract manufacturing, materials, labor, and manufacturing overhead incurred internally to produce the products. Shipping and handling costs incurred by the Company are included in cost of revenue. We expense all inventory excess and 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.

Product cost for the year ended December 31, 2022 decreased to $5.3 million as compared to $5.7 million for the year ended December 31, 2021. The $0.4 million decrease primarily relates to a $0.7 million decrease in materials costs, which is primarily related to a Lease Buyout in the prior period. This decrease is partially offset by a $0.2 million increase in supplies cost and $0.1 million increase in consulting costs.

Service cost for the year ended December 31, 2022 increased to $2.2 million as compared to $1.8 million for the year ended December 31, 2021. The $0.4 million increase primarily relates to an increase in personnel-related costs of $0.4 million. 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.

Lease cost for the year ended December 31, 2022 decreased to $3.4 million as compared to $3.6 million for the year ended December 31, 2021. The $0.2 million decrease primarily relates to a decrease in materials costs.

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 continue to substantially increase as we invest in the LUNA™ Surgical System and our digital laparoscopy platform. R&D expenses are expensed as incurred.

R&D expenses for the year ended December 31, 2022 increased 50% to $28.9 million as compared to $19.3 million for the year ended December 31, 2021 as we continue to invest in basic research, clinical studies, and product development in the areas of robotics and digital technologies supporting the LUNA System and our digital laparoscopy platform. All activities are in the effort of building the future for Performance-Guided Surgery. The $9.6 million increase primarily relates to increased contract engineering services, consulting, and other outside services of $5.4 million. The change was also driven by increased personnel costs of $2.5 million, driven by additional headcount, increased supplies costs of $1.5 million and increased travel costs of $0.2 million.

Sales and Marketing

Sales and marketing expenses include costs for sales and marketing personnel, travel, demonstration product, market development, physician training, tradeshows, marketing clinical studies and consulting expenses.

Sales and marketing expenses for the year ended December 31, 2022 increased 10% to $14.8 million compared to $13.4 million for the year ended December 31, 2021. The $1.4 million increase was primarily related to increased employee related costs of $1.1 million due to an increase in headcount, increased consulting costs of $0.6 million, increased travel costs of $0.5 million, partially offset by decreased supplies costs of $0.5 million and decreased depreciation expense of $0.3 million.

General and Administrative

General and administrative expenses consist of personnel costs related to the executive, finance, legal 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, 2022 increased 5% to $20.2 million compared to $19.3 million for the year ended December 31, 2021. The $0.9 million increase was primarily related to increased software costs of $0.6 million and increased travel costs of $0.3 million.

Amortization of Intangible Assets

Amortization of intangible assets for the year ended December 31, 2022 decreased to $7.7 million compared to $11.3 million for the year ended December 31, 2021. The $3.6 million decrease is primarily related to the developed technologies intangibles that fully depreciated during the year ended December 31, 2022 with no offset.

Change in Fair Value of Contingent Consideration

The change in fair value of contingent consideration in connection with the Senhance Acquisition was a $1.1 million decrease for the year ended December 31, 2022 compared to a $1.6 million decrease for the year ended December 31, 2021. The decrease was primarily due to changes in the Company’s forecast of future product revenue, including changes in market assumptions and discount rate utilized.

Property and Equipment Impairment

During the year ended December 31, 2022, the Company recorded an impairment charge of $1.4 million to reduce the carrying value of property and equipment to its estimated fair value. The property and equipment impairment is associated with returned Senhance Systems under operating leases and Senhance Systems currently under operating leases that are not expected to generate future cash flows sufficient to recover their net book value. No impairment charge was recognized for the year ended December 31, 2021.

Other Income (Expense), net
The Company recognized $0.4 million other income for the year ended December 31, 2022, compared to $2.4 million other income for the year ended December 31, 2021. Other income for the year ended December 31, 2021 primarily related to the gain on extinguishment of debt of $2.8 million and $1.3 million refund for the Employee Retention Credit (ERTC), partially offset by the change in the fair value of Series B Warrants of $2.0 million. No related income or expense was recorded in the year ended December 31, 2022.

Income Tax Expense
The Company recognized $0.3 million income tax expense for the year ended December 31, 2022, compared to $0.2 million income tax expense for the year ended December 31, 2021. Income tax expense consisted primarily of current income taxes related to profitable foreign jurisdictions in Japan, Israel, and the Netherlands.

Liquidity and Capital Resources

Going Concern
The Company's consolidated financial statements are prepared using U.S. GAAP applicable to a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. The Company had an accumulated deficit of $860.9 million and working capital of $76.5 million as of December 31, 2022. The Company has not established sufficient revenues to cover its operating costs and will require additional capital to continue as a going concern. As of December 31, 2022, the Company had cash, cash equivalents, short-term investments and long-term investments, excluding restricted cash, of approximately $74.4 million. We believe that our existing cash, cash equivalents, short-term investments and long-term investments, together with cash received from product, service, and lease sales will be sufficient to meet our anticipated cash needs into the first quarter of 2024.

The Company will need to obtain additional financing to proceed with its business plan. Management's plan to obtain additional resources for the Company may include additional sales of equity, traditional financing, such as loans, entry into a strategic collaboration, entry into an out-licensing arrangement or provision of additional distribution rights in some or all of our markets. However, management cannot provide any assurance that the Company will be successful in accomplishing any or all of its plans. If sufficient funds are not received on a timely basis, the Company would then need to purse a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection. The ability to successfully resolve these factors raise substantial doubt about the Company's ability to continue as a going concern within one year from the date that these financial statements are issued. The consolidated financial statements of the Company do not include any adjustments that may result from the outcome of these aforementioned uncertainties.

The Company believes the COVID-19 pandemic and other geopolitical factors 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.

The Company is subject to risks similar to other similarly sized companies in the medical device industry. These risks include, without limitation: negative impacts on the Company's operations caused by the COVID-19 pandemic and other geopolitical factors; the historical lack of profitability; the Company's ability to grow its placements and increase utilization of the Senhance System by customers, the Company's ability to raise additional capital; the success of its market development efforts; 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 healthcare regulatory environments of the United States, the European Union, Japan, Taiwan and other countries in which the Company operates or intends to operate; its ability to attract and retain key management, marketing and scientific personnel; its ability to successfully prepare, file, prosecute, maintain, defend and enforce patent claims and other intellectual property rights; its ability to successfully transition from a research and development company to a marketing, sales and distribution concern; competition in the market for robotic and digital surgical devices; and its ability to identify and pursue development of additional products.

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

Consolidated Cash Flow Data

(In millions)	Year Ended December 31, 2022	2021
Net cash (used in) provided by		
Operating activities	$ (58.9)	$ (40.7)
Investing activities	47.5	(119.7)
Financing activities	(0.3)	161.7
Effect of exchange rate changes on cash and cash equivalents	(0.1)	0.4
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (11.8)	$ 1.7

Operating Activities

For the year ended December 31, 2022, cash used in operating activities of $58.9 million consisted of a net loss of $75.6 million, changes in operating assets and liabilities of $4.7 million, offset by non-cash items of $21.4 million. The non-cash items primarily consisted of $8.4 million of stock-based compensation expense, $7.7 million of amortization of intangible assets, $3.4 million of depreciation, $1.4 million of property and equipment impairment, $0.6 million change in inventory reserves, $0.6 million net amortization of discounts and premiums on investments, $0.3 million deferred tax expense, and $0.1 million loss on disposal of property and equipment, offset by $1.1 million of change in fair value of contingent consideration. The decrease in cash from changes in operating assets and liabilities primarily relates to a $3.9 million decrease in accrued expenses, $2.3 million increase in inventory net of transfers to property and equipment, $2.1 million increase in other current and long-term assets, $1.5 million increase in accounts receivable, and $0.4 million increase in prepaid expenses, offset by $4.5 million increase in accrued employee compensation and benefits, $0.8 million decrease in employee retention tax credit receivable, and $0.2 million decrease in operating lease right-of-use assets.

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, $0.9 million decrease in accrued employee compensation and benefits, $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 $0.4 million increase 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.

Investing Activities

For the year ended December 31, 2022, net cash provided by investing activities was $47.5 million. This amount consists of $82.7 million of proceeds from maturities of available-for-sale investments, offset by $33.9 million of purchases of available-for-sale investments and $1.3 million purchases of property and equipment.

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.

Financing Activities

For the year ended December 31, 2022, net cash used in financing activities was $0.3 million, primarily related to taxes paid for the net share settlement of vesting of restricted stock units.

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.

Operating Capital and Capital Expenditure Requirements

We intend to spend substantial amounts on research and development activities, including product development, regulatory and compliance, and clinical studies in support of the development of the LUNA System and our digital solutions platform. We intend to use financing opportunities strategically to continue to strengthen our financial position.

Cash and cash equivalents held by our foreign subsidiaries totaled $3.2 million as of December 31, 2022, 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, 2022, 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, contingent consideration, 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, 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.

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 of Senhance Systems, Senhance System components, and instruments and accessories. Service revenue consists of revenue related to Senhance System service agreements. Lease revenue consists of revenue generated from utilizing the Senhance System, instruments and accessories, and servicing of the Senhance System under operating lease agreements. 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 upon delivery. 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, 2022, 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 lease 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. Determination of the realizability of deferred tax assets requires management’s judgment. Valuation allowances are established when necessary to reduce deferred tax assets and liabilities to the estimated amounts expected to be realized.

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, 2022 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 89% and 87% of revenue for year ended December 31, 2022 and 2021, 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, 2022, would result in revenue changing by $0.6 million. This change would not be material to our cash flows and our results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

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

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Inventories Valuation

Inventories totaled approximately $13.8 million at December 31, 2022, including approximately $5.5 million classified as noncurrent. 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 historical consumption and 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:

- Evaluating the reasonableness of management’s assumption that future consumption of raw materials and sale of instruments and accessories approximates actual consumption and sales of identical items in historical periods and evaluating the time period over which management expects future consumption and sales to occur.
- Evaluating the reasonableness of management’s forecasted demand for Senhance Systems based on the results of historical sales and leasing efforts, expectations with respect to future sales and lease placements, and expectations with respect to product life cycles.
- Testing management’s estimation of the net realizable value of completed Senhance Systems and system components, included in finished goods inventories, by evaluating the Company’s assumptions with respect to selling prices and lease terms.

/s/ BDO USA, LLP

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

Raleigh, North Carolina
March 2, 2023

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

	December 31, 2022	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	$ 6,329	$ 18,129
Short-term investments, available-for-sale	64,195	80,262
Accounts receivable, net	2,256	749
Inventories	8,284	8,634
Prepaid expenses	3,584	3,255
Employee retention tax credit receivable	554	1,311
Other current assets	1,671	957
Total Current Assets	86,873	113,297
Restricted cash	1,141	1,154
Long-term investments, available-for-sale	3,865	37,435
Inventories, net of current portion	5,469	7,074
Property and equipment, net	9,542	10,971
Intellectual property, net	1,576	9,892
Net deferred tax assets	174	288
Operating lease right-of-use assets, net	4,950	5,348
Other long-term assets	2,463	1,014
Total Assets	$ 116,053	$ 186,473
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 3,348	$ 3,448
Accrued employee compensation and benefits	4,508	3,559
Accrued expenses and other current liabilities	1,293	1,617
Operating lease liabilities - current portion	800	683
Deferred revenue	465	543
Total Current Liabilities	10,414	9,850
Long-Term Liabilities:		
Contingent consideration	1,256	2,371
Noncurrent operating lease liabilities	4,738	5,006
Total Liabilities	16,408	17,227
Commitments and Contingencies (Note 16)		
Stockholders' Equity:		
Common stock $0.001 par value, 750,000,000 shares authorized at December 31, 2022 and December 31, 2021; 236,895,440 and 235,218,552 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	237	235
Preferred stock, $0.01 par value, 25,000,000 shares authorized, no shares issued and outstanding at December 31, 2022 and December 31, 2021	-	-
Additional paid-in capital	962,731	954,649
Accumulated deficit	(860,935)	(785,374)
Accumulated other comprehensive loss	(2,388)	(264)
Total Stockholders' Equity	99,645	169,246
Total Liabilities and Stockholders' Equity	$ 116,053	$ 186,473

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,	
	2022	**2021**
Revenue:		
Product	$ 4,327	$ 5,399
Service	1,373	1,520
Lease	1,387	1,313
Total revenue	7,087	8,232
Cost of revenue:		
Product	5,303	5,741
Service	2,174	1,799
Lease	3,395	3,556
Total cost of revenue	10,872	11,096
Gross loss	(3,785)	(2,864)
Operating Expenses:		
Research and development	28,942	19,348
Sales and marketing	14,756	13,395
General and administrative	20,172	19,323
Amortization of intangible assets	7,708	11,254
Change in fair value of contingent consideration	(1,115)	(1,565)
Property and equipment impairment	1,431	-
Total Operating Expenses	71,894	61,755
Operating Loss	(75,679)	(64,619)
Other Income (Expense), net		
Gain on extinguishment of debt	-	2,847
Change in fair value of warrant liabilities	-	(1,981)
Interest income	1,141	590
Interest expense	(410)	(370)
Employee retention tax credit	-	1,311
Other expense, net	(295)	(15)
Total Other Income (Expense), net	436	2,382
Loss before income taxes	(75,243)	(62,237)
Income tax expense	(318)	(225)
Net loss	(75,561)	(62,462)
Comprehensive loss:		
Net loss	(75,561)	(62,462)
Foreign currency translation loss	(1,867)	(2,985)
Unrealized loss on available-for-sale investments	(257)	(247)
Comprehensive loss	$ (77,685)	$ (65,694)
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.32)	$ (0.28)
Weighted average number of shares used in computing net loss per common share - basic and diluted	236,492	226,960

See accompanying notes to consolidated financial statements.

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

	Common Stock		Treasury Stock					
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
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	72	-	-	131,857	-	-	131,929
Exercise of stock options and warrants	45,630	46	-	-	33,029	-	-	33,075
Award of restricted stock units	1,571	1	-	-	-	-	-	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**
Stock-based compensation	-	-	-	-	8,416	-	-	8,416
Exercise of stock options	43	-	-	-	18	-	-	18
Award of restricted stock units	1,633	2	-	-	-	-	-	2
Return of common stock to pay withholding taxes on restricted stock	-	-	443	-	(352)	-	-	(352)
Cancellation of treasury stock	-	-	(443)	-	-	-	-	-
Other comprehensive loss	-	-	-	-	-	-	(2,124)	(2,124)
Net loss	-	-	-	-	-	(75,561)	-	(75,561)
Balance, December 31, 2022	**236,895**	**$ 237**	-	**$** -	**$ 962,731**	**$ (860,935)**	**$ (2,388)**	**$ 99,645**

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2022	**2021**
Operating Activities:		
Net loss	$ (75,561)	$ (62,462)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	3,368	2,857
Amortization of intangible assets	7,708	11,254
Amortization of discounts and premiums on investments, net	565	409
Stock-based compensation	8,416	9,429
Gain on extinguishment of debt	-	(2,847)
Deferred tax expense	318	225
Change in inventory reserves	620	(492)
Bad debt expense	9	144
Property and equipment impairment	1,431	-
Loss on disposal of property and equipment	122	-
Change in fair value of warrant liabilities	-	1,981
Change in fair value of contingent consideration	(1,115)	(1,565)
Changes in operating assets and liabilities:		
Accounts receivable	(1,528)	174
Inventories	(2,302)	(611)
Operating lease right-of-use assets	232	(4,254)
Prepaid expenses	(450)	146
Employee retention tax credit receivable	757	(1,311)
Other current and long-term assets	(2,101)	902
Accounts payable	35	1,614
Accrued employee compensation and benefits	4,523	(859)
Accrued expenses	(3,955)	384
Deferred revenue	(55)	(229)
Operating lease liabilities	26	4,452
Net cash and cash equivalents used in operating activities	(58,937)	(40,659)
Investing Activities:		
Purchase of available-for-sale investments	(33,886)	(122,330)
Proceeds from maturities of available-for-sale investments	82,702	4,030
Purchase of property and equipment	(1,279)	(1,368)
Net cash and cash equivalents provided by (used in) investing activities	47,537	(119,668)
Financing Activities:		
Proceeds from issuance of common stock, net of issuance costs	-	131,929
Taxes paid related to net share settlement of vesting of restricted stock units	(350)	(1,063)
Proceeds from exercise of stock options and warrants	18	30,839
Net cash and cash equivalents (used in) provided by financing activities	(332)	161,705
Effect of exchange rate changes on cash and cash equivalents	(81)	376
Net (decrease) increase in cash, cash equivalents and restricted cash	(11,813)	1,754
Cash, cash equivalents and restricted cash, beginning of period	19,283	17,529
Cash, cash equivalents and restricted cash, end of period	$ 7,470	$ 19,283
Supplemental Disclosure for Cash Flow Information		
Cash paid for leases	$ 984	$ 1,490
Cash paid for taxes	$ 165	$ 170
Supplemental Schedule of Non-cash Investing and Financing Activities:		
Transfer of inventories to property and equipment	$ 2,693	$ 3,244
Reclass of warrant liability to common stock and additional paid-in-capital	$ -	$ 2,236
Lease liabilities arising from obtaining right-of-use assets	$ 577	$ 5,119

See accompanying notes to consolidated financial statements.

Asensus Surgical, Inc.
Notes to Consolidated Financial Statements

1. Description of the Business

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.

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.

Going Concern
The Company's consolidated financial statements are prepared using U.S. GAAP applicable to a going concern, which contemplate the realization of assets and liquidation of liabilities in the normal course of business. The Company had an accumulated deficit of $860.9 million and working capital of $76.5 million as of December 31, 2022. The Company has not established sufficient sales revenues to cover its operating costs and requires additional capital to proceed with its operating plan. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable.

The Company will need to obtain additional financing to proceed with its business plan. Management's plan to obtain additional resources for the Company may include additional sales of equity, traditional financing, such as loans, entry into a strategic collaboration, entry into an out-licensing arrangement or provision of additional distribution rights in some or all of our markets. However, management cannot provide any assurance that the Company will be successful in accomplishing any or all of its plans. The ability to successfully resolve these factors raise substantial doubt about the Company’s ability to meet its existing obligations, and to continue as a going concern within one year from the date that these financial statements are issued. The consolidated financial statements of the Company do not include any adjustments that may result from the outcome of these aforementioned uncertainties.

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 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 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, 2022 and 2021 were not material.

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. Revenue and cost of revenue for leases were historically included in product and service revenue and corresponding cost of revenue on the consolidated statements of operations and comprehensive loss for the year ended December 31, 2021. Accrued employee compensation and benefits were historically included in accrued expenses and other current liabilities on the consolidated balance sheets for the year ended December 31, 2021.

Revision of Previously Disclosed Amounts
During the course of preparing the Company's unaudited consolidated financial statements as of and for the six months ended June 30, 2022, the Company determined that its December 31, 2021 inventory footnote presentation overstated raw materials and understated finished goods by $2.5 million. For comparative purposes, Note 7 – Inventories, has been revised to reflect the adjustment to raw materials and finished goods as of December 31, 2021. The revision had no effect on the previously reported total gross and net carrying value of inventory. The revision also had no effect on the previously reported consolidated balance sheets, statements of operations and comprehensive loss, cash flows and stockholders' equity.

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: negative impacts on the Company's operations caused by the COVID-19 pandemic and other geopolitical factors; the historical lack of profitability; the Company's ability to raise additional capital; the success of its market development efforts; 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 healthcare 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.

Use of Estimates
The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant items subject to such estimates and assumptions include impairment considerations for long-lived assets, fair value estimates related to contingent consideration, stock compensation expense, revenue recognition, 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.

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, 2022 and 2021 includes $1.1 million 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, 2022 consisted of commercial paper, corporate bonds, and United States government agencies 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 loss on the consolidated balance sheets until realized. 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. There were no gross realized gains or loss for the year ended December 31, 2022. The Company recognized an immaterial amount of gross realized losses for the year ended December 31, 2021. There were no gross realized gains for the year ended December 31, 2021.

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.

There have been no credit losses for the years ended December 31, 2022 and 2021, and no allowance for credit losses as of December 31, 2022. Factors considered in determining whether a credit loss exists include credit ratings and other qualitative factors for each security type in the portfolio.

Fair Value Measurements

The Company measures the fair value of money market funds, certain U.S. treasury securities, and equity investments with readily determinable value based on quoted prices in active markets for identical assets as Level 1 securities. Marketable securities measured at fair value using Level 2 inputs are primarily comprised of commercial paper and corporate notes and bonds without readily determinable value. The Company reviews trading activity and pricing for these investments as of the measurement date. When sufficient quoted pricing for identical securities is not available, the Company uses market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data. This approach results in the Level 2 classification of these securities within the fair value hierarchy. The Company measures contingent consideration at fair value using a Monte-Carlo simulation utilizing Level 3 inputs. These inputs include 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.

Concentrations and Credit Risk

The Company’s principal financial instruments subject to potential concentration of credit risk are cash and cash equivalents (including restricted cash), 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 had one customer that accounted for 69% of the Company’s net accounts receivable as of December 31, 2022. The Company had three customers that accounted for 26%, 20%, and 14%, respectively, of the Company’s net accounts receivable as of December 31, 2021. The Company had one customer who accounted for 47% of revenue in 2022, and two customers who accounted for 36% and 16% of revenue in 2021, respectively.

Accounts Receivable

Accounts receivable are recorded at net realizable value, which includes an allowance for expected credit losses. The allowance for expected credit losses is based on the Company’s assessment of collectability of customer accounts. The Company regularly reviews the allowance by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer’s ability to pay. The allowance for expected credit losses was $1.6 million and $1.7 million as of December 31, 2022, and December 31, 2021, respectively. The Company recorded an immaterial amount for expected credit losses during the year ended December 31, 2022 and $0.1 million during the year ended December 31, 2021.

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 historical consumption and 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.

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) a 2018 acquisition 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 years ended December 31, 2022 and 2021.

Property and Equipment

Property and equipment consists primarily of operating lease Senhance System assets, machinery, manufacturing equipment, demonstration equipment, computer equipment, furniture, and leasehold improvements, which are recorded at cost 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

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.

During the year ended December 31, 2022, the Company recorded a non-cash asset impairment charge of $1.4 million to reduce the carrying value of property and equipment to its estimated fair value. The property and equipment impairment is associated with returned Senhance Systems under operating leases and Senhance Systems currently under operating leases that are not expected to generate future cash flows sufficient to recover their net book value. The fair value was estimated based on the discounted cash flows expected to be produced by the property and equipment. The impairment was recorded in property and equipment impairment on the consolidated statements of operations and comprehensive loss. No such impairment charges were recorded during the year ended December 31, 2021.

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.

The Company accounts for lease components and non-lease components 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. 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.

The interest rate implicit in our 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.

Implementation Costs in a Cloud Computing Arrangement
The Company capitalizes qualified implementation costs incurred in a hosting arrangement that is a service contract. These capitalized implementation costs are recorded within other current and long-term assets, and are generally amortized over the fixed, non-cancellable term of the associated hosting arrangement on a straight-line basis and included within operating expenses.

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. 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 received notification from the IRS that the relevant conditions of the employee retention credit provision were met and that it will receive the credit. The Company received $0.7 million of the ERTC refund during the year ended December 31, 2022. The remaining $0.6 million is recorded as a current asset on the consolidated balance sheets as of December 31, 2022.

Notes Payable
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.

As of December 31, 2022, the Company has $0.6 million available under a letter of credit. No amounts have been utilized by the Company as of December 31, 2022.

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"), an Italian company, 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, 2022, the Company has accrued $1.3 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. In 2022, Sofar assigned its right to receive the contingent payment to Three Heads Investment S.r.l.

Warrant Liabilities
The Company's Series B Warrants were measured at fair value using a simulation model which considered, 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 of Senhance Systems, Senhance System components, and instruments and accessories. Service revenue consists of revenue related to Senhance System service agreements. Lease revenue consists of revenue generated from utilizing the Senhance System, instruments and accessories, and servicing of the Senhance System under operating lease agreements. 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 upon delivery. 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 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, and are included in accounts receivable.

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. For the years ended December 31, 2022 and 2021, variable lease revenue related to usage-based arrangements was not material.

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, 2022 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. As of December 31, 2022 future minimum lease payments due from customers was $2.2 million, which is expected to be received over the next one to three years.

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 performance-based restricted stock 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. See "Note 13 – Stock-Based Compensation," for a detailed discussion of the Company's stock plans and stock-based compensation expense.

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.

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.

Impact of Recently Issued Accounting Standards

The Company has evaluated issued ASUs not yet adopted and believes the adoption of these standards will not have a material impact on its consolidated financial statements.

3. Revenue Recognition

The following table presents revenue disaggregated by type and geography:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
U.S.		
Systems	$ -	$ -
Instruments and accessories	211	273
Services	300	383
Leases	256	377
Total U.S. revenue	767	1,033
Outside of U.S. ("OUS")		
Systems	2,551	3,286
Instruments and accessories	1,565	1,840
Services	1,073	1,137
Leases	1,131	936
Total OUS revenue	6,320	7,199
Total		
Systems	2,551	3,286
Instruments and accessories	1,776	2,113
Services	1,373	1,520
Leases	1,387	1,313
Total revenue	$ 7,087	$ 8,232

Remaining Performance Obligations
The 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 as of December 31, 2022 was $1.1 million, which is expected to be recognized over one to four years.

Contract Assets and Liabilities

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, 2022 and 2021 that was included in the deferred revenue balance at the beginning of each reporting period was $0.5 million and $0.6 million, respectively.

The following information summarizes the Company's contract assets and liabilities:

	December 31, 2022	December 31, 2021
	(in thousands)	
Contract Assets	$ 116	$ 91
Deferred Revenue	$ 465	$ 543

4. Cash, Cash Equivalents, and Restricted Cash

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

	December 31, 2022	December 31, 2021
	(in thousands)	
Cash	$ 3,473	$ 8,343
Money Market	2,856	5,287
Commerical Paper	-	4,499
Total cash and cash equivalents	$ 6,329	$ 18,129
Restricted Cash	1,141	1,154
Total	$ 7,470	$ 19,283

Restricted cash at December 31, 2022 and 2021 includes $1.1 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 cumulative unrealized gains and losses determined on an individual investment security basis and included in other comprehensive loss are as follows:

	December 31, 2022 (in thousands)					
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value	Short-term investments	Long-term investments
Commercial Paper	$ 12,364	$ -	$ (49)	$ 12,315	$ 12,315	$ -
Corporate Bonds	55,201	-	(447)	54,754	50,889	3,865
U.S. Government Agencies	999	-	(8)	991	991	-
Total Investments	$ 68,564	$ -	$ (504)	$ 68,060	$ 64,195	$ 3,865

	December 31, 2021 (in thousands)					
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value	Short-term investments	Long-term investments
Commercial 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:

	December 31, 2022 (in thousands)	
	Amortized Cost	Fair Value
Mature in less than one year	$ 64,662	$ 64,195
Mature in one to two years	3,902	3,865
Total	$ 68,564	$ 68,060

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 for the years ended December 31, 2022 or 2021, respectively. There were no realized gains or losses for the years ended December 31, 2022. 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 following are categories of assets and liabilities measured at fair value on a recurring basis 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, 2022 (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]	$ 6,329	$ -	$ -	$ 6,329
Restricted cash	1,141	-	-	1,141
Short-term investments	-	64,195	-	64,195
Long-term investments	-	3,865	-	3,865
Total assets measured at fair value	$ 7,470	$ 68,060	$ -	$ 75,530
Liabilities measured at fair value				
Contingent consideration	$ -	$ -	$ 1,256	$ 1,256
Total liabilities measured at fair value	$ -	$ -	$ 1,256	$ 1,256

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

	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.

The carrying values of accounts receivable, prepaid expenses, employee retention tax credit receivables, other current assets, accounts payable, accrued employee compensation and benefits, accrued expenses, deferred revenue, and other current liabilities as of December 31, 2022, and December 31, 2021, approximate their fair values due to the short-term nature of these items.

The Company's financial liabilities consisted of contingent consideration payable to Three Heads Investment S.r.l., related to the Company's 2015 acquisition of the Senhance Surgical System from an assignor to Three Heads Investment S.r.l. (the "Senhance Acquisition"). 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 utilizing a Monte-Carlo simulation as of December 31, 2022 and December 31, 2021:

	Valuation Methodology	**Significant Unobservable Input**	**December 31, 2022**	**December 31, 2021**
Contingent consideration	Probability weighted income approach	Milestone dates	2032	2031
		Discount rate	16.5%	9.5%
		Revenue volatility	45.0%	39.0%
		EUR-to-USD exchange rate	1.07	1.14

The following table presents the current and long-term portion of the contingent consideration for the year ended December 31, 2022 and summarizes the change in fair value, as determined by Level 3 inputs for the contingent consideration for the year ended December 31, 2022 and 2021:

	Fair Value Measurement at Reporting Date (Level 3)
	(in thousands)
	Contingent consideration
Balance at December 31, 2020	$ 3,936
Change in fair value	(1,565)
Balance at December 31, 2021	$ 2,371
Change in fair value	(1,115)
Balance at December 31, 2022	$ 1,256
Current portion	$ -
Long-term portion	1,256
Balance at December 31, 2022	$ 1,256

7. Inventories

The components of inventories are as follows:

	December 31, 2022		
	(in thousands)		
	Gross Carrying Amount	Reserve Balance	Net Carrying Amount
Finished goods	$ 15,337	$ (4,129)	$ 11,208
Raw materials	4,718	(2,173)	2,545
Total inventories	$ 20,055	$ (6,302)	$ 13,753
Current Portion	$ 9,399	$ (1,115)	$ 8,284
Long-term portion	10,656	(5,187)	5,469
Total inventories	$ 20,055	$ (6,302)	$ 13,753

	December 31, 2021		
	(in thousands)		
	Gross Carrying Amount	Reserve Balance	Net Carrying Amount
Finished goods	$ 13,066	$ (2,987)	$ 10,079
Raw materials	8,324	(2,695)	5,629
Total inventories	$ 21,390	$ (5,682)	$ 15,708
Current Portion	$ 9,931	$ (1,297)	$ 8,634
Long-term portion	11,459	(4,385)	7,074
Total inventories	$ 21,390	$ (5,682)	$ 15,708

8. Property and Equipment

Property and equipment consisted of the following:

	December 31, 2022	December 31, 2021
	(In thousands)	
Machinery, manufacturing, and demonstration equipment	$ 8,450	$ 8,289
Operating lease assets - Senhance System leasing	10,251	10,143
Computer equipment	600	325
Furniture	831	644
Leasehold improvements	1,654	1,259
Construction in process	436	-
Total property and equipment	22,222	20,660
Accumulated depreciation and amortization	(12,680)	(9,689)
Property and equipment, net	$ 9,542	$ 10,971

Depreciation expense was approximately $3.4 million and $2.9 million for the years ended December 31, 2022 and 2021, respectively.

9. Intellectual Property

The components of gross intellectual property, accumulated amortization, and net intellectual property are as follows:

	December 31, 2022 (in thousands)			
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation Impact	Net Carrying Amount
Developed technology	$ 68,838	$ (66,562)	$ (874)	$ 1,402
Technology and patents purchased	400	(239)	13	174
Total intellectual property	$ 69,238	$ (66,801)	$ (861)	$ 1,576

	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	$ 69,238	$ (59,111)	$ (235)	$ 9,892

The weighted average remaining useful life of the developed technology and technology and patents purchased was 4.2 years and 4.3 years, respectively, as of December 31, 2022. 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 intellectual property as of December 31, 2022 is as follows (in thousands):

	Year Ending December 31, 2022
2023	$ 377
2024	377
2025	377
2026	377
2027	68
Total	$ 1,576

10. Leases

Lessee Information

Components of operating lease expense are primarily recorded in general and administrative on the consolidated statements of operations and comprehensive loss were as follows:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Long-term Operating	$ 1,557	$ 1,826
Short-term Operating	-	-
Total Operating lease expense	$ 1,557	$ 1,826

Supplemental balance sheet information related to operating leases was as follows:

	December 31, 2022	December 31, 2021
Weighted-average remaining lease term (in years)	6.8	7.8
Weighted-average discount rate	8.4%	7.8%
Incremental borrowing rate	6.1% - 14.5%	6.1% - 8.5%

Maturities of operating lease obligations as of December 31, 2022 were as follows (in thousands):

Fiscal Year	
2023	$ 1,222
2024	1,136
2025	1,058
2026	837
2027	775
Thereafter	2,195
Total minimum lease payments	$ 7,223
Less: Amount of lease payments representing interest	(1,685)
Present value of future minimum lease payments	$ 5,538

11. Accrued Expenses

The following table presents the components of accrued expenses:

	December 31, 2022	December 31, 2021
	(In thousands)	
Consulting and other vendors	$ 155	$ 128
Other	—	124
Royalties	24	247
Legal and professional fees	275	503
Taxes and other assessments	839	615
Total	$ 1,293	$ 1,617

12. Income Taxes

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

	2022	2021
Current income taxes		
Federal	$ -	$ -
State	-	-
Foreign	239	232
Deferred income taxes		
Federal	-	-
State	-	-
Foreign	79	(7)
Total income tax expense	$ 318	$ 225

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

	2022	2021
United States	$ (44,802)	$ (32,094)
Foreign	(30,441)	(30,143)
Total loss from operations before taxes	$ (75,243)	$ (62,237)

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

	2022	2021
Deferred Tax assets:		
Stock-based compensation	$ 2,840	$ 2,440
Accrued expenses and other	2,538	2,423
Research credit carryforward	1,341	564
Fixed Assets	162	101
Capitalized start-up costs and other intangibles	921	1,109
Capitalized research costs	4,382	-
Net operating loss carryforwards	83,908	75,237
	96,092	81,874
Valuation Allowance	(94,704)	(78,294)
Net deferred tax asset	1,388	3,580
Deferred tax liabilities		
Fixed assets and other	(1,214)	(1,176)
Purchase accounting intangibles	-	(2,116)
Net deferred tax liability	(1,214)	(3,292)
Net deferred tax asset (liability)	$ 174	$ 288

During 2021, 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.

At December 31, 2022 and 2021, 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 $16.4 million from the prior year. At December 31, 2022, the Company had U.S. federal net operating loss carryforwards of $419.4 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 $164.9 million carry forward indefinitely. At December 31, 2022, the Company had U.S. state net operating loss carryforwards of $328.9 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), $317.4 million of state NOLs begin to expire in 2022, while the remaining $11.5 million carry forward indefinitely. At December 31, 2022, the Company had federal research credit carryforwards in the amount of $10.2 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, 2022, the Company had foreign operating loss carryforwards in Italy of approximately $24.6 million, which can be carried forward indefinitely; foreign operating loss carryforwards in Luxembourg of approximately $95.9 million, which will begin to expire in 2034; foreign operating loss carryforwards in Switzerland of approximately $116.5 million, which begin to expire in 2023, and foreign operating loss carryforwards in Canada of approximately $0.9 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, 2022, the Company had gross unrecognized tax benefits of approximately $0.3 million. Of the total, none would reduce the Company's effective tax rate if recognized. The Company does not anticipate a significant change in total unrecognized tax benefits or the Company's effective tax rate due to the settlement of audits or the expiration of statutes of limitations within the next twelve months. Furthermore, the Company does not expect any cash settlement with the taxing authorities as a result of these unrecognized tax benefits as the Company has sufficient unutilized carryforward attributes to offset the tax impact of these adjustments.

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

	2022	2021
Beginning balance	$ 141	$ -
Gross increases for tax positions related to current periods	194	141
Gross decreases related to 382 limitations	-	-
Ending balance	$ 335	$ 141

The Company recognizes interest and penalties related to uncertain tax positions in the provision for income taxes. As of December 31, 2022 and 2021, 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 2019, although carryforward attributes that were generated prior to 2019 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:

	2022		2021	
	Amount	Percent of Pretax Earnings	Amount	Percent of Pretax Earnings
United States federal tax at statutory rate	$ (15,801)	21.0%	$ (13,070)	21.0%
State taxes (net of deferred benefit)	(2,912)	3.9%	(2,205)	3.5%
Nondeductible expenses	1,077	(1.4%)	(440)	0.7%
Change in fair market value of contingent consideration	(283)	0.4%	(397)	0.6%
Warrant remeasurment and financing costs	-	-	502	(0.8%)
Research & Development	(970)	1.3%	(705)	1.1%
Change in unrecognized tax benefits	194	(0.3%)	141	(0.2%)
Foreign tax rate differential	2,676	(3.6%)	1,911	(3.1%)
True-up to Stock Compensation - Cancellations	49	(0.1%)	2,832	(4.6%)
Change in enacted tax rates and other, net	(96)	0.2%	731	(1.0%)
Change in valuation allowance	16,384	(21.8%)	10,925	(17.6%)
Income tax expense (benefit)	$ 318	(0.4%)	$ 225	(0.4%)

13. 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, 2022, there were 32,072,308 shares authorized for issuance, and 11,038,824 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.

Stock Options

The following table summarizes the Company's stock option activity, including grants to non-employees, for the year ended December 31, 2022:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Balance at December 31, 2021	4,640,660	$ 6.64	5.66
Granted	3,153,881	0.70	
Forfeited	(129,134)	1.60	
Cancelled	(36,987)	21.11	
Exercised	(43,453)	0.41	
Balance at December 31, 2022	7,584,967	$ 4.22	5.31

The aggregate intrinsic value of stock options exercised under the Company's stock plans was not material during the year ended December 31, 2022.

The following table summarizes information about stock options outstanding at December 31, 2022:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Millions)
Exercisable at December 31, 2022	3,524,473	$ 7.40	4.75	$ -
Vested or expected to vest at December 31, 2022	7,350,141	$ 4.32	5.28	$ -

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

	Years Ended December 31,	
	2022	2021
Expected dividend yield	0%	0%
Expected volatility	126% - 133%	118% - 139%
Risk-free interest rate	1.25% - 4.40%	0.33% - 1.11%
Expected life (in years)	3.8 - 4.5	3.8 - 4.5

Restricted Stock Units
The following is a summary of the restricted stock units activity, including performance restricted stock units, for the year ended December 31, 2022:

	Number of Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Unvested December 31, 2021	3,839,030	$ 2.36
Granted	6,996,822	0.71
Vested	(2,076,663)	2.34
Forfeited	(275,698)	1.19
Unvested December 31, 2022	8,483,491	$ 1.04

Performance Restricted Stock Units
In 2022 and 2021, 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 2022 and 2021 awards are based on achieving designated corporate goals. These operational targets were achieved for 2022 and 2021, therefore the performance-based restricted stock units are fully earned and remain subject to three-year time-based vesting requirements.

Stock-based Compensation Expense
The following table summarizes non-cash stock-based compensation expense by award type for the years ended December 31, 2022, and 2021:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Stock options	$ 3,654	$ 4,535
Restricted stock units	3,319	3,954
Performance restricted stock units	1,443	940
	$ 8,416	$ 9,429

As of December 31, 2022, the Company had future employee stock-based compensation expense of approximately $2.1 million related to unvested stock options, which is expected to be recognized over an estimated weighted-average period of 1.5 years. As of December 31, 2022, the unrecognized stock-based compensation expense related to unvested restricted stock units and performance restricted stock units was approximately $4.2 million, which is expected to be recognized over a weighted average period of approximately 1.4 years.

14. Equity Offerings

Equity financing transactions for the years ended December 31, 2022 and 2021, include:

2020 ATM Offering. 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 (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 net proceeds of $28.6 million.

2021 ATM Offering. On May 19, 2021, we entered into a Controlled Equity Offering℠ 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 2021 and 2020 ATM Offering 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
Commisssion earned by Sales Agents	$ 928
Net proceeds	$ 30,015

2021 Exercise of Warrants. During the year ended December 31, 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.

2022 ATM Offering. On March 18, 2022, the Company entered a Controlled Equity Offering Sales Agreement (the "2022 Sales Agreement"), with Cantor Fitzgerald & Co., and Oppenheimer & Co. Inc. The Company commenced an at-the-market offering (the "2022 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. No sales of common stock were made under the 2022 ATM Offering during the year ended December 31, 2022.

15. 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, and warrants. No adjustments have been made to the weighted average outstanding common shares figures for the years ended December 31, 2022 or 2021 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,	
	2022	2021
Stock options	7,584,967	4,640,660
Stock warrants	1,021,076	1,120,300
Nonvested restricted stock units	8,483,491	3,839,030
Total	17,089,534	9,599,990

16. Commitments and Contingencies

License and Supply Agreements

As part of the Company's acquisition of the Senhance System in 2015, the Company assumed certain license and supply agreements. The Company has purchase orders with various suppliers for certain tooling, supplies, contract engineering and research services. Commitments related to license agreements and purchase orders are as follows (in thousands):

Fiscal Year	
2023	$ 5,976
2024	407
2025	313
2026	303
Total commitments	$ 6,999

17. Segments and Geographic Areas

The following table presents consolidated assets and long-lived assets by geographic area, which includes property and equipment, intellectual property, and operating lease assets:

	December 31, 2022	
	Long-Lived Assets	**Total Assets**
U.S.	35%	72%
EMEA		
Switzerland	46%	24%
Italy	8%	2%
Other	8%	1%
Total EMEA	62%	27%
Asia	3%	1%
Total	100%	100%

	December 31, 2021	
	Long-Lived Assets	**Total Assets**
U.S.	26%	77%
EMEA		
Switzerland	34%	16%
Italy	36%	5%
Other	4%	1%
Total EMEA	74%	22%
Asia	0%	1%
Total	100%	100%

The following table presents sales by geographic area based on the country in which the customer is based.

	Years Ended December 31,	
	2022	**2021**
US	11%	13%
EMEA	77%	62%
Asia	12%	25%
Total	100%	100%

18. Related Party 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 $290,000 and $186,000 for the years ended December 31, 2022 and 2021, 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, 2022. 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, 2022, our disclosure controls and procedures were not effective due to ongoing remediation efforts described below.

Material Weakness in Internal Control over Financial Reporting

During the year ended December 31, 2022, management identified a deficiency constituting a material weakness related to the design and implementation of information technology general controls ("ITGCs") related to the implementation of our new global enterprise resource planning system ("ERP") utilized in the preparation of our consolidated financial statements. Specifically, we did not design and maintain user access controls to adequately restrict user and privileged access to the financial application and data to appropriate Company personnel.

The material weakness identified above did not result in any identified misstatements to our consolidated financial statements, and our management has concluded that the consolidated financial statements present fairly, in all material respects, our financial position, results of operations, and cash flows in conformity with U.S. GAAP. Based on this material weakness, management concluded that as of December 31, 2022, our internal control over financial reporting was not effective.

Remediation Efforts

We have commenced measures to remediate the identified material weakness. Management has been and will continue designing and implementing an improved process for requesting, authorizing, and reviewing user access to key systems which impact our financial reporting, including identifying access to roles where manual business process controls may be required. This implementation will include the addition of detection controls which will include the review of user access and activity logs related to systems that were accessed. We will also enhance the training of our personnel regarding their roles and responsibilities within the information technology general controls objectives and activities. The material weakness will not be considered remediated until management designs and implements effective controls that operate for a sufficient period of time for management to conclude, through testing, that the controls are operating effectively. The material weakness is not considered remediated as of December 31, 2022 as remediation efforts are ongoing.

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, 2022, 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, 2022, our internal control over financial reporting was not effective.

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, 2022 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

Not applicable.

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 Stockholders expected to be filed with the SEC on or prior to May 1, 2023.

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 Stockholders expected to be filed with the SEC on or prior to May 1, 2023.

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 Stockholders expected to be filed with the SEC on or prior to May 1, 2023.

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, 2022:

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	15,901,792	4.30	11,038,824
Equity compensation plans not approved by security holders (3)	166,666	0.42	0
Total	16,068,458		11,038,824

(1) Includes 7,434,967 shares underlying outstanding stock options awarded under the Plan and 8,466,825 restricted stock units awarded under the Plan.

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

(3) Represents 150,000 shares underlying outstanding stock options awarded prior to the Merger under the 2006 Plan and assumed in the Merger and ---16,666 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 Stockholders expected to be filed with the SEC on or prior to May 1, 2023.

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 Stockholders expected to be filed with the SEC on or prior to May 1, 2023.

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:

(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).
3.2	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 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).
4.3	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).
4.4	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).
4.5	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 (incorporated by reference to Exhibit 10.4.1 to our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 28, 2022).
10.4.2 +	Form of Employee Restricted Stock Unit/Performance Restricted Stock Unit Award Notice (incorporated by reference to Exhibit 10.4.2 to our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 28, 2022).
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 for the year ended December 31, 2020, 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 for the year ended December 31, 2020, 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 10.4.7 to our Annual Report on Form 10-K for the year ended December 31, 2020, 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 10.4.8 to our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 11, 2021 and incorporated herein by reference).
10.5+	Non-Qualified Deferred Compensation Plan, adopted December 8, 2021 (incorporated by reference to Exhibit 10.5 to our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 28, 2022).
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 (incorporated by reference to Exhibit 10.6.1 to our Annual Report on Form 10K for the year ended December 31, 2021, filed with the SEC on February 28, 2022).
10.7 +	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).
10.8	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).
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, 2022, 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.

March 2, 2023

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
/s/ Anthony Fernando Anthony Fernando	President, Chief Executive Officer and a Director (principal executive officer)	March 2, 2023
/s/ Shameze Rampertab Shameze Rampertab	Executive Vice President and Chief Financial Officer (principal financial officer and principal accounting officer)	March 2, 2023
/s/ David B. Milne David B. Milne	Chairman of the Board and a Director	March 2, 2023
/s/ Andrea Biffi Andrea Biffi	Director	March 2, 2023
/s/ Kevin Hobert Kevin Hobert	Director	March 2, 2023
/s/ Elizabeth Kwo, M.D. Elizabeth Kwo, M.D.	Director	March 2, 2023
/s/ Richard C. Pfenniger, Jr. Richard C. Pfenniger, Jr.	Director	March 2, 2023
/s/ William N. Starling, Jr. William N. Starling, Jr.	Director	March 2, 2023

Exhibit 21.1

Subsidiaries

(As of February 24, 2023)

Name of Subsidiary	Jurisdiction of Incorporation
Asensus Surgical US, Inc.	**Delaware**
Asensus International, Inc.	**Delaware**
Asensus Surgical Italia, S.r.l.	**Italy**
Asensus Surgical Europe S.à r.l.	**Luxembourg**
Asensus Surgical Netherlands B.V.	**Netherlands**
Asensus Surgical Israel Ltd	**Israel**
Asensus Surgical Canada, Inc.	**Ontario, Canada**
Asensus Surgical Japan K.K.	**Japan**
Asensus Taiwan Ltd.	**Taiwan**

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Asensus Surgical, Inc.
Durham, North Carolina

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-1 (No. 333-238471), Form S-3 (No. 333-263711 and No. 333-224049), and Form S-8 (No. 333-161291, No. 333-190184, No. 333-191011, No. 333-193234, No. 333-203950, No. 333-211972, No. 333-219111, No. 333-225231, No. 333-231078, No. 333-239018, No. 333-249895 and 333-258160) of Asensus Surgical, Inc. of our report dated March 2, 2023, relating to the consolidated financial statements which appear in this Annual Report on Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

Raleigh, North Carolina
March 2, 2023

Exhibit 31.1

SECTION 302 CERTIFICATION
CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER

I, Anthony Fernando, certify that:

(1) I have reviewed this Annual Report on Form 10-K of Asensus Surgical, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its unconsolidated investments, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2023

By: /s/ Anthony Fernando
Anthony Fernando
President and Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

SECTION 302 CERTIFICATION
CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER

I, Shameze Rampertab, certify that:

(1) I have reviewed this Annual Report on Form 10-K of Asensus Surgical, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its unconsolidated investments, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2023

By: /s/ Shameze Rampertab
Shameze Rampertab
Executive Vice President and Chief Financial Officer (Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the accompanying Annual Report on Form 10-K of Asensus Surgical, Inc. for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge and belief, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Asensus Surgical, Inc.

Date: March 2, 2023

By: /s/ Anthony Fernando
Anthony Fernando
President and Chief Executive Officer (Principal Executive Officer)

The certification set forth above is being furnished as an Exhibit solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and is not being filed as part of the Report or as a separate disclosure document of Asensus Surgical, Inc. or the certifying officers.

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the accompanying Annual Report on Form 10-K of Asensus Surgical, Inc. for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge and belief, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Asensus Surgical, Inc.

Date: March 2, 2023

By: /s/ Shameze Rampertab
Shameze Rampertab
Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

The certification set forth above is being furnished as an Exhibit solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and is not being filed as part of the Report or as a separate disclosure document of Asensus Surgical, Inc. or the certifying officers.