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, 2023

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, 2023, 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 $120.1 million.

The number of shares outstanding of the registrant's common stock as of March 15, 2024 was 271,986,369.

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 2024 Annual Meeting of Stockholders.

ASENSUS SURGICAL, INC.

ANNUAL REPORT ON FORM 10-K

DECEMBER 31, 2023

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FORWARD-LOOKING STATEMENTS

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

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

- our history of operating losses;
- our ability to continue as a going concern;
- our ability to raise capital to finance our business activities;
- 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 digital surgery offerings and grow our business as a result;
- 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 pioneer a new era of surgery, that we refer to as Performance-Guided Surgery™, or PGS, by unlocking clinical intelligence to enable surgeons to deliver consistently superior outcomes to patients. Built upon the foundation of digital laparoscopy and laparoscopic minimally invasive surgery, or MIS, (which remains the gold standard of surgery today), the Company is pioneering 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 Senhance® Surgical System, combined with the Intelligent Surgical Unit™, or ISU™, we intend to holistically address the current clinical, surgeon performance (fatigue and ergonomics), and economic shortcomings that impact surgical outcomes in a value-based healthcare environment. We are also working to incorporate all of this in our next generation robotic system we call the LUNA™ Surgical System.

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, which we believe is the missing element in surgery today.

Recent Developments

As of the date of this filing, the Company continues to manage cash prudently and believes it has cash into early June 2024. We are actively pursuing a number of financing options, including collaborations, contractual relationships and strategic transactions. However, we are aware that such alternatives are and may continue to be time consuming and that successful consummation of a transaction or transactions is not assured. We may need to pursue alternative pathways, including, but not limited to, debt financing, sale of assets or equity-based financing. If none of these alternatives are consummated, we may need to suspend our product development programs, including the LUNA System, and take other actions to preserve cash. We may also need to seek bankruptcy if these measures are insufficient or unsuccessful.

The disclosures in this Annual Report describe our business activities during 2023 and reflect our future product development plans if sufficient financing becomes available.

During 2023, we focused our research and development, or R&D, activities on advancing the LUNA Surgical System, our next generation robotic system, and the ongoing developments in our ISU and digital surgery offerings.

We believe the LUNA System we are developing will be a best in class robot that will use 3mm and 5mm instruments (as contrasted with most current systems available that use 8mm instruments), including TrueWrist™ fully wristed 5mm instruments. The LUNA System will also feature 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 and unconstrained handles with improved digital features while retaining haptic feedback.

In December 2023, we successfully hosted a surgeon lab to conduct an in vivo evaluation of the LUNA System’s hardware, software and instruments in porcine models. The lab allowed nine participating independent surgeons to evaluate the LUNA System’s functionality through thirteen surgical procedures across gynecology, urology and general surgery.

Also, to prepare for pilot manufacturing of the LUNA System, in 2023 we entered into an agreement with Flextronics Medical Sales and Marketing, Ltd. for the design and manufacturing support.

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 compared to competitive robotic options.

Our 2023 development efforts for digital surgery with the ISU included:

- initial development of an analytical tools feature set, which includes intra-operative surgical planning capabilities that will help surgeons to map out and plan for specific surgical actions intraoperatively using the ISU's Augmented Intelligence features;

- creation of a safety tools feature set which includes real-time identification, notifications to the surgical team, and marking of potential anatomical hazards (such as arteries or nerves) during the operation, and providing visual cues to help surgeons and surgical team protect these structures; and

- advancing a training tools and education feature set which allows 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.

During 2023 we entered into an agreement with NVIDIA to allow us to enhance the capabilities of the ISU. Using a suite of NVIDIA tools, we will refine ISU features like digital tags, 3D measurement and enhanced intra-operative camera control. 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.

During 2023 we announced a multi-year collaboration with Google Cloud to integrate Google Cloud's secure cloud data architecture and machine learning technologies to further expand cloud capabilities. The Asensus Cloud is being designed to enable customer access to a web portal and/or mobile application that can provide data, analytics and/or insights to assist in pre-operative surgical planning, post-operative surgical analysis and best practices guidance.

We are also developing an ISU that can be utilized on a stand-alone basis apart from robotic surgery. We believe, given the market opportunity in traditional laparoscopic procedures, the data collected from such stand-alone units will add significantly to our cumulative digital database and help to accelerate development of innovative solutions across the surgical continuum to reduce complications and improve efficiency.

Market Overview

Over the past three decades, laparoscopic surgery has emerged as a minimally invasive alternative to open surgery. In laparoscopic surgery, multiple incisions 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. Traditional 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 distal 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 MIS. We believe that robotic devices that replicate laparoscopic motion are more straightforward for surgeons to adopt. Our Senhance System is designed to mimic laparoscopic surgery. The Senhance System is focused on the laparoscopic surgical market as we believe it separates us from our competitors and allows surgeons to perform MIS 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, when developed, the LUNA System, and allow us to continue to expand our capabilities adding new Augmented Intelligence and decision support capabilities in the future. 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.

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 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.

The global digital surgery technologies market continues to expand with increased investment in research and development of digital tools and capabilities. We have seen technological advancements in Augmented Intelligence, the Internet of Things, or IoT, big data capture, extended reality, or XR, offerings and digitalization of surgery. We believe we are well positioned, with our ISU, TRUST™ Registry and learnings from our Senhance System to advance our footprint in digital surgery and provide products that can be used to add value throughout the surgical process.

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 MIS. We are also addressing the need for clinically relevant data and analysis through our PGS offerings.

From our inception, we have 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.

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.

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	March 2021 General laparoscopic surgical procedures and laparoscopic gynecologic surgery including a total of 31 labeled 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 adult 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	March 2023	February 2020	N/A
● Intelligent 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	November 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

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 is CE marked in the EU for laparoscopic abdominal and pelvic surgery, as well as limited adult 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, 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.); and

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

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

2023 Senhance Surgical System Programs

The Senhance System is available for sale in Europe, the United States, Japan, Taiwan, the CIS and other selected countries. 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). 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 2023, we initiated eight Senhance System programs, one in the United States, one in Germany, one in Romania, three in Japan and two in the Commonwealth of Independent States, or CIS region.

Pediatric Update
During 2023, we received regulatory clearance from the FDA for the Senhance System, making the Senhance System the first cleared digital laparoscopic or robotic surgery product offering 3mm instruments. The one Senhance System placement in the U.S. in 2023 was for pediatric indications, growing our global Senhance System pediatric placements in 2023 to four.

Procedure Volumes
In 2023, surgeons performed over 3,550 procedures utilizing the Senhance System, representing a 13% increase over the previous year. These procedures included general surgery, gynecology, urology, colorectal, bariatric and pediatric surgical procedures.

Senhance Connect
Senhance Connect is a tele-presence 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 PGS, enabling the ability to provide real-time digital collaboration capabilities to surgeons facilitating 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.

Senhance Simulation
Senhance Simulation is a mobile platform part of our PGS offering and designed to integrate with the Senhance System. It allows surgeons to practice at the console through a series of virtual exercises, potentially minimizing the need to schedule and secure lab-based training activities with robotic manipulator arms.

Clinical Registry (TRUST)
We believe TRUST is the largest multi-specialty digital laparoscopy registry in the industry. In 2023, 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. We also continued to drive enrollment as well as support peer-reviewed publications through this registry.

Clinical Validation
During 2023, there were nine peer-reviewed clinical papers published providing further support for the clinical utility of the Senhance Surgical System across pediatric, gynecology, general surgery, urology, and colorectal procedures demonstrating the utility breadth and the complexity of procedures being performed with the device.

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. In March 2020, we received FDA clearance for the ISU. On September 23, 2020, we announced the first surgical procedures successfully completed using the ISU. In January 2021, we received CE mark certification for the ISU, allowing us to expand our Augmented Intelligence capabilities to all global areas accepting the CE mark. We received clearance from the FDA for additional Augmented Intelligence features of the ISU in August 2021, and approval for enhanced Augmented Intelligence features for our CE mark certification in January 2023.

The ISU enables machine vision-driven control of the camera for a surgeon by responding to commands and recognizing certain objects and locations in the surgical fields and allows a surgeon to change the visualized field of view using the movement of their instruments. The newest ISU features expand upon these capabilities and introduce additional advanced features including 3D measurement, digital tagging, 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 certified 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 in development.

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. 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.

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 micro laparoscopic surgeries, allowing for tiny incisions. We currently offer approximately 80 instruments and accessories in our portfolio. We have also 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.

Our Performance-Guided Surgery Initiative

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, enrich collaboration, and enhance predictability for all surgeons (independent of skill level and experience). Our Performance-Guided Surgery strategy is comprised of three strategic pillars:

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

During 2023, we developed and piloted with select Asensus Cloud connected customers across the US & EU, two iterative versions of our customer portal website with an analytics dashboard and video library. The analytics dashboard provides a variety of potentially useful information for both the surgeon and OR administration, including the number of cases completed per month, average case times compared to global averages, procedure time trends, and frequency of instrument and digital feature use with Senhance. The video library offers case specific information in addition to the endoscopic procedure video files, such as a timeline of events to help track time of setup, frequency of warnings, and times when various instruments were in use. This is the first of our customer-facing, cloud-enabled solutions related to the third strategic pillar noted above. We believe that leveraging stored videos and surgical procedure data analysis from the ISU and Asensus Cloud will provide valuable insights for both post-operative analysis and pre-operative planning.

Our Performance-Guided Surgery strategy leverages our capabilities across robotics, Augmented Intelligence and cloud/big data and will be executed across all three 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 instrument selection, to create a large and constantly expanding database of surgeries to enable surgeons to better inform their surgical approach and setup;

- Intra-operative – we believe the Senhance System provides, and the LUNA System will provide, "perceptive real-time guidance" for intra-operative tasks, allowing surgeons performing a procedure with such robotic system and ISU to execute multiple tasks while benefitting from the collective knowledge of other successful robotic-based procedures delivered through Augmented Intelligence in real time. Not only does this have the potential to 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; and

- 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 surgical team community.

We believe that future outcomes of MIS 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 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.

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; 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.

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 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 System, which digitizes laparoscopic 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 micro laparoscopic 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, currently with the Senhance System, the ISU and currently offered instruments, and with the LUNA System in the future, 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 and cloud and data connectivity 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 2023, we initiated eight Senhance surgical programs, one in the U.S., one in Germany, one in Romania, 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, 2023, the Company's patent portfolio includes approximately 90 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 rights, titles and interests 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. We also have four issued U.S. patents that resulted from filings related to the LUNA System. The earliest of these LUNA-related patents will remain in force until 2039. 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 2023 and 2022, and some forward steps by a number of existing entrants in 2023. 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 MIS. 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, Medicaroid and CMR Surgical Ltd. We are aware that more entrants anticipate introducing additional robotic-based instruments in the next few years, including Johnson & Johnson.

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 the Medtronic acquisition of Digital Surgery with their Touch Surgery offerings and Intuitive Surgical with their My Intuitive app and Intuitive Hub platforms. 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 toward better outcomes. Several medical device companies are actively engaged in research and development of robotic systems, digital surgery capabilities or other medical devices and tools used in MIS 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 or support life, and generally require approval of a Pre-Market Approval application, or PMA, by the FDA.

Our current medical device 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 described above or PMA process described below.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

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 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 by statute takes 180 days, though it frequently takes substantially longer, and can take up to one to two years or more. 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.

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.

Regulatory requirements in all jurisdictions where we seek certification, clearance or approval of our products are continuing to evolve with respect to the cybersecurity risk and prevention. Such evolving regulations may prolong the regulatory process for our products and products in development.

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. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. These requirements impose certain procedural and documentation requirements upon us and our third-party manufacturers related to the methods used in and the facilities and controls used for designing, manufacturing, packaging, labeling and storing medical devices. As a manufacturer, we and our contract manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. Following these inspections, the FDA may assert noncompliance with QSR requirements on a Form 483, which is a report of observations from an inspection, or by way of "untitled letters" or "warning letters" that could cause us or any third-party manufacturers to modify certain activities. A Form 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated QSR or other FDA requirements. We cannot be certain that we or our present or any future third-party manufacturers or suppliers will be able to comply with QSR or other FDA regulatory requirements to the agency's satisfaction. Failure to comply with these obligations may lead to possible legal or regulatory enforcement action by the FDA.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing or delaying our requests for regulatory approvals or clearances of new products or modified products;
- withdrawing a PMA that has already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

In the EU, we comply with the requirements of the 93/42/EEC Medical Devices Directive, or MDD, for ultrasonic, and appropriately affix the CE mark on our products to attest to such compliance. We also comply with (EU) 745/17 Medical Device Regulation, or MDR, for the other products (robotic and instruments), and appropriately affix the CE mark on our products to attest such compliance. Asensus Surgical Italia S.r.l. is the legal manufacturer in the EU. Our products marketed in the EU meet the "Essential requirements" of the MDD or of MDR, as applicable, 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. 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 incidents to the appropriate authorities. We also must comply with additional requirements of individual countries in which our products are marketed. In the EU, 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 Devices Directive was replaced by the new Medical Device Regulation (Regulation (EU) 2017/745), or MDR. Any of our products that were certified under the MDD have been or will have to be re-assessed by a designated Notified Body according to the new regulation before their CE Certificates of Conformity issued under the MDD expires or in case we want to make a substantial change to any product. To date, the Senhance System (with the ISU included), instruments, and adapters for articulating instruments have been certified under the MDR process. The MDR places 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 certification. Currently, there are certain transitional provisions in place which allow manufacturers to continue benefiting from CE Certificates of Conformity issued under the MDD and therefore provide more time to transition to the new MDR regime. These transitional provisions allow CE Certificates of Conformity issued under the MDD to remain valid until 31 December 2027 for Class IIb implantable devices (and others) and 31 December 2028 for Class IIa devices (and others) under the following main 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 should undertake the necessary steps to launch the certification process under the MDR, such as adaptation of their quality management system to the MDR and submission of an application for MDR certification to a Notified Body. Some of our legacy devices in class IIb still require MDR transition (ultrasonic). Full transition to the MDR 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. The time required to obtain a CE Certificate of Conformity from a notified body in the EU is lengthy and unpredictable - the MedTech Europe industry association has recently reported a time-to-certification of 13-18 months on average under the MDR across all device categories.

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.

- Many states have privacy laws similar to or more expansive than HIPAA. As noted in “Business-International Regulation and Potential Impact” we comply with the EU GDPR regulations.

- 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, certain other health care professionals and teaching hospitals and ownership interests held by physicians and their families, and reporting to the federal government and public disclosure of these data. 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.

Efforts to ensure that our business arrangements with third parties are compliant with applicable healthcare laws and regulations will involve the expenditure of appropriate, and possibly significant, resources. Nonetheless, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of such laws that apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, such as Medicare and Medicaid, and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Health Care Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. By way of example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In March 2010, the Affordable Care Act, or ACA, went into effect, which, among other things, includes changes to the coverage and payment for products under government health care programs. 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.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 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. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Some of the provisions of the ACA and related laws have been, and may continue to be, subject to judicial and Congressional challenges, and to modifications in their interpretation or implementation. Congress continues to consider legislation to modify the ACA. It is unclear whether new legislation modifying the ACA will be enacted, and, if so, precisely what the new legislation will provide, when it will be enacted and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. We plan to continue to evaluate the effect that the ACA and its possible modification may have on our business.

There has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing and review the relationship between pricing and manufacturer programs. Individual states in the U.S. have also become increasingly active in enacting legislation and implementing regulations designed to control product pricing. We expect that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products.

There have been, and likely will continue to be, legislative and regulatory proposals at the national level in the U.S. and other jurisdictions globally, as well as at some regional, state and/or local levels within the U.S. or other jurisdictions, directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenues from product that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop products.

Significant uncertainty exists regarding the coverage and reimbursement status of products approved by the FDA and other government authorities. In the United States, sales of our products depend in significant part on the availability and adequacy of coverage and reimbursement from third party payors for our product and for services that use our products. Third-party payors include government authorities, managed care providers, private health insurers, and other organizations. The process for determining whether a payor will provide coverage may be separate from the process for setting the reimbursement rate that the payor will pay for the product or service. Moreover, a payor's decision to provide coverage does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Our products are sold or leased to facilities, such as hospitals, and are not for use in the home such that they are not durable medical equipment. Devices such as ours used in surgical procedures are normally not paid separately by payers, but are reimbursed by third-party payors as part of the payment made for the performed surgical procedure when performed on an outpatient basis, or as part of the payment made for the inpatient stay when the patient undergoing the procedure is an inpatient of a hospital. As a result, these types of devices are subject to significant price competition that can place a small manufacturer at a competitive disadvantage as facilities attempt to negotiate lower prices for products such as the ones we develop and sell.

Third-party payors are increasingly challenging the prices charged for, examining the medical necessity, safety, and efficacy of, and assessing the cost-effectiveness of medical procedures, including those that use our products. The U.S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls and restrictions on reimbursement. Any such downward pressure on the reimbursement for the services with which our products are used could limit our ability to realize an appropriate return on our investment in product development.

International Regulation and Potential Impact

Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations, or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, health care providers are employed by their government, therefore our dealings with these providers are subject to regulation under the FCPA. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

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 selected 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, or the GDPR, including as implemented in the U.K. and in effect across the European Economic Area, or EEA, imposes many stringent requirements for controllers and processors of personal data (personally identifiable information, or PII), including ensuring the lawfulness of processing personal data (including obtaining valid consent of the individuals to whom the personal data relates, where applicable), the processing details disclosed to the individuals, the adequacy, relevance and necessity of the personal data collected, the retention of personal data collected, the sharing of personal data with third parties, the transfer of personal data out of the EEA/UK to third countries including the US, contracting requirements (such as with clinical trial sites and vendors), the use of personal data in accordance with individual rights, the security of personal data and security breach/incident notifications. Restrictions on the ability of companies to transfer personal data from the EEA/U.K. to the United States and other countries, 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.

Finally, the Japanese Act on the Protection of Personal Information, as amended, includes extraterritorial application, requirements related to data transfers to third parties in foreign countries and data breach reporting obligations that are applicable to our business in Japan.

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 in all of our locations. 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 through the implementation of rigorous safety protocols which are drafted and reviewed with assistance from third-party safety consultants and ongoing training programs. We also ensure health check-ups are completed in those of our locations where such check-ups are mandatory.

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, 2023, we had 209 employees, including 207 full-time employees, of whom 89 were in the R&D Department, 16 were in Quality and Regulatory Affairs, 39 were in Marketing and Sales, 30 were in Corporate Administration, and 24 were in Customer Excellence. The increase in employees in our R&D Department relates to the LUNA System development efforts. As of December 31, 2023, approximately 29% of the Company's workforce were female, and people of color represented approximately 30% of the Company's workforce, a marked increase from 2022 which we believe resulted from our DEI activities. As of December 31, 2023, approximately 57% of the Company's employees were in the United States and 43% were outside of the United States. In 2023, our turnover rate was approximately 18% and we hired 36 full-time employees. Our turnover rate increased to 2021 levels. We believe the increase was largely related to performance-based terminations and reduced hiring activities.

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 2023, we held biweekly meetings of the DEI committee, organized a field trip to the International Civil Rights Center & Museum, attended the Raleigh Chamber's Diversity, Equity & Inclusivity Conference in July, shared information on our social media pages about relevant events and holidays, and held various cultural, coaching and education events including DEI focused movie watch parties with follow-up discussion groups and volunteering activities. We are also focused on incorporating DEI principles into our governance structure and believe having a 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).

Health & Wellness
Throughout 2023, 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, engagement 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 the 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 2023, we maintained our high engagement score from the prior year and saw an increase in the percentage of actively engaged employees. 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. 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 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; and (4) Risks Related to the Regulation of our Business.

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 $939.4 million, and our working capital was $23.8 million as of December 31, 2023. 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. 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. As of December 31, 2023, our accumulated deficit was $939.4 million, and our working capital was $23.8 million. We believe that our existing cash, cash equivalents and short-term investments, together with cash received from product, service, and lease sales will be sufficient to meet our anticipated cash needs into early June 2024. However, we will need additional financing to implement our next generation products strategy. Management's plans to obtain additional resources for the Company may include additional sales of equity, traditional financing, such as loans, entry into strategic collaborations, entry into an out-licensing arrangement or provision of additional distribution rights in some or all of its markets. 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 reduce costs further and/or pursue a plan to license or sell its assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection. 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.

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. Any delays in raising additional capital will delay the current anticipated timelines for development and commercialization. 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.

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 improvement in our business or financial condition.

In order to compete successfully within the surgical robotics and digital surgery industry, we need to continue to evolve our robotic surgery products and our digital surgery offerings. Failure to develop, obtain regulatory approval for and successfully 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. In addition, we entered into an agreement with NIVDIA and need to successfully harness the additional opportunities this agreement presents to us. 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 commercial activities related to our ISU as a vital part of our Performance-Guided Surgery initiative. If we are not successful in commercializing the ISU, including a standalone 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 are focusing our development efforts on developing the LUNA System. If our development efforts are not successful, or if the LUNA System is not a commercial success, our business opportunities and financial position will be adversely affected.

The primary focus of our product development efforts are focused on our next generation robotic LUNA System. Development of a robotic system is difficult, time-consuming and expensive. We could suffer development setbacks, not meet our projected development schedule, become unable to finance the needed development efforts, fail to receive necessary regulatory clearance or approvals, or encounter difficulties in the manufacturing process. In addition, even if we do develop the LUNA System and receive the necessary regulatory clearances and approvals, we may be unable to successfully commercialize the LUNA System. If any of these risks occur, our business and financial position will be adversely affected.

The success of the LUNA System development efforts will be impacted by the results of the regulatory pathway.

We believe the regulatory pathway for the LUNA System will follow the 510(k) clearance pathway applicable to our other products. If the FDA determines that the LUNA System is “not substantially equivalent” to a previously cleared device, we might then need to fulfill the more rigorous PMA requirements, or request a risk-based classification determination for the device in accordance with the “de novo” process. Either alternative pathway would add significant time to our pursuit of FDA approval of the LUNA System, which could 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 agreements with NVIDIA and Flex related to our ISU and LUNA System development efforts. If we are not successful in capitalizing on these collaborations, our reputation and our operations and financial condition may be harmed.

We cannot give any assurance that the Senhance System can be successfully commercialized.
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. 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 on continued commercial success of 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 can assist the laparoscopic surgeon to 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.

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 use distributors to sell our Senhance Systems.
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 buy-in by surgeons and approval of the capital purchase by administration. We use distributors and sales agents in a number of geographic locations where we do not have sales personnel. We have procedures in place that 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 our ability to sell products in such jurisdictions.

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 companies that are researching and marketing products to address minimally invasive and robotic-assisted surgery, including new entrants in the 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 that we do or expect to compete with include Medtronic plc, Intuitive Surgical Inc., Vicarious Surgical, Inc., Momentis Surgical, Distalmotion SA, CMR Surgical Ltd., Activ Surgical, Inc., Theator Surgical, CareSyntax Inc. and a number of MIS and robotic surgical device manufacturers and providers of solutions that are designed to reduce the need for or attractiveness of surgical intervention. In addition, many universities and private and public research institutions are or may become active in research involving surgical devices for MIS and robotic-assisted surgery.

We are also expanding the potential market for robotic surgical systems with our focus on laparoscopic surgery which may lead to additional competition with companies with substantially greater 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 lower 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; the effectiveness of our sales and marketing efforts; and acceptance of future products by physicians and other healthcare providers.

We have also seen a trend in the market for large medical device companies to acquire, invest in, or form alliances with smaller companies in order to diversify their product offerings and participate in the digital health space. We may find increased competition from other companies, many better capitalized than we are.

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 while maintaining compliance with all regulatory and legal requirements. Responding to the actions of our competitors 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 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.

Issues relating to the use of artificial intelligence and machine learning in our offerings could adversely affect our business and operating results.

We integrate artificial intelligence, AI, and machine learning in our products. Issues relating to the use of new and evolving technologies such as AI and machine learning may cause us to experience brand or reputational harm, competitive harm, legal liability, and new or enhanced governmental or regulatory scrutiny, and we may incur additional costs to resolve such issues. As with many innovations, AI presents risks and challenges that could undermine or slow its adoption, and therefore harm our business. For example, perceived or actual technical, legal, compliance, privacy, security, ethical or other issues relating to the use of AI may cause public confidence in AI to be undermined, which could slow our customers' adoption of our products and services that use AI. In addition, litigation or government regulation related to the use of AI may also adversely impact our and others' abilities to develop and offer products that use AI, as well as increase the cost and complexity of doing so. Further, market demand and acceptance of AI technologies are uncertain, and we may be unsuccessful in our product development efforts.

Negative publicity, whether true or not, concerning us or our products could reduce market acceptance of our products.

There have been social media and other publications regarding us 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 our products 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. We have entered into agreements related to the manufacture of portions of our LUNA System in development. If we are unable to manufacture the LUNA System under the terms of these agreements, our business could be negatively impacted.

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, CIS 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.

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 including PII, and other confidential 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.

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. Cyber-attacks are expected to accelerate on a global basis in both frequency and magnitude as threat actors are becoming increasingly sophisticated in using techniques and tools (including artificial intelligence) that circumvent controls, evade detection and even remove forensic evidence of the infiltration. There can be no assurance that the systems we have designed to prevent or limit the effects of cyber incidents or attacks will be sufficient to prevent or detect material consequences arising from such incidents or attacks, or avoid a material adverse impact on our systems after such incidents or attacks do occur. Even if we successfully defend our own digital technologies, we also rely on providers of third-party products, services, and networks, with whom we may share data and services, and who may be unable to effectively defend their digital technologies and services against attack.

Unauthorized access to or modification of, or actions disabling our ability to obtain authorized access to, our customers' data, other external data, personal data, or our own data, as a result of a cyber incident, attack or exploitation of a security vulnerability, or loss of control of our clients' operations could result in significant damage to our reputation or disruption of the services we provide to our customers or of our customers' businesses. In addition, allegations, reports, or concerns regarding vulnerabilities affecting our digital products or services could damage our reputation. 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 encumber 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. 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.

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. 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.

The conflict in Israel and Gaza is likely to have a material adverse impact on us and our employees.

We have an office and valued employees who live and work in Israel. The current conflict in Israel could have a material adverse impact on our business and operations. Our digital surgery software development efforts are centered in our Israeli subsidiary, and the conflict could cause unexpected delays in our development efforts. Some of our employees have been called to active military duty. In addition, a third-party manufacturer of our ISU located in Israel could be negatively impacted affecting our ability to meet our supply obligations, and export of such ISUs, and other supply management activities and materials due to transport restrictions. If the conflict is prolonged or significantly worsens, these factors could have a material adverse impact on our business operations and employees.

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.

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 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.

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, 2023, the market price of our common stock fluctuated from a high of $1.19 per share to a low of $0.20 per share. The market price of our common stock may continue to fluctuate significantly. In addition, a prolonged low stock price may subject us to delisting or require us to take action, such as a reverse stock split, to maintain our listing.

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 all of 2023. If our stock price continues to remain under $1.00 per share for an extended period, that makes fundraising more difficult and impacts our ability to attract long-term investors.

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.

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. If a third-party has proprietary rights covering our products, we may require licenses, which may not be available on commercially reasonable terms, or 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 proprietary 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 patents. Likewise, we may need to resort to litigation to enforce our patents or to determine the scope and validity of patents of others. In addition, a third-party may claim that we have improperly obtained or used its 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 any litigation could limit our ability to continue our operations.

If any parties successfully claim that our activities infringe their intellectual property rights, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed. 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 market some of our 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. We rely on such licensed technology for our Senhance System. We may license additional technology from third parties in the future. The EU agreement gives us rights for the commercial exploitation of the licensed patents, subject to certain provisions of the 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 would have an adverse effect on our business.

Further, our success will depend in part on the ability of us, the EU and other third-party licensors to obtain, maintain and enforce the licensed patents and, in particular, those patents to which hold exclusive rights. We, the EU or other third-party licensors may not successfully prosecute the patent applications which are licensed to us, may fail to maintain the patents, and may determine not to pursue litigation against other companies that are infringing the 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 rely on other proprietary rights, including protection of trade secrets, know-how 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. Our agreements with employees also 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. If 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 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 rights to some patents required for us to commercialize our proposed products. Third parties may have filed patent applications for technology covered by our 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 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 for inventions we develop jointly during certain collaborations. The process of obtaining patents is expensive and time-consuming. If our 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 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 US Patent and Trademark Office, or the USPTO, may commence interference proceedings involving our patents or patent applications. Any 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.

Our pending patent applications may not result in issued patents. A business's patent position, 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 US or in foreign countries cannot be predicted with certainty, and, as a result, such patents 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 issue or 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.

Risks Related to Regulation of our Business

For our existing product clearances, approvals, or certifications and for our future 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. If we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.
Once regulatory clearance, approval or certification has been obtained, the cleared, approved or certified product and its manufacturer are subject to ongoing regulatory requirements. Any cleared, approved or certified product may be promoted only for its intended uses. In addition, if the FDA, other non-U.S. regulatory authorities, or our Notified Body clear, approve, or certify 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.

Regulatory authorities, such as the FDA in the U.S., and notified bodies enforce regulatory requirements through periodic inspections, among other activities. 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, Untitled 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 limitation or withdrawal of regulatory clearances, approvals, or certifications; 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.

Our future success depends on our ability to develop, receive regulatory clearance, 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, de-novo authorization or PMA approval, or that a Notified Body will issue the relevant CE Certificates of Conformity, of/to our future products on a timely basis, if at all, and failure to obtain necessary clearances, approvals or certifications 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. If we do not receive clearance for any device enhancements, modifications or expanded indication, we will not be able to market the modified device in the U.S. or other foreign countries until such clearance, approval, authorization or certification 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 or our distributor 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 or our distributor 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 (the MDR) became applicable in the European Union on May 26, 2021. The MDR, which replaced the MDD in May 2021 (subject to certain transitional provisions) 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 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.

Our products may cause or contribute to adverse events or be subject to failures or malfunctions that we are required to report to the FDA or comparable foreign regulatory authorities and 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 adverse events or 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.

All manufacturers bringing medical devices to market in the EEA are legally bound to report any incident that directly or indirectly led, might have led or might lead to the death or serious deterioration in the state of health of a patient, user or other person, or to a serious public health threat, 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 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. 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. 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.

Clinical trials may be necessary to support our future product submissions to the FDA or Notified Bodies and such trials are lengthy, regulatory nuanced, interactive and involve working with third parties. These and other factors may affect our ability to complete clinical trials and may lead to delays or failures that would affect our business and financial prospects.

Initiating and completing clinical trials necessary to support any future products, including those that may require PMAs, and additional safety and efficacy data beyond that typically required for a 510(k) clearance, for our possible future product candidates, will be time-consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials. The results of preclinical studies and clinical trials of our products and product candidates conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. Failure can occur at any stage of clinical testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

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. For example, the FDA just finalized a rule to replace the QSR by adopting ISO 13485. Companies are required to come into compliance with this new rule by February 2026. This, and 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. Restrictions under applicable federal and state healthcare laws and regulations that may affect our operations (including our marketing, promotion, educational programs, pricing, and relationships with healthcare providers or other entities, among other things) and expose us to areas of risk are described in the "Business-Health Care Regulation" section of this Annual Report.

Additionally, some state privacy laws, may include private rights of action and can lead to class action litigation. Other laws, such as the FCA, can be enforced through *qui tam* actions brought by individuals on behalf of the government. Efforts to ensure that our business arrangements with third parties are compliant with applicable healthcare laws and regulations will involve the expenditure of appropriate, and possibly significant, resources. Nonetheless, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of such laws that apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal, and administrative penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs such as Medicare and Medicaid, and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Failure of our customers to obtain adequate reimbursement for procedures using our current or new products could limit our ability to market those products and decrease our ability to generate revenue.

Our products are sold or leased to facilities, such as hospitals, and are not for use in the home such that they are not durable medical equipment. Devices such as ours used in surgical procedures are normally not paid separately by payers, but are reimbursed by third-party payors as part of the payment made for the performed surgical procedure when performed on an outpatient basis, or as part of the payment made for the inpatient stay when the patient undergoing the procedure is an inpatient of a hospital. As a result, these types of devices are subject to significant price competition that can place a small manufacturer at a competitive disadvantage as facilities attempt to negotiate lower prices for products such as the ones we develop and sell.

The pricing of products and procedures have come under increasing scrutiny as part of a global trend toward healthcare cost containment. Resulting changes in healthcare law and policy, including changes to Medicare, may impact our business in ways that we cannot currently predict, which could have a material adverse effect on our business and financial condition.

The United States is considering, or has already enacted or implemented, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably, described in a streamlined manner below and are described in the "Business-Health Care Regulation" section of this Annual Report Form 10-K. We expect to experience pricing pressures in connection with the sale of any products that we develop, and the procedures in which they are used, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative and regulatory measures.

The U.S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls and restrictions on reimbursement. If healthcare policies or reforms intended to curb healthcare costs are adopted, the prices that we charge for our products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our product and any future products, if approved, may be negatively impacted.

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 processing of information relating to identified or identifiable persons ("Personal Information") and other categories of 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 Economic Area ("EEA"), the United Kingdom and Switzerland 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 EU privacy laws and regulations. For example, the General Data Protection Regulation (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 Information or could cause our costs to increase and harm our business and financial condition. Non-compliance with the GDPR and the applicable EEA Member State laws may result in fines of up to 4% of the total worldwide annual turnover of the preceding financial year and other administrative penalties, as well as adverse publicity. It also confers the right for data subjects to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

Global laws such as the GDPR are increasingly restricting and regulating the cross-border transfer of Personal Information, which may require us to implement additional and, potentially, costly safeguards to receive Personal Information from overseas customers or transfer such data, including to our vendors. l For example,, in June 2021, the European Commission adopted a new set of Standard Contractual Clauses ("SCCs"), aimed at enabling lawful transfers of Personal Information to non-adequate countries outside the EEA,and on July 10, 2023 the European Commission adopted its adequacy decision for the EU-US Data Privacy Framework, meaning that personal data can now flow freely from the EEA to US companies that participate in the Data Privacy Framework. A lack of valid transfer mechanisms for Personal Information subject to GDPR could increase exposure to enforcement actions as described above, and may affect our business operations and require commercial cost (including potentially limiting our ability to collaborate/work with certain third parties and/or requiring an increase in our data processing capabilities in the EU/U.K.). Further, the EEA/U.K., and Swiss data protection laws (including laws on data transfers as set out above) may also be updated/revised, accompanied by new guidance and/or judicial/regulatory interpretations, which could entail further impacts on our compliance efforts and increased cost.

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, the privacy and security laws and regulations, as well as self-regulatory standards that are applicable to us and our customers' businesses may limit the use and adoption of our products, reduce overall demand and may incur substantial cost or require us to change our business practices. Non-compliance with our customers' specific requirements may lead to termination of contracts with these customers or liabilities to the customers.

ITEM 1.B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1.C. CYBERSECURITY

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 including PII, 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.

Risk Management and Strategy

We maintain a cybersecurity risk management program designed to identify, assess, manage, mitigate, and respond to cybersecurity threats. This program is integrated within our enterprise risk management system and addresses the corporate information technology environment, the data we collect through our products and retain in the TRUST registry and Asensus Cloud, and customer information.

The underlying controls of the cybersecurity risk management program are based on recognized best practices and standards for cybersecurity and information technology, including the National Institute of Standards and Technology, or NIST, Cybersecurity Framework, or CSF, and the International Organization Standardization, or ISO, 27001 Information Security Management System Requirements. We have an annual assessment, performed by a third party, of the Company's cyber risk management program against the NIST CSF.

We monitor our global cybersecurity environment constantly and coordinate the investigation and remediation of any alerts. We have developed a program for incident response, including drills, to prepare support teams in the event of a significant incident. We have engaged third-party consultants to assist us with designing controls and our cybersecurity risk management framework, and to perform penetration testing. We also retain third parties to assist us with the monitoring and detection of cybersecurity threats and responding to any cybersecurity threats or incidents.

With respect to third parties that manage or use our information technology or data, we obtain reports to assess the security of their systems and processes. We engage in ongoing monitoring of all third-party providers to ensure compliance with our cybersecurity standards.

We have not encountered cybersecurity threats or incidents that have had a material impact on our business. We face risks from cybersecurity threats that could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation. See "***RISK FACTORS – Risks Related to the Operation of our Business – 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***."

Our Manager of Data and Information Technology and Vice President of Customer Excellence, with consultation and collaboration with senior management lead our cybersecurity efforts. The cybersecurity team is responsible for assessing and managing our cyber risk management program, informing executive management regarding the prevention, detection, mitigation, and remediation of cybersecurity incidents and supervises such efforts. The cybersecurity team has experience selecting, deploying, and operating cybersecurity technologies, initiatives, and processes, and relies on threat intelligence as well as other information obtained from governmental, public or private sources, including external consultants engaged by us.

Governance

The Corporate Governance and Nominating Committee of the Board of Directors oversees our cybersecurity risk exposures and the steps taken by management to monitor and mitigate cybersecurity risks. The cybersecurity team briefs the Corporate Governance and Nominating Committee on the effectiveness of our cyber risk management program on a regular basis. We believe locating this oversight function in the Corporate Governance and Nominating Committee is appropriate given that the reach of our cybersecurity risk monitoring programs are not limited to financial programs or functions. In addition, cybersecurity risks are reviewed by our Board of Directors, at least annually.

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 renewal term ending on May 31, 2025, 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 March 15, 2024, there were approximately 67 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

Asensus Surgical, Inc. (along with its subsidiaries, the "Company") is a medical device company that is digitizing the interface between the surgeon and patient to pioneer a new era called "Performance-Guided Surgery™", or PGS, by unlocking clinical intelligence for surgeons to enable consistently superior outcomes to patients. Built upon the foundations of digital laparoscopy and laparoscopic minimally invasive surgery (which remains the gold standard of surgery today), the Company is pioneering 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 Senhance® Surgical System, combined with the Intelligent Surgical Unit™ (ISU™) the Company intends to holistically address the current clinical, surgeon performance (fatigue and ergonomics) and economic shortcomings that impact surgical outcomes in a value-based healthcare environment. The Company is also working to incorporate all of this in its next generation robotic system we call the LUNA™ Surgical System.

The Senhance System is available for sale in Europe, the United States, Japan, Taiwan, Russia (to the extent lawful), and select other countries. The Company also enters 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").

During 2023, the Company focused its research and development, or R&D, activities on advancing the LUNA Surgical System, its next generation robotic system, and the ongoing developments in the ISU and digital surgery offerings.

We believe the LUNA System we are developing will be a "best in class" robot that will use 3mm and 5mm instruments (as contrasted with most current systems available that use 8mm instruments), including TrueWrist™ fully wristed 5mm instruments. The LUNA System will also feature monopolar and bipolar electrosurgery capabilities, rapid instrument exchange with the Company's 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 and unconstrained handles with improved digital features while retaining haptic feedback.

In December 2023, the Company successfully hosted a surgeon lab to conduct an in vivo evaluation of the LUNA System's hardware, software and instruments in porcine models. The lab allowed nine participating independent surgeons to evaluate the LUNA System's functionality through thirteen surgical procedures across gynecology, urology and general surgery.

Also, to prepare for pilot manufacturing of the LUNA System, in 2023 the Company entered into an agreement with Flextronics Medical Sales and Marketing, Ltd. for the design and manufacturing support.

The LUNA System will continue the Company's tradition of providing instruments that are reusable and can be re-sterilized and reprocessed, and, with improvements in manufacturing, are expected to have lower costs per procedure compared to competitive robotic options.

The Company's 2023 development efforts for digital surgery with the ISU included:

- initial development of an analytical tools feature set which includes intra-operative surgical planning capabilities that will help surgeons to map out and plan for specific surgical actions intraoperatively using the ISU's Augmented Intelligence features;
- creation of a safety tools feature set which includes real-time identification, notifications to the surgical team and marking of potential anatomical hazards (such as arteries or nerves) during the operation, and providing visual cues to help surgeons and surgical team protect these structures; and
- advancing a training tools and education feature set which allows 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.

During 2023 the Company entered into an agreement with NVIDIA to allow the Company to enhance the capabilities of the ISU. Using a suite of NVIDIA tools, the Company will refine ISU features like digital tags, 3D measurement and enhanced intra-operative camera control. The Company believes 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.

During 2023, the Company announced a multi-year collaboration with Google Cloud to integrate Google Cloud's secure cloud data architecture and machine learning technologies to further expand cloud capabilities. The Asensus Cloud is being designed to enable customer access to a web portal and/or mobile application that can provide data, analytics and/or insights to assist in pre-operative surgical planning, post-operative surgical analysis and best practices guidance.

The Company is also developing an ISU that can be utilized on a stand-alone basis apart from robotic surgery. The Company believes, given the market opportunity in traditional laparoscopic procedures, the data collected from such stand-alone units will add significantly to its cumulative digital database and help to accelerate development of innovative solutions across the surgical continuum to reduce complications and improve efficiency.

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, 2023, we had an accumulated deficit of $939.4 million, and there is substantial doubt about our ability to continue as a going concern. We operate in one business segment.

As of the date of this filing, the Company continues to manage cash prudently and believes it has cash into early June 2024. We are actively pursuing a number of financing options, including collaborations, contractual relationships and strategic transactions. However, we are aware that such alternatives are and may continue to be time consuming and that successful consummation of a transaction or transactions is not assured. We may need to pursue alternative pathways, including, but not limited to, debt financing, sale of assets or equity-based financing. If none of these alternatives are consummated, we may need to suspend our product development programs, including the LUNA System, and take other actions to preserve cash. We may also need to seek bankruptcy if these measures are insufficient or unsuccessful.

Recent Financing Transactions

2022 At-the -Market 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. Sales during the year ended December 31, 2023, under the 2022 ATM Offering are as follows (in thousands except for share and per share amounts):

	Year Ended December 31, 2023
Total shares of common stock sold	933,672
Average price per share	$ 0.43
Gross proceeds	$ 403
Commission paid to Agents	$ 12
Net proceeds	$ 391

2023 Registered Direct Offering

On July 27, 2023, the Company sold, in a registered direct offering, an aggregate of 23,809,524 shares of common stock, and warrants to purchase 23,809,524 of the Company's common stock shares at an exercise price of $0.42 per common share (the "warrants"), for an aggregate purchase price of $10.0 million. Warrants are exercisable at any time on or after the date of issuance and will expire five years after the date of issuance. Based on the assessment of the warrants' specific terms and applicable authoritative guidance in ASC 480 and ASC 815, the Company determined that warrants do not meet the requirements for equity classification. Accordingly, warrants are recorded as a liability on the Company's balance sheet at their initial estimated fair value on the date of issuance. For additional information regarding the fair value of warrant liability, please refer to Note 6 – Fair Value Measurements.

The Company allocated $7.1 million of the aggregate proceeds to warrants based on their estimated fair value, with the residual amount of $2.9 million allocated to common stock. Offering related issuance costs were approximately $1.0 million and consisted primarily of placement agent's fees and legal expenses. Issuance costs were allocated to common stock and warrant liability proportionally to the allocation of the purchase price. For the year ended December 31, 2023, the Company recorded $0.7 million of other expense in the statement of operations related to issuance costs allocated to warrant liability.

Results of Operations for the Years Ended December 31, 2023 and 2022

Revenue
Both in 2023 and 2022, revenue consisted of the sales of Senhance Systems, ongoing System leasing payments, sales of instruments and accessories, and services revenue for Senhance Systems sold or placed in Europe, Asia, and the U.S. in prior periods.

Product revenue for the year ended December 31, 2023 increased to $5.5 million compared to $4.3 million for the year ended December 31, 2022. The $1.2 million increase was primarily the result of three Senhance System sales in the current year compared to two Senhance System sales in the prior year.

Service revenue for the year ended December 31, 2023 decreased to $1.1 million compared to $1.4 million for the year ended December 31, 2022. The $0.3 million decrease was due to a decrease in the number of Senhance Systems under service contracts.

Lease revenue for the year ended December 31, 2023 increased to $2.0 million compared to $1.4 million for the year ended December 31, 2022. The $0.6 million increase was the result of additional lease placements in 2023.

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. The Company expenses 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.

Product cost for the year ended December 31, 2023 increased to $6.9 million as compared to $5.3 million for the year ended December 31, 2022. The $1.6 million increase consists of a $0.9 million increase in materials costs primarily related to three Senhance System sales in the current year compared to two Senhance System sales in the prior year, a $0.5 million increase in personnel costs, a $0.1 million increase in supplies and a $0.1 million increase in consulting expenses.

Service cost for the year ended December 31, 2023 increased to $2.3 million as compared to $2.2 million for the year ended December 31, 2022. The $0.1 million increase primarily relates to a $0.2 million increase in supplies and a $0.1 million increase in personnel costs partially offset by a $0.1 million decrease in material costs and a $0.1 million decrease in consulting expenses. Service cost typically 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, 2023 increased to $4.0 million as compared to $3.4 million for the year ended December 31, 2022. The $0.6 million increase primarily relates to a $0.3 million increase in material costs as a result of a higher number of systems under lease and a $0.3 million increase in depreciation.

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 products and legal services associated with the Company's efforts to obtain and maintain broad protection for the intellectual property related to its products. In future periods, the Company expects R&D expenses to continue to substantially increase as it invests in the LUNA™ Surgical System and digital laparoscopy platform. R&D expenses are expensed as incurred.

R&D expenses for the year ended December 31, 2023 increased 28% to $37.0 million as compared to $28.9 million for the year ended December 31, 2022 as the Company continues to invest in basic research, clinical studies, and product development in the areas of robotics and digital technologies supporting the LUNA System and its digital laparoscopy platform. All activities are in the effort of building the future for Performance-Guided Surgery. The $8.1 million increase primarily relates to a $2.9 million increase in personnel costs, a $2.3 million increase in contract engineering services, consulting, and other outside services, an $1.4 million increase in IT costs, an $1.3 million increase in supplies costs and a $0.2 million increase in testing and enhancement of our products.

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, 2023 increased 14% to $16.9 million compared to $14.8 million for the year ended December 31, 2022. The $2.1 million increase was primarily related to a $2.7 million increase in personnel costs and a $0.2 million increase in supplies, partially offset by a $0.4 million decrease in consulting expenses, $0.2 million decrease in depreciation and $0.2 million decrease in other costs.

General and Administrative

General and administrative expenses consist of personnel costs related to the executive, finance, legal, IT 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, 2023 decreased 5% to $19.2 million compared to $20.2 million for the year ended December 31, 2022. The $1.0 million decrease was primarily related to a $1.1 million reduction in IT costs, an $0.8 million decrease in personnel costs and an $0.2 million decrease in corporate insurance expenses, partially offset by an $0.8 million increase in amortization of the implementation costs of the enterprise resource planning system and software licensing fees, and a $0.3 million increase in consulting expenses.

Amortization of Intangible Assets

Amortization of intangible assets for the year ended December 31, 2023 decreased to $0.5 million compared to $7.7 million for the year ended December 31, 2022. The $7.2 million decrease is primarily related to the developed technologies intangibles that fully depreciated during the year ended December 31, 2022.

Change in Fair Value of Contingent Consideration

The change in fair value of contingent consideration in connection with the Senhance Acquisition was a $1.0 million increase for the year ended December 31, 2023 compared to a $1.1 million reduction for the year ended December 31, 2022. The increase was primarily due to changes in market assumptions and the discount rate utilized.

Property and Equipment Impairment

During the year ended December 31, 2023, the Company recorded an impairment charge of $0.4 million compared to $1.4 million for the year ended December 31, 2022, to reduce the carrying value of property and equipment to its estimated fair value. The change was primarily related to lower returned Senhance Systems under operating leases and a reduction in Senhance Systems under operating leases that are not expected to generate future cash flows sufficient to recover their net book value.

Other Income, net
The Company recognized $1.3 million other income for the year ended December 31, 2023, compared to $0.4 million other income for the year ended December 31, 2022. The change was primarily related to a $1.2 million increase in the fair value of warrant liabilities recorded in the year ended December 31, 2023, a $0.4 million increase in interest income and a decrease in interest expense of $0.4 million, partially offset by a $1.1 million increase in other expenses as a result of $0.7 million in issuance costs allocated to warrant liability and $0.4 million in other expenses.

Income Tax Expense
The Company recognized $0.3 million income tax expense for the year ended December 31, 2023 and 2022.

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 $939.4 million and working capital of $23.8 million as of December 31, 2023. 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, 2023, the Company had cash, cash equivalents, short-term investments and long-term investments, excluding restricted cash, of approximately $21.1 million. The Company believes that 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 its anticipated cash needs into early June 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 its 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 is subject to risks similar to other similarly sized companies in the medical device industry. These risks include, without limitation: the historical lack of profitability; the Company's ability to raise additional capital, the success of the Company's LUNA System development plans and its ability to fund such plans, the Company's ability to grow its placements and increase utilization of the Senhance System by customers; its ability to successfully develop, clinically test, obtain regulatory clearance for and commercialize its products and products in development; negative impacts on the Company's operations caused by the hostilities in the Middle East and other geopolitical factors; the success of its market development efforts; 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 and digital surgical devices; and its ability to identify and pursue development of additional products.

Sources of Liquidity
Our principal sources of liquidity to date have been cash proceeds from issuance of common stock pursuant to public offerings, incurrence of debt and proceeds from sales and maturities of investments.

Consolidated Cash Flow Data

	Year Ended December 31,	
	2023	2022
	(in millions)	
Net cash (used in) provided by		
Operating activities	$ (63.6)	$ (58.9)
Investing activities	64.5	47.5
Financing activities	9.6	(0.3)
Effect of exchange rate changes on cash and cash equivalents	0.8	(0.1)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 11.3	$ (11.8)

Operating Activities

For the year ended December 31, 2023, cash used in operating activities of $63.6 million consisted of a net loss of $78.4 million, offset by changes in non-cash items of $11.7 million, and operating assets and liabilities of $3.1 million. The non-cash items primarily consisted of $7.9 million of stock-based compensation expense, $3.3 million of depreciation, $1.0 change in fair value of contingent consideration, $0.4 million of amortization of intangible assets, $0.4 million of property and equipment impairment, $0.3 million change in inventory reserves, and $0.1 million deferred tax expense partially offset by $1.2 million change in fair value of warrant liabilities and $0.5 million in accretion of discounts and premiums on investments. The increase in cash from changes in operating assets and liabilities primarily relates to a $1.2 million decrease in other current and long-term assets, $0.9 million increase in accrued employee compensation and benefits, $0.6 million increase in accounts payable, $0.6 million decrease in employee retention tax credit receivable, $0.4 million decrease in prepaid expenses, $0.4 million increase in accrued expenses, $0.2 million increase in deferred revenue, $0.1 million decrease in inventory net of transfers to property and equipment and $0.1 million decrease in operating lease liabilities, partially offset by $1.2 million increase in accounts receivable and $0.2 million increase in operating lease right-of-use assets.

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.

Investing Activities

For the year ended December 31, 2023, net cash provided by investing activities was $64.5 million. This amount consists of $77.3 million of proceeds from maturities of available-for-sale investments, offset by $12.3 million of purchases of available-for-sale investments and $0.5 million purchases of property and equipment.

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.

Financing Activities

For the year ended December 31, 2023, net cash used in financing activities was $9.6 million, primarily related to proceeds from issuance of common stock and warrants of $10.1 million, offset by $0.5 million taxes paid for the net share settlement of vesting of restricted stock units.

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.

Operating Capital and Capital Expenditure Requirements

The Company intends 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 its digital solutions platform. The Company intends to use financing opportunities strategically to continue to strengthen its financial position as it looks to extend its available cash for operations.

Cash and cash equivalents held by foreign subsidiaries totaled $4.9 million as of December 31, 2023, including restricted cash. The Company does not intend or currently foresee a need to repatriate cash and cash equivalents held by its foreign subsidiaries. If these funds are needed in the United States, the Company believes that the potential U.S. tax impact to repatriate these funds would be immaterial.

Off-Balance Sheet Arrangements

As of December 31, 2023, the Company did not have any off-balance sheet arrangements.

Critical Accounting Estimates

The discussion and analysis of the Company's 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 the Company's consolidated, audited financial statements and notes thereto appearing in Item 8 of this Annual Report. The preparation of these consolidated, audited financial statements requires the Company 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, the Company evaluates its critical accounting policies and estimates, including identifiable intangible assets, contingent consideration, stock-based compensation, inventory, revenue recognition and income taxes. The Company bases its 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 estimates 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.

Stock-Based Compensation

The Company 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 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. The Company has 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. The Company 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. The Company records 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 could include a five-year service period; the first year of service is generally free and included in the Senhance System sale arrangement with an option to purchase the remaining four years 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.

The Company enters 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, 2023, 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.

The Company invoices 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, the Company has 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

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 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, 2023 and 2022, 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 92% and 89% of revenue for years ended December 31, 2023 and 2022, 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, 2023, would result in revenue changing by $0.8 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, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, 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 the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of Senhance Surgical System Inventories

As indicated in Note 2 to the consolidated financial statements, inventories are stated at the lower of cost or net realizable value. Management considers historical activity and forecast demand in relation to the inventories on hand, competitiveness of product offerings, and product life cycles when estimating net realizable value. As indicated in Note 7 to the consolidated financial statements, the Company recorded $11.2 million of inventories as of December 31, 2023, including $9.2 million of finished goods.

We identified management's estimation of the net realizable value of Senhance Surgical Systems included in finished goods inventories as a critical audit matter. The Company's limited sales history and development plans for new systems require management to make significant judgments and assumptions with respect to future demand and product life cycles for the Company's Senhance Surgical Systems that affect the estimation of the net realizable value of Senhance Surgical System inventories. Auditing these elements involved especially challenging auditor judgment due to the nature and extent of audit effort required to address these matters.

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

- Evaluating the reasonableness of management's forecasted demand for Senhance Surgical 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 Sehance product life cycles.
- Testing management's estimation of the net realizable value of completed Senhance Surgical Systems, included in finished goods inventories, by comparing the cost of finished Senhance Systems to recent system sales.

/s/ BDO USA, P.C.

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

Raleigh, North Carolina
March 21, 2024

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

	December 31, 2023	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	$ 17,096	$ 6,329
Short-term investments, available-for-sale	3,971	64,195
Accounts receivable, net	3,508	2,256
Inventories	7,172	8,284
Prepaid expenses	3,143	3,584
Employee retention tax credit receivable	-	554
Other current assets	1,496	1,671
Total Current Assets	36,386	86,873
Restricted cash	1,642	1,141
Long-term investments, available-for-sale	-	3,865
Inventories, net of current portion	4,043	5,469
Property and equipment, net	8,959	9,542
Intellectual property, net	1,237	1,576
Net deferred tax assets	44	174
Operating lease right-of-use assets, net	5,165	4,950
Other long-term assets	1,610	2,463
Total Assets	$ 59,086	$ 116,053
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 4,145	$ 3,348
Accrued employee compensation and benefits	5,390	4,508
Accrued expenses and other current liabilities	1,636	1,293
Operating lease liabilities - current portion	1,036	800
Deferred revenue	421	465
Total Current Liabilities	12,628	10,414
Long-Term Liabilities:		
Deferred revenue - less current portion	290	-
Contingent consideration	2,220	1,256
Warrant liabilities	5,888	-
Noncurrent operating lease liabilities	4,646	4,738
Total Liabilities	25,672	16,408
Commitments and Contingencies (Note 16)		
Stockholders' Equity:		
Common stock $0.001 par value, 750,000,000 shares authorized at December 31, 2023 and December 31, 2022; 264,921,526 and 236,895,440 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	265	237
Preferred stock, $0.01 par value, 25,000,000 shares authorized, no shares issued and outstanding at December 31, 2023 and December 31, 2022	-	-
Additional paid-in capital	973,129	962,731
Accumulated deficit	(939,368)	(860,935)
Accumulated other comprehensive loss	(612)	(2,388)
Total Stockholders' Equity	33,414	99,645
Total Liabilities and Stockholders' Equity	$ 59,086	$ 116,053

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,	
	2023	**2022**
Revenue:		
Product	$ 5,519	$ 4,327
Service	1,052	1,373
Lease	2,006	1,387
Total revenue	8,577	7,087
Cost of revenue:		
Product	6,866	5,303
Service	2,293	2,174
Lease	3,996	3,395
Total cost of revenue	13,155	10,872
Gross loss	(4,578)	(3,785)
Operating expenses:		
Research and development	37,023	28,942
Sales and marketing	16,921	14,756
General and administrative	19,155	20,172
Amortization of intangible assets	453	7,708
Change in fair value of contingent consideration	964	(1,115)
Impairment of property and equipment	374	1,431
Total operating expenses	74,890	71,894
Operating loss	(79,468)	(75,679)
Other income (expense), net		
Change in fair value of warrant liabilities	1,232	-
Interest income	1,553	1,141
Interest expense	-	(410)
Other expense, net	(1,436)	(295)
Total other income (expense), net	1,349	436
Loss before income taxes	(78,119)	(75,243)
Income tax expense	(314)	(318)
Net loss	(78,433)	(75,561)
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.31)	$ (0.32)
Weighted average number of shares used in computing net loss per common share - basic and diluted	249,685	236,492
Comprehensive loss:		
Net loss	(78,433)	(75,561)
Foreign currency translation gain (loss)	1,280	(1,867)
Unrealized gain (loss) on available-for-sale investments	496	(257)
Comprehensive loss	$ (76,657)	$ (77,685)

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 Loss	Total Stockholders' Equity
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
Issuance of common stock related to vesting of restricted stock units	1,633	2	-	-	-	-	-	2
Shares withheld related to net share settlement of equity awards	-	-	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
Stock-based compensation	-	-	-	-	7,918	-	-	7,918
Exercise of stock options	13	-	-	-	5	-	-	5
Issuance of common stock related to vesting of restricted stock units	3,270	2	-	-	-	-	-	2
Shares withheld related to net share settlement of equity awards	-	-	657	1	(497)	-	-	(496)
Cancellation of treasury stock	-	-	(657)	(1)	-	-	-	(1)
Issuance of common stock, net of issuance costs	24,744	26	-	-	2,972	-	-	2,998
Other comprehensive income	-	-	-	-	-	-	1,776	1,776
Net loss	-	-	-	-	-	(78,433)	-	(78,433)
Balance, December 31, 2023	264,922	$ 265	-	$ -	$ 973,129	$ (939,368)	$ (612)	$ 33,414

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,	
	2023	**2022**
Operating Activities:		
Net loss	$ (78,433)	$ (75,561)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	3,276	3,368
Amortization of intangible assets	453	7,708
(Accretion) amortization of discounts and premiums on investments, net	(482)	565
Stock-based compensation	7,918	8,416
Deferred tax expense	132	318
Change in inventory reserves	324	620
Bad debt expense	-	9
Property and equipment impairment	374	1,431
Loss on disposal of property and equipment	-	122
Change in fair value of warrant liabilities	(1,232)	-
Change in fair value of contingent consideration	964	(1,115)
Changes in operating assets and liabilities:		
Accounts receivable	(1,178)	(1,528)
Inventories	129	(2,302)
Operating lease right-of-use assets	(206)	232
Prepaid expenses	424	(450)
Employee retention tax credit receivable	554	757
Other current and long-term assets	1,173	(2,101)
Accounts payable	574	35
Accrued employee compensation and benefits	881	4,523
Accrued expenses	365	(3,955)
Deferred revenue	233	(55)
Operating lease liabilities	130	26
Net cash and cash equivalents used in operating activities	(63,627)	(58,937)
Investing Activities:		
Purchase of available-for-sale investments	(12,268)	(33,886)
Proceeds from maturities of available-for-sale investments	77,335	82,702
Purchase of property and equipment	(561)	(1,279)
Net cash and cash equivalents provided by investing activities	64,506	47,537
Financing Activities:		
Proceeds from issuance of common stock and warrants, net of issuance costs	10,118	-
Taxes paid related to net share settlement of vesting of restricted stock units	(497)	(350)
Proceeds from exercise of stock options and warrants	5	18
Net cash and cash equivalents provided by (used in) financing activities	9,626	(332)
Effect of exchange rate changes on cash and cash equivalents	763	(81)
Net increase (decrease) in cash, cash equivalents and restricted cash	11,268	(11,813)
Cash, cash equivalents and restricted cash, beginning of period	7,470	19,283
Cash, cash equivalents and restricted cash, end of period	$ 18,738	$ 7,470
Supplemental Disclosure for Cash Flow Information		
Cash paid for leases	$ 1,475	$ 984
Cash paid for taxes	$ 352	$ 165
Supplemental Schedule of Non-cash Investing and Financing Activities:		
Transfer of inventories to property and equipment	$ 2,941	$ 2,693
Lease liabilities arising from obtaining right-of-use assets	$ 1,143	$ 577

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 micro-laparoscopic 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 $939.4 million and working capital of $23.8 million as of December 31, 2023. 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 which was $0.6 million and $1.9 million as of December 31, 2023 and 2022, respectively.

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, 2023 and 2022 were not material.

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: the historical lack of profitability; the Company's ability to raise additional capital; its ability to successfully develop, clinically test, obtain regulatory clearance for and commercialize its products and products in development; negative impacts on the Company's operations caused by the hostilities in the Middle East and other geopolitical factors; the success of its market development efforts; 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 and digital 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 investments, changes in 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, 2023 and 2022 includes $1.6 million and $1.1 million, respectively, in cash accounts held as collateral primarily under the terms of office operating leases, credit cards, and automobile leases, and a guarantee required by the government of a country for a 2019 VAT refund.

The Company's investments as of December 31, 2023 consisted of corporate bonds that 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 are included in interest expense, net. There were no gross realized gains or loss for the years ended December 31, 2023 and 2022.

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, 2023 and 2022, and no allowance for credit losses as of December 31, 2023 and 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 83% and 69% of the Company's net accounts receivable as of December 31, 2023 and December 31, 2022, respectively. The Company had two customers that accounted for 33% and 19% of revenue in 2023, and one customer who accounted for 47% of revenue in 2022, 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 and future economic conditions that may affect a customer's ability to pay. The allowance for expected credit losses was $1.6 million as of December 31, 2023 and 2022.

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 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, 2023 and 2022.

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 3-10

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 years ended December 31, 2023 and 2022, the Company recorded a non-cash asset impairment charge of $0.4 million and $1.4 million, respectively, 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.

Operating Leases

The Company has operating leases for its corporate office buildings, vehicles, and machinery and equipment. At inception, the Company determines whether an agreement represents a lease, and at commencement, it evaluates 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 its 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 lease contracts is typically not readily determinable. As such, the Company utilizes 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, the Company 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 $0.7 million of the ERTC refund during the year ended December 31, 2022 and received the remaining $0.6 million during the year ended December 31, 2023.

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, 2023, the Company has accrued $2.2 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 warrants (see "Note 14 – Equity Offerings,") are measured at fair value using a Black-Scholes-Merton model option-pricing model which takes into account, as of the valuation date, factors including the current exercise price, the expected life of the warrant, the current price of the underlying stock, its expected stock price volatility, the expected dividend yield which is assumed to be zero since The Company has not paid and does not anticipate paying cash dividends on its shares of common stock and the risk-free interest rate is based on U.S. Treasury rates whose term is consistent with the term of the warrant (see "Note 6 – Fair Value,"). The warrant liability is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.

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 considerations 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 could include a five-year service period; the first year of service is generally free and included in the Senhance System sale arrangement with an option to purchase the remaining four years 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.

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, 2023 and 2022, 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, 2023 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, 2023, future minimum lease payments due from customers was $2.2 million, which is expected to be received over the next one to two 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 adjusts 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 MIS. 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
In November 2023, the FASB issued Accounting Standards Update, or ASU, No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. This ASU looks to provide improvements to the segment disclosure by providing users with more decision-useful information about reportable segments in a public entity. The main provisions require a company to disclose, on an annual and interim basis, significant expenses included within each reported measure of segment profit or loss, an amount for other segment items by reportable segment and a description of its composition. It also requires all annual disclosures about a reportable segments' profit or loss and assets to be reported on an interim basis.

The ASU is to be applied retrospectively to all prior periods presented in the financial statements with an effective date for all public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact of this ASU.

In December 2023, the FASB issues ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. This ASU looks to enhance the transparency and decision usefulness of income tax disclosures primarily related to the rate reconciliation and income taxes paid information. The main provisions to the rate reconciliation disclosure require public entities on an annual basis to: disclose specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. The main provisions to the income taxes paid disclosure require that all entities disclose on an annual basis: the amount of income taxes paid disaggregated by federal, state and foreign taxes and the amount of income taxes paid disaggregated by individual jurisdictions in which income taxes paid meets a quantitative threshold. This ASU also requires all entities to disclose: income (loss) from continuing operations before income tax expense (benefit) disaggregated between domestic and foreign and income tax expense (benefit) from continuing operations disaggregated by federal, state and foreign.

This ASU is to be applied on a prospective basis with an effective date for all public entities for annual periods beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact of this ASU.

3. Revenue Recognition

The following table presents revenue disaggregated by type and geography:

	Years Ended December 31,	
	2023	2022
	(in thousands)	
U.S.		
Instruments and accessories	$ 205	$ 211
Services	294	300
Leases	196	256
Total U.S. revenue	695	767
Outside of U.S. ("OUS")		
Systems	3,645	2,551
Instruments and accessories	1,669	1,565
Services	758	1,073
Leases	1,810	1,131
Total OUS revenue	7,882	6,320
Total		
Systems	3,645	2,551
Instruments and accessories	1,874	1,776
Services	1,052	1,373
Leases	2,006	1,387
Total revenue	$ 8,577	$ 7,087

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, 2023 was $0.9 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, 2023 and 2022 was $0.5 million, which was included in the deferred revenue balance of $0.5 million as of December 31, 2022 and 2021.

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

	December 31, 2023	December 31, 2022
	(in thousands)	
Contract assets	$ 95	$ 116
Deferred revenue	$ 711	$ 465

4. Cash, Cash Equivalents, and Restricted Cash

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

	December 31, 2023	December 31, 2022
	(in thousands)	
Cash	$ 4,588	$ 3,473
Money market	5,521	2,856
U.S. treasuries	6,987	-
Total cash and cash equivalents	$ 17,096	$ 6,329
Restricted cash	1,642	1,141
Total	$ 18,738	$ 7,470

Restricted cash at December 31, 2023 and 2022 includes $1.6 million and $1.1 million, respectively, in cash accounts held as collateral primarily under the terms of an office operating lease, credit cards, automobile leases, and a guarantee required by the government of a country for a 2019 VAT refund.

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, 2023				
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value	Short-term investments
			(in thousands)		
Corporate bonds	$ 3,981	$ -	$ (10)	$ 3,971	$ 3,971
Total investments	$ 3,981	$ -	$ (10)	$ 3,971	$ 3,971

	December 31, 2022					
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value	Short-term investments	Long-term investments
			(in thousands)			
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

The following table summarizes the contractual maturities of the Company's available-for-sale investments:

	December 31, 2023	
	Amortized Cost	Fair Value
	(in thousands)	
Mature in less than one year	$ 3,981	$ 3,971
Total	$ 3,981	$ 3,971

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, 2023 or 2022, respectively. There were no realized gains or losses for the years ended December 31, 2023 and 2022 respectively.

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, 2023			
Description	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**
	(in thousands)			
Assets measured at fair value				
Cash and cash equivalents (1)	$ 17,096	$ -	$ -	$ 17,096
Restricted cash	1,642	-	-	1,642
Short-term investments	-	3,971	-	3,971
Total assets measured at fair value	$ 18,738	$ 3,971	$ -	$ 22,709
Liabilities measured at fair value				
Contingent consideration	$ -	$ -	$ 2,220	$ 2,220
Warrant Liabilities	-	-	5,888	5,888
Total liabilities measured at fair value	$ -	$ -	$ 8,108	$ 8,108

	December 31, 2022			
Description	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**
	(in thousands)			
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.

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, 2023 and December 31, 2022, approximate to their fair values due to the short-term nature of these items and are considered to be Level 1.

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, 2023 and December 31, 2022:

	Valuation Methodology	Significant Unobservable Input	December 31, 2023	December 31, 2022
Contingent consideration	Probability weighted income approach	Milestone dates	2032	2032
		Discount rate	10.0%	16.5%
		Revenue volatility	35.0%	45.0%
		EUR-to-USD exchange rate	1.10	1.07

The following table presents the long-term portion of the contingent consideration for the year ended December 31, 2023 and summarizes the change in fair value, as determined by Level 3 inputs for the contingent consideration for the year ended December 31, 2023 and 2022:

	Fair Value
	(in thousands)
Balance at December 31, 2021	$ 2,371
Change in fair value	(1,115)
Balance at December 31, 2022	$ 1,256
Change in fair value	964
Balance at December 31, 2023	$ 2,220

Warrant Liabilities

During 2023, the Company recorded warrant liabilities related to common stock warrants issued in the registered direct offering in July 2023 (for additional information about the offering, please refer to Note 14 -Equity Offerings).

Warrant liabilities were recorded at their initial estimated fair value. Adjustments associated with changes in fair value of the warrant liabilities are included in the Company's consolidated statements of operations and comprehensive loss. The following table summarizes changes in estimated fair value of the warrant liabilities for the warrants issued in July 2023 as of December 31, 2023:

	Fair Value
	(in thousands)
Balance at December 31, 2022	$ -
Issuance of warrants	7,120
Change in fair value	(1,232)
Balance at December 31, 2023	$ 5,888

The fair value of the warrant liabilities were estimated using the Black-Scholes option pricing model, which is based on unobservable inputs and is designated as Level 3 in the fair value hierarchy. The following table summarizes the assumptions used in determining fair value of warrant liabilities:

	As of December 31, 2023
Expected dividend yield	0%
Expected volatility	117%
Risk-free interest rate	3.8%
Expected life (in years)	4.6

7. Inventories

The components of inventories are as follows:

	December 31, 2023	December 31, 2022
	(in thousands)	
Finished goods	$ 9,200	$ 11,208
Raw materials	2,015	2,545
Total inventories	$ 11,215	$ 13,753
Current Portion	$ 7,172	$ 8,284
Long-term portion	4,043	5,469
Total inventories	$ 11,215	$ 13,753

8. Property and Equipment

Property and equipment consisted of the following:

	December 31, 2023	December 31, 2022
	(in thousands)	
Machinery, manufacturing, and demonstration equipment	$ 9,089	$ 8,450
Operating lease assets - Senhance System leasing	12,848	10,251
Computer equipment	603	600
Furniture	715	831
Leasehold improvements	1,721	1,654
Construction in process	70	436
Total property and equipment	25,046	22,222
Accumulated depreciation and amortization	(16,087)	(12,680)
Property and equipment, net	$ 8,959	$ 9,542

Depreciation expense was approximately $3.3 million and $3.4 million for the years ended December 31, 2023 and 2022, respectively.

9. Intellectual Property

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

	December 31, 2023			
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation Impact	Net Carrying Amount
	(in thousands)			
Developed technology	$ 68,838	$ (66,902)	$ (837)	$ 1,099
Technology and patents purchased	400	(279)	17	138
Total intellectual property	$ 69,238	$ (67,181)	$ (820)	$ 1,237

	December 31, 2022			
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation Impact	Net Carrying Amount
	(in thousands)			
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

The weighted average remaining useful life of the developed technology and technology and patents purchased was 3.2 years and 3.3 years, respectively, as of December 31, 2023. 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 estimated future amortization expense of intellectual property as of December 31, 2023 is as follows (in thousands):

	Year Ending December 31, 2023
2024	$ 388
2025	388
2026	389
2027	72
Total	$ 1,237

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,	
	2023	2022
	(in thousands)	
Long-term operating	$ 1,888	$ 1,557

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

	Years Ended December 31,	
	2023	2022
Weighted-average remaining lease term (in years)	5.7	6.8
Weighted-average discount rate	9.2%	8.4%
Incremental borrowing rate	7.1% - 23.0%	6.1% - 14.5%

Maturities of finance and operating lease obligations as of December 31, 2023 were as follows (in thousands):

Fiscal Year	
2024	$ 1,491
2025	1,377
2026	1,160
2027	904
2028	834
Thereafter	1,406
Total minimum lease payments	$ 7,172
Less: Amount of lease payments representing interest	(1,490)
Present value of future minimum lease payments	$ 5,682

11. Accrued Expenses and Other Current Liabilities

The following table presents the components of accrued expenses and other current liabilities:

	Years Ended December 31,	
	2023	2022
	(in thousands)	
Consulting and other vendors	$ 461	$ 155
Royalties	9	24
Legal and professional fees	411	275
Taxes and other assessments	755	839
Total	$ 1,636	$ 1,293

12. Income Taxes

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

	2023	2022
	(in thousands)	
Current income taxes		
Federal	$ -	$ -
State	-	-
Foreign	196	239
Deferred income taxes	-	
Federal	-	-
State	-	-
Foreign	118	79
Total income tax expense	$ 314	$ 318

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

	2023	2022
	(in thousands)	
United States	$ (53,226)	$ (44,802)
Foreign	(24,893)	(30,441)
Total loss from operations before taxes	$ (78,119)	$ (75,243)

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

	2023	2022
	(in thousands)	
Deferred Tax assets:		
Stock-based compensation	$ 3,119	$ 2,840
Accrued expenses and other	2,666	2,538
Research credit carryforward	2,859	1,341
Fixed assets	319	162
Capitalized start-up costs and other intangibles	644	921
Capitalized research costs	9,064	4,382
Net operating loss carryforwards	93,332	83,908
	112,003	96,092
Valuation allowance	(110,511)	(94,704)
Net deferred tax asset	1,492	1,388
Deferred tax liabilities		
Fixed assets and other	(1,448)	(1,214)
Net deferred tax liability	(1,448)	(1,214)
Net deferred tax asset	$ 44	$ 174

At December 31, 2023 and 2022, 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 $15.8 million from the prior year. At December 31, 2023, the Company had U.S. federal net operating loss carryforwards of $446.7 million, of which $253 million are expected to expire unused under the limitations imposed by Internal Revenue Code Section 382. Of the total amount of Federal NOLs (notwithstanding the 382 limitation), $254.5 million begin to expire in 2027, while the remaining $192.2 million carry forward indefinitely. At December 31, 2023, the Company had U.S. state net operating loss carryforwards of $336.3 million, of which $199 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), $323.0 million of state NOLs begin to expire in 2024, while the remaining $13.3 million carry forward indefinitely. At December 31, 2023, the Company had federal research credit carryforwards in the amount of $11.7 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, 2023, the Company had foreign operating loss carryforwards in Italy of approximately $25.0 million, which can be carried forward indefinitely; foreign operating loss carryforwards in Luxembourg of approximately $95.6 million, which will begin to expire in 2034; foreign operating loss carryforwards in Switzerland of approximately $135.3 million, which begin to expire in 2024, and foreign operating loss carryforwards in Canada of approximately $1.4 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, 2023, the Company had gross unrecognized tax benefits of approximately $0.7 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):

	2023	2022
	(in thousands)	
Beginning balance	$ 335	$ 141
Gross increases for tax positions related to current periods	328	194
Gross decreases related to 382 limitations	52	-
Ending balance	$ 715	$ 335

The Company recognizes interest and penalties related to uncertain tax positions in the provision for income taxes. As of December 31, 2023 and 2022, 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 2020, although carryforward attributes that were generated prior to 2020 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:

	2023		2022	
	Amount	Percent of Pretax Earnings	Amount	Percent of Pretax Earnings
	(in thousands)			
United States federal tax at statutory rate	$ (16,405)	21.0%	$ (15,801)	21.0%
State taxes (net of deferred benefit)	(2,493)	3.2%	(2,912)	3.9%
Nondeductible expenses	755	(1.0%)	1,077	(1.4%)
Change in fair market value of contingent consideration	244	(0.3%)	(283)	0.4%
Warrant remeasurement and financing costs	(140)	0.2%	-	-
Research & development	(1,898)	2.4%	(970)	1.3%
Change in unrecognized tax benefits	380	(0.5%)	194	(0.3%)
Foreign tax rate differential	3,176	(4.1%)	2,676	(3.6%)
True-up to stock compensation - cancellations	-	-	49	(0.1%)
Change in enacted tax rates and other, net	659	(0.8%)	(96)	0.0
Change in valuation allowance	16,036	(20.5%)	16,384	(21.8%)
Income tax expense (benefit)	$ 314	(0.4%)	$ 318	(0.4%)

13. Stock-Based Compensation

Incentive Compensation Plan Information

On June 6, 2023, at the 2023 Annual Meeting of Stockholders, the Company's stockholders voted to approve an amendment and restatement of the Company's 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, 2023, there were 54,072,307 shares authorized for issuance, and 22,185,899 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, restricted stock units and stock awards.

Under the Plan, which is administered by the Compensation Committee, the Company may grant stock options, stock appreciation rights, restricted stock units, restricted stock or stock awards to employees, officers, non-employee 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, 2023:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Balance at December 31, 2022	7,584,967	$ 4.22	5.31
Granted	3,047,615	0.71	
Forfeited	(149,430)	0.78	
Cancelled	(25,173)	27.32	
Exercised	(13,300)	0.38	
Balance at December 31, 2023	10,444,679	$ 3.20	4.80

The weighted-average grant date fair value of stock options was $0.59 during the years ended December 31, 2023 and 2022. The aggregate intrinsic value of stock options exercised under the Company's stock plans was not material during the years ended December 31, 2023 and 2022.

The following table summarizes information about stock options outstanding at December 31, 2023:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Millions)
Exercisable at December 31, 2023	5,726,280	$ 5.02	4.12	$ -
Vested or expected to vest at December 31, 2023	10,105,084	$ 3.28	4.77	$ -

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,	
	2023	2022
Expected dividend yield	0%	0%
Expected volatility	124% - 130%	126% - 133%
Risk-free interest rate	3.53% - 4.14%	1.25% - 4.40%
Expected life (in years)	3.8 - 4.5	3.8 - 4.5

Restricted Stock Units

The following is a summary of the restricted stock unit activity, including performance restricted stock units, for the year ended December 31, 2023:

	Number of Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Unvested December 31, 2022	8,483,491	$ 1.04
Granted	8,616,931	0.70
Vested	(3,937,130)	1.10
Forfeited	(837,115)	0.76
Unvested December 31, 2023	12,326,177	$ 0.81

Performance Restricted Stock Units

In 2023 and 2022, the Company granted performance-based restricted stock units ("PRSUs"). The number of shares earnable under the 2023 and 2022 awards were based on achieving certain operational targets by December 31, 2023 (for the PRSUs granted in 2023) and October 1, 2023 (for the PRSUs granted in 2022), respectively. In February 2024, the Board determined that the operational targets for PRSU awards granted in 2023 were 50% achieved and as a result, the 2023 PRSUs were 50% earned and remain subject to three-year time-based vesting requirements. The other 50% of the 2023 PRSUs were forfeited. The operational targets were achieved for the PRUSs granted in 2022, therefore the 2022 PRSUs were 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, 2023, and 2022:

	Years Ended December 31,	
	2023	2022
	(in thousands)	
Stock options	$ 2,338	$ 3,654
Restricted stock units	3,954	3,319
Performance restricted stock units	1,626	1,443
	$ 7,918	$ 8,416

As of December 31, 2023, the unrecognized stock-based compensation expense related to unvested stock options was approximately $1.6 million, which is expected to be recognized over an estimated weighted-average period of 1.4 years. As of December 31, 2023, the unrecognized stock-based compensation expense related to unvested restricted stock units and performance restricted stock units was approximately $4.4 million, which is expected to be recognized over a weighted average period of approximately 1.2 years.

14. Equity Offerings

Equity financing transactions for the years ended December 31, 2023 and 2022, include:

2022 At-The-Market Offering

On March 18, 2022, the Company entered into a Controlled Equity Offering Sales Agreement (the "2022 Sales Agreement") with Cantor Fitzgerald & Co. and Oppenheimer & Co. Inc., collectively, "the Agents". The Company commenced an at-the-market offering (the "2022 ATM Offering") pursuant to which the Company could offer and sell, from time to time, at its option, shares of its common stock for an aggregate offering price of up to $100.0 million. The aggregate compensation payable to the Agents was 3.0% of the aggregate gross proceeds from each sale of the Company's common stock. No shares were sold under the 2022 ATM Offering in 2022.

The following table presents details about common stock issued pursuant to the 2022 ATM Offering (in thousands, except share and per share amounts):

	Year Ended December 31, 2023
Total shares of common stock sold	933,672
Average price per share	$ 0.43
Gross proceeds	$ 403
Commission paid to agents	$ 12
Net proceeds	$ 391

2023 Registered Equity Offering

On July 27, 2023, the Company sold, in a registered direct offering, an aggregate of 23,809,524 shares of common stock, and warrants to purchase 23,809,524 of the Company's common stock shares at an exercise price of $0.42 per common share (the "warrants"), for an aggregate purchase price of $10.0 million. The warrants are exercisable at any time on or after the date of issuance and will expire five years after the date of issuance. Based on the assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480 – Distinguishing Liabilities from Equity and ASC 815 – Derivatives and Hedging, the Company determined that warrants did not meet the requirements for equity classification. Accordingly, the warrants were recorded as a liability on the Company's balance sheet at their initial estimated fair value on the date of issuance. For additional information regarding the fair value of warrant liabilities, please refer to Note 4 – Fair Value Measurements.

The Company allocated $7.1 million of the aggregate proceeds to warrants based on their estimated fair value, with the residual amount of $2.9 million allocated to common stock. Offering related issuance costs were approximately $1.0 million and consisted primarily of placement agent's fees and legal expenses. Issuance costs were allocated to common stock and warrant liability proportionally to the allocation of the purchase price. During the year ended December 31, 2023, the Company recorded $0.7 million of other expense, net, in the consolidated statement of operations related to issuance costs allocated to warrant liabilities.

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. 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, 2023 or 2022 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,	
	2023	**2022**
Stock options	10,444,679	7,584,967
Nonvested restricted stock units	12,326,177	8,483,491
Stock warrants	24,830,500	1,021,076
Total	47,601,356	17,089,534

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		
2024	$	3,263
2025		300
2026		320
Total commitments	$	3,883

17. Segments and Geographic Areas

The Company operates in one business segment—the research, development, and sale of medical devices to improve MIS. 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.

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, 2023	
	Long-Lived Assets	Total Assets
US	29%	46%
EMEA	68%	52%
Asia	3%	2%
Total	100%	100%

	December 31, 2022	
	Long-Lived Assets	Total Assets
US	35%	72%
EMEA	62%	27%
Asia	3%	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,	
	2023	2022
US	8%	11%
EMEA	82%	77%
Asia	10%	12%
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 $0.1 million and $0.3 million for the years ended December 31, 2023 and 2022, respectively.

In October 2023, Asensus Surgical US, Inc. entered into an agreement with Synchrony Labs, LLC to support preclinical evaluation of the LUNA Surgical System. William Starling, a current member of the Company's Board of Directors, owns more than 10% of Synchrony Labs, LLC. Expenses under the agreement were approximately $0.1 million for the year ended December 31, 2023.

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, 2023. 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, 2023, our disclosure controls and procedures were not effective due to ongoing remediation efforts described below.

Material Weakness in Internal Control over Financial Reporting

For the period ended December 31, 2022, management identified a material weakness related to information technology general controls ("ITGCs") in user access over certain information technology ("IT") systems that support the Company's financial reporting processes. Remediation of this material weakness has extended into the year ended December 31, 2023, and is currently ongoing.

The 2022 material weakness did not result in any material misstatements in our consolidated financial statements included in this Annual Report. Our management concluded that the consolidated financial statements included in this Annual Report, present fairly, in all material respects, our financial position, results of operations, and cash flows for the periods presented in accordance with accounting principles generally accepted in the United States.

Management's Plan to Remediate the Material Weakness

Our remediation efforts are ongoing and we will continue our initiatives to implement measures designed to ensure that control deficiencies contributing to the material weakness are remediated, such that these controls are designed, implemented, and operating effectively. We are committed to making the necessary changes and improvements to our system of controls to address the material weakness in internal control over financial reporting described above.

Our renewed emphasis of designing and implementing improved processes and controls will involve but is not limited to the following:

- Expand available resources with experience designing and implementing control activities, including ITGCs and automated controls, both by hiring internally and the use of third-party consultations and specialists.
- Adjust access profiles in IT systems and relevant software, and adjust access review and user activity review controls accordingly.
- Refine the IT policies and procedures that relate to the provisioning of access, reviewing of access, and reviewing of user activity.
- Refine control activities related to the information used in the controls for further completeness and accuracy regarding the provisioning of access, reviewing of access, and reviewing of user activity.

We are in the process of implementing the remediation activities as of the date of this report and believe that upon completion, we will have remediated the identified material weakness. However, material weaknesses are not considered remediated until new internal controls have been operational for a period of time, are tested, and management concludes that these controls are operating effectively. We expect to complete the remediation activities in the fiscal year 2024. We will continue to monitor the effectiveness of these remediation measures, and we will make any changes to the design of this plan and take such other actions that we deem appropriate given the circumstances.

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, 2023, 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, 2023, our internal control over financial reporting was not effective.

Changes in Internal Controls Over Financial Reporting

We developed a plan to remediate the material weakness in fiscal year 2023. Except for the remediation efforts described above, including the initiation of new internal controls and conducting testing in respect to the material weakness, there were no changes in the Company's internal control over financial reporting during the quarter ended December 31, 2023, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

We are taking additional measures to address the material weakness and may need to modify the planned remediation steps. We cannot be certain that the measures we have taken, and expect to take, to improve our internal controls will be sufficient to address the issues identified, to ensure that our internal controls are effective or to ensure that the identified material weakness will not result in a material misstatement of our annual consolidated financial statements. Moreover, we cannot assure you that we will not identify additional material weaknesses in our internal control over financial reporting in the future. If we are unable to remediate the material weakness, our ability to record, process and report financial information accurately, and to prepare financial statements with the time periods specified by the rules and forms of the Securities and Exchange Commission, could be adversely affected.

Notwithstanding the identified material weakness, management does not believe that the deficiencies had an adverse effect on our reported operating results or financial condition, and management has determined that the financial statements and other information included in this report and other periodic filings present fairly in all material respects our financial condition and results of operations at and for the periods presented.

ITEM 9.B. OTHER INFORMATION

During the three months ended December 31, 2023, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement”, as such terms are defined in Item 408 of Regulation S-K.

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 April 29, 2024.

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 April 29, 2024.

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 April 29, 2024.

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
8	Increase the number of shares reserved for issuance under the Plan to 54,072,307 shares	June 6, 2023

The Plan is used for plan-based awards for officers, other employees, consultants, advisors and non-employee directors.

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, 2023:

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	22,620,856	3.24	22,185,899
Equity compensation plans not approved by security holders (3)	150,000	0.42	0
Total	22,770,856		22,185,899

(1) Includes 10,294,679 shares underlying outstanding stock options awarded under the Plan and 12,326,177 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 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 April 29, 2024.

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 April 29, 2024.

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).
4.6	Form of Common Stock Purchase Warrant (filed as Exhibit 4.1 to our Current Report on Form 8-K, filed with the SEC on July 28, 2023, 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 +	Asensus Surgical Amended and Restated Incentive Compensation Plan, as amended and restated June 6, 2023 (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on June 6, 2023 and incorporated herein by reference).
10.3.1 +	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).
10.3.2 + *	Form of Employee Restricted Stock Unit/Performance Restricted Stock Unit Award Notice.
10.3.3 +	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).
10.3.4 +	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).
10.3.5 +	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).
10.3.6 +	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).
10.4+	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).
10.5 ++	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).
10.5.1 +++	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 10-K for the year ended December 31, 2021, filed with the SEC on February 28, 2022).
10.6 +	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).
10.7	Securities Purchase Agreement, dated as of July 27, 2023, among the Company and the purchasers signatory thereto (filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on July 28, 2023 and incorporated herein by reference).
21.1 *	Subsidiaries of the Registrant
23.1 *	Consent of BDO USA, P.C.
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.
97 *	Compensation Recoupment Policy of Asensus Surgical, Inc., effective October 2, 2023.
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, 2023, 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 21, 2024

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 re-substitution 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 21, 2024
/s/ Shameze Rampertab Shameze Rampertab	Executive Vice President and Chief Financial Officer (principal financial officer and principal accounting officer)	March 21, 2024
/s/ David B. Milne David B. Milne	Chairman of the Board and a Director	March 21, 2024
/s/ Andrea Biffi Andrea Biffi	Director	March 21, 2024
/s/ Kevin Hobert Kevin Hobert	Director	March 21, 2024
/s/ Elizabeth Kwo, M.D. Elizabeth Kwo, M.D.	Director	March 21, 2024
/s/ Richard C. Pfenniger, Jr. Richard C. Pfenniger, Jr.	Director	March 21, 2024
/s/ William N. Starling, Jr. William N. Starling, Jr.	Director	March 21, 2024

ASENSUS SURGICAL, INC.
[RESTRICTED STOCK UNITS] [PERFORMANCE RESTRICTED STOCK UNITS] AWARD NOTICE

Asensus Surgical, Inc., a Delaware corporation (the "Company"), has granted [performance-based] restricted stock units award [the "RSUs")][(the "PRSUs")] to acquire shares (the "Shares") of its common stock, par value $0.001 per share (the "Common Stock") to the individual named below. The terms and conditions of the [RSUs][PRSUs] are set forth in this award cover sheet and in the attachment (collectively, the "Award Notice") and in the Company's Amended and Restated Incentive Compensation Plan (as further amended or amended and restated, the "Plan"). The [RSUs][PRSUs] are awarded to the Participant as a Deferred Stock Award under the Plan. All capitalized terms used in this Award Notice without definition have the meanings set forth in the Plan.

Grant Number: Click here to enter text.

Grant Date: Click here to enter text.

Name of Participant:
Number of Shares of Common Stock Underlying the [RSUs][PRSUs]:

[Percentage of Shares of Common Stock Underlying the PRSUs shall be applicable to Goal[s]]

[Performance Goals:]

Lapse of Forfeiture Restrictions (Vesting Schedule):

Date	Shares

Thank you for your efforts on behalf of the Company.

_____
Name: Click here to enter text.

This is not a stock certificate or a negotiable instrument.

[Performance Vesting	If a Performance Goal is achieved prior to the end of the ____ Performance Period, then the PRSUs associated with the attainment of such attained Goal will vest in full and be earned on each Vesting Date. If a Performance Goal is not achieved by the end of the Performance Period, the PRSUs associated with the attainment of such Goal shall be forfeited and shall not vest. The number of Shares underlying the PRSUs vested and earned shall be adjusted if the Company engages in any stock split, reverse stock split or other capitalization affecting all common stock during the Performance Period.]
Settlement	Upon vesting of all or any portion of the [RSUs][PRSUs], settlement will be made by issuance of the number of Shares equal to the vesting [RSUs][PRSUs].
No Dividend Equivalents	No dividend equivalents are authorized as part of this award of [RSUs][PRSUs].
Withholding	The Participant shall pay to the Company promptly upon request, and in any event at the time the Participant recognizes taxable income in respect of the [RSUs][PRSUs], an amount equal to the federal, state or local taxes the Company determines it is required to withhold with respect to the vesting [RSUs][PRSUs]. Such payment shall be made by check or, for (1) employees other than executive officers, (2) employees not in possession of material non-public information, or (3) employees in jurisdictions that do not allow "sell to cover," by selling Shares on the open market to cover the tax obligations. Upon approval by the Committee or the Board, the Participant may pay the applicable withholding by having the Company withhold from the Shares which would otherwise be delivered to the Participant hereunder Shares with a Fair Market Value sufficient to satisfy the minimum withholding required with respect thereto to the extent permitted by the Company, or in a combination of such methods, as irrevocably elected by the Participant prior to the applicable tax due date with respect to such [RSUs][PRSUs]. [The net settlement of the Shares underlying the vested [RSUs][PRSUs] and the delivery of Shares previously owned are hereby specifically authorized alternatives for the satisfaction of the foregoing withholding obligation.] The Company provides no advice regarding the availability of "sell to cover" at any specific point in time.
Issuance of Shares	Following the applicable vesting date with respect to the [RSUs][PRSUs], and subject to the terms and conditions of the Plan, the Company will cause to be issued a direct registration/book-entry statement ("DRS") for the Shares issuable with respect to such vested [RSUs][PRSUs]. Such issuance shall take place as soon as practicable following the applicable vesting date (but in no event later than two and one-half months following the end of the calendar year in which the vesting date occurs). The certificates or DRS representing the Shares issued in respect of the [RSUs][PRSUs] shall be subject to such stop transfer orders and other restrictions as the Committee may determine is required by the rules, regulations, and other requirements of the Securities and Exchange Commission, any stock exchange upon which such Shares are listed, any applicable federal or state laws and the Company's Certificate of Incorporation and Bylaws, and the Committee may cause a legend or legends to be put on any such certificates to make appropriate reference to such restrictions.

Transferability of [RSUs][PRSUs]	The [RSUs][PRSUs] are not transferable and may not be sold, assigned, transferred, disposed of, pledged or otherwise encumbered by the Participant, other than by will or the laws of descent and distribution. Upon such transfer (by will or the laws of descent and distribution), such transferee in interest shall take the rights granted herein subject to all the terms and conditions hereof.
Transferability of Shares	Shares issued to the Participant with respect to vested [RSUs][PRSUs] can only be sold by the Participant following registration of such Shares under the Securities Act of 1933, as amended, or pursuant to an exemption therefrom.
Change in Control	The provisions of Article 9 of the Plan shall apply to the [RSUs][PRSUs] under this Agreement.
Imposition of Other Requirements	The Company reserves the right to impose other requirements on the [RSUs][PRSUs] and on any Shares acquired under the Plan, to the extent the Company determines it is necessary or advisable in order to comply with local law or facilitate the administration of the Award, and to require the Participant to sign any agreements or undertakings that may be necessary to accomplish the foregoing. The Participant agrees, upon demand of the Company or the Committee, to do all acts and execute, deliver and perform all documents, instruments and agreements which may be reasonably required by the Company or the Committee, as the case may be, to implement the provisions and purposes of this Award Notice.
No Stockholder Rights	Neither the Participant nor any personal representative (or beneficiary) shall be, or shall have any of the rights and privileges of, a stockholder of the Company with respect to any Shares issuable upon the vesting of the [RSUs][PRSUs], in whole or in part, prior to the date on which the Shares are issued.
No Right to Continued Employment	Neither the [RSUs][PRSUs] nor this Award Notice shall confer upon the Participant any right to continued employment or service with the Company.
Interpretation/Provisions of Plan Control	This Award Notice is subject to all the terms, conditions and provisions of the Plan, including, without limitation, the amendment provisions thereof, and to such rules, regulations and interpretations relating to the Plan adopted by the Committee as may be in effect from time to time. If and to the extent that this Award Notice conflicts or is inconsistent with the terms, conditions and provisions of the Plan, the Plan shall control, and this Award Notice shall be deemed to be modified accordingly. The Participant accepts the [RSUs][PRSUs] subject to all of the terms and provisions of the Plan. All decisions or interpretations of the Committee upon any questions arising under the Plan shall be binding, conclusive and final, unless shown to have been made in an arbitrary and capricious manner.
Notices	Any notice under this Award Notice shall be in writing and shall be deemed to have been duly given when delivered personally or when deposited in the United States mail, registered, postage prepaid, and addressed, in the case of the Company, to the Company's Secretary at 1 TW Alexander Drive, Suite 160, Durham NC 27703, or if the Company should move its principal office, to such principal office, and, in the case of the Participant, to the Participant's last permanent address as shown on the Company's records, subject to the right of either to designate some other address at any time hereafter in a notice satisfying the requirements of this Notice section.

Data Privacy

In order to administer the Plan, the Company may process personal data about you. Such data includes, but is not limited to the information provided in this Award Notice and any changes thereto, other appropriate personal and financial data about you such as home address and business addresses and other contact information, payroll information and any other information that might be deemed appropriate by the Company to facilitate the administration of the Plan.

By accepting these [RSUs][PRSUs], you give explicit consent to the Company to process any such personal data. You also give explicit consent to the Company to transfer any such personal data outside the country in which you work or are employed, including, with respect to non-U.S. resident grantees, to the United States, to transferees who shall include the Company and other persons who are designated by the Company to administer the Plan.

Consent to Electronic Delivery

The Company may choose to deliver certain statutory materials relating to the Plan (if any) in electronic form. By accepting this grant you agree that the Company may deliver the Plan prospectus and the Company's annual report to you in an electronic format. If at any time you would prefer to receive paper copies of these documents, as you are entitled to, the Company would be pleased to provide copies. Please contact the Company's Secretary to request paper copies of these documents.

Code Section 409A

For U.S. taxpayers, it is intended that this Award comply with Section 409A of the Code ("Section 409A") or an exemption to Section 409A, and shall be interpreted and administered accordingly. To the extent that the Company determines that the Participant would be subject to the additional 20% tax imposed on certain nonqualified deferred compensation plans pursuant to Section 409A as a result of any provision of any this Award Notice, such provision shall be deemed amended to the minimum extent necessary to avoid application of such additional tax. The nature of any such amendment shall be determined by the Company.

Notwithstanding anything to the contrary in the Plan, neither the Company, any Affiliate, the Board, nor the Committee shall have any obligation to take any action to prevent the assessment of any excise tax or penalty on you under Section 409A, and neither the Company, any Affiliate, the Board, nor the Committee shall have any liability to you or other person for such tax or penalty.

No Tax Advice

Except for the information provided in any prospectus applicable to U.S. taxpayers, the Company is not providing the Participant with any information, advice or recommendations with respect to the tax consequences of this Award including, without limitation, whether this Award is taxable upon grant or lapse of forfeiture restrictions. Please consult with your tax advisor to determine the tax consequences in your tax jurisdiction.

Exhibit 21.1

Subsidiaries

(As of March 15, 2024)

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

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (No. 333-238471), Form S-3 (No. 333-263711), and Forms S-8 (No. 333-161291, No. 333-190184, No. 333-193234, No. 333-203950, No. 333-211972, No. 333-219111, No. 333-225231, No. 333-231078, No. 333-239018, No. 333-249895, No. 333-258160 and No. 333-27253) of Asensus Surgical, Inc. of our report dated March 21, 2024, 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, P.C.

Raleigh, North Carolina
March 21, 2024

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 21, 2024

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 21, 2024

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, 2023 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 21, 2024

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, 2023 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 21, 2024

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.

Exhibit 97

Asensus Surgical, Inc.

Compensation Recoupment Policy

Approved – November 30, 2023, Effective October 2, 2023

1. INTRODUCTION

The Board of Directors (the "***Board***") of Asensus Surgical, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 7 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Section 311 of the NYSE American Company Guide (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure(s) specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. ADMINISTRATION

Except as specifically set forth herein, this Policy shall be administered by the Committee. The Committee shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Committee with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Committee is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Committee may authorize and empower any officer or employee of the Company to take any and all actions that the Committee, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

Any members of the Committee, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law, any agreement with the Company and any Company insurance policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law, any agreement with the Company or Company insurance policy.

4. **RECOUPMENT**

(a) **Applicability of Policy**. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) **Required Recoupment.** Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) **Impracticability of Recovery.** Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) **Sources of Recoupment.** To the extent permitted by applicable law, the Committee shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Committee may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Committee may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Committee need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) **No Indemnification of Covered Officers.** Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) **No** "**Good Reason**" **for Covered Officers.** Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. **NO IMPAIRMENT OF OTHER REMEDIES**

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. If a Covered Officer fails to repay Recoverable Incentive Compensation that is owed to the Company under this Policy at the time and in the manner contemplated by this Policy, the Covered Officer shall be required to reimburse the Company for all expenses (including legal expenses) incurred by the Company in recovering such Recoverable Incentive Compensation.

This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("**SOX 304**") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

6. **MISCELLANEOUS**

(a) **Amendment and Termination.** The Committee may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Committee shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

(b) **Severability.** If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

(c) **Successors.** This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

7. **DEFINITIONS**

"Accounting Restatement" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"Accounting Restatement Date" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"Committee" means the Compensation Committee of the Board or, in the absence of such committee, the Board.

"Code" means the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"Covered Officer" means each current and former Executive Officer.

"Exchange" means The NYSE American.

"Exchange Act" means the Securities Exchange Act of 1934, as amended.

"Executive Officer" means the Company's president, principal executive officer, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"Financial Reporting Measures" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"Incentive Compensation" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure or Financial Reporting Measures.

"Lookback Period" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"Recoverable Incentive Compensation" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regard to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Committee will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"SEC" means the Securities and Exchange Commission.

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Asensus Surgical, Inc.

Compensation Recoupment Policy

Form of Acknowledgment

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the Asensus Surgical, Inc. Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Asensus Surgical, Inc. (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Committee (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement, including executing any further acknowledgment or documents reasonably requested by the Committee. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

_____

Name: _____

Title: _____

Date: _____