

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

**January 8, 2024
Date of Report (date of earliest event reported)**

Asensus Surgical, Inc.
(Exact name of Registrant as specified in its charter)

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

**0-19437
(Commission
File Number)**

**11-2962080
(I.R.S. Employer
Identification Number)**

**1 TW Alexander Drive, Suite 160
Durham, NC 27703
(Address of principal executive offices)
919-765-8400
(Registrant's telephone number, including area code)**

**Not Applicable
(Former name or former address, if changed since last report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock \$0.001 par value per share	ASXC	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition

On January 8, 2024, Asensus Surgical, Inc., a Delaware corporation (the “Company”), issued a press release announcing its preliminary unaudited financial results for the fourth quarter and year ended December 31, 2023. A copy of the press release is furnished herewith as Exhibit 99.1.

The press release includes a link to a specific item on the Company’s website. The Company’s website is not incorporated by reference into this Form 8-K.

The information included herein and in Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (“Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated January 8, 2024
104	Cover Page Interactive Data File (formatted in inline XBRL)

SIGNATURES

Pursuant to the requirements 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.

ASENSUS SURGICAL, INC.

Date: January 8, 2024

/s/ Shameze Rampertab

Shameze Rampertab

Executive Vice President and Chief Financial Officer

Asensus Surgical Provides Preliminary 2023 Year-End Corporate Update

RESEARCH TRIANGLE PARK, N.C.--(GLOBE NEWSWIRE)--Jan 8, 2024-- Asensus Surgical, Inc. (NYSE American: ASXC), a medical device company that is digitizing the interface between the surgeon and patient, provided a preliminary 2023 year-end corporate update.

2023 Full Year Highlights

- Over 3,550 procedures were performed globally, representing 14% growth compared to 2022
- In 2023, eight Senhance Surgical Programs were initiated, which is in line with guidance of 8-10 systems
- The Company had unaudited cash, cash equivalents and short-term investments, excluding restricted cash of approximately \$21.0 million on December 31, 2023
- Full year 2023 unaudited revenue is expected to be approximately \$8.2 - \$8.8 million

Fourth Quarter Highlights

- Over 835 procedures were performed globally using the Senhance® Surgical System
- Five Senhance Surgical Programs were initiated, including one in Germany, one in Romania, two in the CIS region and one in Japan at Nagoya University Hospital
- Fourth quarter unaudited revenue is expected to be approximately \$5.1 - \$5.7 million

"I'm pleased with the progress we've made throughout 2023 and the solid foundation we've built for the future," said Anthony Fernando, Asensus Surgical President and CEO. "Looking ahead to 2024, we're optimistic about reaching important milestones in the coming quarters. The LUNA™ Surgical System program is on track, with our primary focus on the testing and evaluation phase before regulatory submissions. Additionally, we're excited to see positive developments in the pediatrics space, reflecting our commitment to advancing surgical technology for all patients through the unique features of the Senhance System."

Market Development

2023 Senhance Program Initiations

During the fourth quarter of 2023, the Company initiated five new Senhance Surgical System placements, one in Germany, one in Romania, two in the CIS region and one in Japan at Nagoya University Hospital.

In 2023, the Company initiated eight new Senhance Surgical System placements: one in the United States, one in Germany, three in Japan, one in Romania, and two in the CIS region.

Procedure Volumes

In 2023, surgeons performed over 3,550 procedures utilizing the Senhance System, representing a 14% increase over the previous year. These procedures included general surgery, gynecology, urology, colorectal, pediatric, and bariatric surgical cases.

Pediatric Update

In 2023, the Company made notable progress in improving pediatric care. A key milestone was the FDA's clearance for the Senhance System, marking it as the first approved digital laparoscopic surgery solution for pediatric patients in the U.S. This clearance, alongside existing approvals in the EU and Japan, highlights the Senhance System's unique features, including 3mm instrumentation, a 5mm camera scope, haptic feedback, and advanced clinical intelligence from the Intelligent Surgical Unit™ (ISU™). These features work together to contribute to a less invasive approach in pediatric robotic surgery. In addition to regulatory milestones, the Company has introduced four Senhance System programs dedicated to pediatric departments in the U.S. and internationally.

Clinical Registry (TRUST)

The Company continues to leverage its growing body of real-world clinical data through the utilization of its TRUST™ clinical registry. The Company believes TRUST is the largest multi-specialty robotic-assisted laparoscopic registry in the industry, with approximately 3,200 patients enrolled to date, a 45% increase from 2022.

Clinical Validation

During the year, there were nine peer-reviewed clinical papers published providing further support for the clinical utility of the Senhance System across a variety of surgical specialties. These papers, along with a library of similar papers, can be found on the Company's website:

<https://www.asensus.com/resources/clinical-publications>.

LUNA™ Surgical Robotic System

LUNA Development

The LUNA Surgical System's development is in progress and is now in the testing and evaluation phase before regulatory submissions. In December 2023, the Company hosted a Surgeon Lab in Research Triangle Park, North Carolina, to conduct an in vivo evaluation of LUNA's hardware, software, and instruments in porcine models. The lab allowed nine participating surgeons to evaluate the LUNA system's functionality through thirteen procedures across gynecology, urology, and general surgery. For a closer look at the Surgeon Lab and insights from the participating surgeons, a video is available at <https://ir.asensus.com/events-and-presentations>. The video provides an overview of the LUNA system's features, demonstrating its range of motion, instrument strength, and ergonomic benefits.

Future milestones include freezing the system's design in early 2024, followed by verification and validation testing, and pilot manufacturing. The Company is confident in the regulatory pathway for the LUNA System. Ongoing communication with the FDA, along with strong in-house regulatory expertise and past successful submissions for the Senhance System, lead the Company to anticipate using a traditional 510(k) submission pathway in the U.S., rather than the more complex de novo pathway. This streamlined approach is expected to apply globally, offering a quicker market entry compared to new entrants. LUNA is currently under development and has not been submitted to, or cleared by, the U.S. FDA or other global regulators, and is not available for sale in any market.

Agreement with Flex for LUNA Surgical System Design and Advanced Manufacturing Services

In November, the Company announced an agreement with Flex for design and manufacturing support for the LUNA Surgical System. This collaboration aims to facilitate the efficient market entry of LUNA by leveraging Flex's expertise in electromechanical systems. The agreement underscores a joint commitment to advancing surgical technology for improved patient care.

Collaboration with NVIDIA to Enhance Augmented Intelligence Capabilities of the ISU

In September, the Company announced a collaboration with NVIDIA to enhance the capabilities of the Company's Intelligent Surgical Unit. The collaboration aims to improve the ISU's Augmented Intelligence features, providing surgeons with advanced clinical insights. Utilizing a suite of NVIDIA tools, Asensus will accelerate the development of ISU, refining real-time features like digital tags, 3D measurement, and enhanced camera control. Since 2021, the ISU, powered by NVIDIA accelerated computing technology, has been contributing to surgical advancements.

BBC - Changing the Face of Surgery

The Company was invited to participate in an online series, Changing the Face of Surgery, as part of the Connecting The Dots online series, presented by MedTech Europe and produced by BBC StoryWorks. Featuring the Senhance Surgical System installation at Evangelisches Krankenhaus Wesel GmbH in Germany, the film demonstrates how Augmented Intelligence is not just transforming surgery, but also nurturing a deeper connection between surgeons and technology. The video is available at <https://www.youtube.com/watch?v=9k41wWp35IQ>.

New Website Launch

Last month, the Company launched its revamped website at <https://www.asensus.com/>. This website serves as a central hub, providing a seamless experience for prospective hospitals, surgeons, and stakeholders. The user experience has been enhanced with better navigation and animation features, and a growing resource library showcasing our innovative approach to surgery. The new site is optimized to provide a consistent experience from any device.

Fourth Quarter and Full Year 2023 Revenue

For the quarter ending on December 31, 2023, the Company estimates preliminary unaudited revenue of approximately \$5.1 - \$5.7 million. For the full year, preliminary unaudited 2023 revenue is expected to be approximately \$8.2 - \$8.8 million, representing revenues from the sale of three Senhance Systems, multiple system leases, and related revenues from instruments, accessories, and services.

Balance Sheet

As of December 31, 2023, the Company had preliminary unaudited cash, cash equivalents and short-term investments, excluding restricted cash, of approximately \$21.0 million, and there were approximately 264.9 million shares of unaudited common stock outstanding.

About Asensus Surgical, Inc.

Asensus Surgical, Inc. is digitizing the interface between the surgeon and patient to pioneer a new era of Performance-Guided Surgery™ by unlocking clinical intelligence for surgeons to enable consistently superior outcomes and a new standard of surgery. Based upon the foundations of Digital Laparoscopy and the Senhance Surgical System, the Company is developing the LUNA Surgical System, a next generation robotic and instrument system as a foundation of its Digital Surgery solution. These systems will be powered by the Intelligent Surgical Unit to increase surgeon control and reduce surgical variability. With the addition of machine vision, Augmented Intelligence, and deep learning capabilities throughout the surgical experience, we intend to holistically address the current clinical, cognitive and economic shortcomings that drive surgical outcomes and value-based healthcare. The Senhance Surgical System is now available for sale in the U.S., EU, Japan and select other countries. For a complete list of indications for use, visit: www.asensus.com/indications-for-use. To learn more about Performance-Guided Surgery, and digital laparoscopy with the Senhance Surgical System visit www.asensus.com.

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Vimeo: <https://vimeo.com/asxc>

Forward-Looking Statements

This press release includes statements relating to the Senhance Surgical System, the LUNA Surgical Robotic System, our preliminary 2023 fourth quarter and year end results. These statements and other statements regarding our future plans and goals constitute "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control and which may cause results to differ materially from expectations and include whether we will be able to continue to progress our strategic plan and reach important milestones in 2024; whether final 2023 fourth quarter and full year revenue will meet expectations; whether the Company's TRUST clinical registry is the largest multi-specialty robotic-assisted laparoscopic registry in the industry and whether the Company will continue to grow the TRUST registry data to support its commercial strategy; whether the Company will be able to use a traditional 510(k) pathway in the U.S. and globally in its regulatory submission for the LUNA Surgical Robotic System and whether the LUNA Surgical Robotic System will be successfully developed and receive regulatory clearances on the timeline the Company anticipates. For a discussion of the risks and uncertainties associated with the Company's business, please review our filings with the Securities and Exchange Commission (SEC). You are cautioned not to place undue reliance on these forward-looking statements, which are based on our expectations as of the date of this press release and speak only as of the origination date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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