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

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**FORM 8-K**

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**CURRENT REPORT**

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

**January 9, 2023  
Date of Report (date of earliest event reported)**

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

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

**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)**

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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:

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

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.

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**Item 8.01 Other Events.**

On January 9, 2023, Asensus Surgical, Inc., a Delaware corporation (the “Company”), issued a press release announcing an update with preliminary financial results for the fourth quarter and full year ended December 31, 2022.

A copy of the press release is filed herewith as Exhibit 99.1 and incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibit

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release dated January 9, 2023</a>
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.

Date: January 12, 2023

**ASENSUS SURGICAL, INC.**

/s/ Shameze Rampertab

Shameze Rampertab

Executive Vice President and Chief Financial Officer

## Asensus Surgical Provides Preliminary 2022 Year-End Corporate Update

RESEARCH TRIANGLE PARK, N.C.--(GLOBE NEWSWIRE)--Jan. 9, 2023-- Asensus Surgical, Inc. (NYSE American: ASXC), a medical device company that is digitizing the interface between the surgeon and the patient to pioneer a new era of Performance-Guided Surgery™, today provided a preliminary 2022 year-end corporate update.

### Fourth Quarter Highlights

- Over 690 procedures were performed globally during the quarter, representing growth of over 23% compared to the fourth quarter 2021
- Five Senhance® Surgical Programs were initiated during the quarter, including two in Germany, two in Japan, and one in the CIS region
- Fourth quarter unaudited revenue is expected to be approximately \$2.2 - \$2.8 million

### 2022 Full Year Highlights

- Approximately 2,650 procedures were performed globally, representing growth of over 26% compared to 2021
- In 2022, nine Senhance Surgical Programs were initiated, in-line with guidance of 8-10 systems
- The Company had unaudited cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of approximately \$74.4 million at December 31, 2022
- Full year 2022 unaudited revenue is expected to be approximately \$6.8 - \$7.4 million

"We are very pleased with what we were able to achieve during 2022; which included making significant progress towards the development of Performance-Guided Surgery, driving the continued adoption of Senhance Surgical Programs, and materially increasing its utilization globally," said Anthony Fernando, Asensus Surgical President and CEO. "As we look ahead to 2023, we remain bullish on our ability to continue to develop the capabilities of our cutting-edge digital clinical intelligence platform to revolutionize the way surgery is performed and ultimately deliver safer, more predictable outcomes for patients."

### Market Development

#### *2022 Senhance Program Initiations*

During the fourth quarter of 2022, the Company initiated five new Senhance Surgical System placements, two in Germany, two in Japan, and one in the CIS region.

In 2022, the Company initiated nine new Senhance Surgical System placements: four in Germany, three in Japan, and two in the CIS region.

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During the fourth quarter, the Company expanded its Senhance Surgical Program at Kitakyushu General Hospital in Japan with the initiation of a second Senhance Surgical System, representing the first hospital to have a second Senhance system.

Germany and Japan, the second and third largest markets for medical devices in the world respectively, remain key geographic focus areas for the Company. The recent acceleration in adoption in these geographies, as well as the CIS, validates the Company's strategy of demonstrating the exceptional capabilities of Senhance and its industry-leading digital intelligence by facilitating in-person hands-on access to the system.

#### *Procedure Volumes*

In 2022, surgeons performed over 2,650 procedures utilizing the Senhance System, representing a 26% increase over the previous year. Compared to 2021, EMEA-based procedures increased over 48%. These procedures included general surgery, gynecology, urology, colorectal, pediatric, and bariatric surgical cases.

#### *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 over 2,200 patients enrolled to date, a 44% increase from 2021. The registered procedures consist of approximately 67% general surgery, including abdominal and thoracic, 15% GYN, and 18% urology.

#### *Clinical Validation*

During the year, there were 16 peer-reviewed clinical papers published providing further support for the clinical utility of the Senhance System across a variety of surgical specialties generated globally to support Senhance. In particular, in October 2022 there was a milestone paper published describing comparable intraoperative and short-term post-operative complications outcomes between DaVinci and Senhance, with significantly lower procedure cost with Senhance when accounting for operative time, estimated blood loss, and other equipment usage.

These papers, along with a library of similar papers, can be found at the Company's website, [www.senhance.com/us/resources](http://www.senhance.com/us/resources).

### **Portfolio Expansion**

#### *Expanded Global ISU Machine Vision Capabilities*

The Company continues to expand the utilization and applicability of the Intelligent Surgical Unit™ (ISU™) globally. The Company is seeking CE Mark approval for expanded machine vision capabilities in Europe, which the Company continues to expect to receive in early 2023. The newest ISU features include: real-time 3D measurement, digital tagging, image enhancement, and enhanced camera control based on real-time data while performing surgery.

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This filing includes a review of the entire Senhance System platform, and if successful, would represent one of the first robotic surgical systems to be approved through the new, more rigorous European Medical Device Regulation (MDR) process. The expanded machine vision capabilities have both U.S. FDA 510(k) clearance and Japanese PMDA approval.

#### *Articulating Instrument Launch*

These instruments were commercially launched in the U.S., Japan and Europe, in the fourth quarter of 2022. Articulating Instruments offer better access to difficult-to-reach areas of the anatomy by providing two additional degrees of freedom.

#### *U.S. Pediatric Regulatory Submission*

The Company submitted its U.S. FDA 510(k) application for pediatric clearance in the U.S. during the third quarter of 2022. The Senhance System's unique combination of 3mm instrumentation with a 5mm camera scope combined with haptic feedback make it a unique robotic assisted laparoscopic solution for pediatric surgeries.

#### **Fourth Quarter and Full Year 2022 Revenue**

For the quarter ended December 31, 2022, the Company estimates preliminary unaudited revenue of approximately \$2.2 - \$2.8 million. For the full year, preliminary unaudited 2022 revenue is expected to be approximately \$6.8 - \$7.4 million, representing revenues from the sale of two Senhance Systems, system leasing, and related revenues from instruments and accessories, and services.

#### **Balance Sheet**

As of December 31, 2022, the Company had preliminary unaudited cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of approximately \$74.4 million, and there were approximately 236.9 million shares of 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. This builds upon the foundation of Digital Laparoscopy with the Senhance Surgical System powered by the Intelligent Surgical Unit (ISU) to increase surgeon control and reduce surgical variability. With the addition of machine vision, augmented intelligence, and deep learning capabilities throughout the surgical experience, we intend to holistically address the current clinical, cognitive and economic shortcomings that drive surgical outcomes and value-based healthcare. Learn more about Performance-Guided Surgery and Digital Laparoscopy with the Senhance Surgical System here: [www.senhance.com](http://www.senhance.com). Now available for sale in the US, EU, Japan, Russia, and select other countries. For a complete list of indications for use, visit: [www.senhance.com/indications](http://www.senhance.com/indications). For more information, visit [www.asensus.com](http://www.asensus.com).

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**Forward-Looking Statements**

This press release includes statements relating to the Senhance Surgical System and our preliminary 2022 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 in 2023; whether final 2022 fourth quarter and full year revenue will meet expectations; whether we will be able to continue to develop our cutting-edge digital clinical intelligence platform to revolutionize the way surgery is performed and ultimately deliver safer, more predictable outcomes for patients; 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 receive CE Mark approval for expanded machine vision capabilities in Europe in early 2023 and whether the Company will receive 510(k) clearance for use of the Senhance System for pediatric patients in the U.S. 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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