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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 10, 2022  
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:

<b>Title of each class</b>	<b>Trading symbol</b>	<b>Name of each exchange on which registered</b>
<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 10, 2022, 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, 2021.

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 10, 2021</a>
104	Cover Page Interactive Data File (formatted in inline XBRL)

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## 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 10, 2022

**ASENSUS SURGICAL, INC.**

/s/ Shameze Rampertab

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Shameze Rampertab

Executive Vice President and Chief Financial Officer

## **Asensus Surgical Provides Preliminary 2021 Year-End Corporate Update**

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Jan. 10, 2022-- 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 2021 year-end corporate update.

### **Fourth Quarter Highlights**

- Over 500 procedures were performed globally during the quarter, representing growth of over 25% over the fourth quarter 2020
- Six Senhance Surgical Programs were initiated during the quarter, including two previously unannounced programs in Germany and Ukraine

### **Year-End Highlights**

- Over 2,000 procedures were performed globally, representing growth of over 42% compared to 2020
- In 2021, 10 Senhance Surgical Programs were initiated
- Received four regulatory clearances:
  - FDA 510(k) clearance for expansion of Machine Vision Capabilities for the Intelligent Surgical Unit™ (ISU™)
  - FDA 510(k) clearance for articulating instruments
  - Expanded FDA 510(k) clearance for general surgery indication
  - CE Mark approval for the ISU
- The Company had unaudited cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of approximately \$135.8 million at December 31, 2021
- Fourth quarter unaudited revenue is expected to be approximately \$2.1 - \$2.5 million
- Full year 2021 unaudited revenue is expected to be approximately \$7.9 - \$8.3 million, representing growth of 147% -159% over the prior year

"Digital transformation is occurring in many sectors and it's a critical time to bring it to the OR to elevate surgery in ways that matter. Last year was a strong one for the company as we continued to empower surgeons around the globe with new tools and Clinical Intelligence for increased control, less variability, and consistently superior outcomes. Driving greater than 42% growth in global Senhance procedure volumes and initiating ten new Senhance programs is encouraging and points to the continued growing demand for Senhance and the clinical utility it delivers to surgeons and hospitals," said Anthony Fernando, Asensus Surgical President and CEO. "We look forward to leveraging the momentum we generated to accelerate adoption of Senhance and continuing to make progress on the promise of Performance-Guided Surgery."

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## **Market Development**

### *2021 Senhance Program Initiations*

Throughout 2021, the Company initiated 10 Senhance Surgical Program initiations: one in the US, six in EMEA, and three in Asia.

During the fourth quarter of 2021, the Company initiated six programs, one in the US, three in EMEA, and two in Asia. Included in this are two previously unannounced program initiations which occurred in December of 2021, at hospitals in Germany and Ukraine, respectively.

### *Procedure Volumes*

In 2021, surgeons performed over 2,000 procedures utilizing the Senhance System, representing a 42% increase over the previous year. Compared to 2020, US-based procedure volumes increased over 90%, Asia procedure volumes increased 14%, and EMEA increased over 42%. These procedures included general surgery, gynecology, urology, colorectal, pediatric, and bariatric surgical cases.

## **Clinical Validation**

During 2021, there were 21 peer-reviewed clinical papers published providing further support for the clinical utility of the Senhance System across a variety of surgical specialties. In particular, there were four milestone papers published:

- In April, a study was published comparing health economic outcomes of the Senhance System versus another robotic system, as well as traditional laparoscopy. According to the study, the Senhance System was less than half the median instrument cost compared to procedures performed on another robotic platform and was comparable to traditional laparoscopic-assisted vaginal hysterectomy costs for certain gynecologic procedures.
  - In May, a study was published which analyzed the outcomes of over 800 Senhance System procedures across multiple specialties including hernia repairs, cholecystectomies, and prostatectomies based on data from the Company's real-world clinical data registry, TRUST. According to the study, Senhance System procedures are safe and reproducible and deliver promising clinical outcomes.
  - In August, a study was published which analyzed the outcomes and experience of utilizing the Senhance System to perform a high volume of urologic procedures. According to the study, the Senhance System is a safe and feasible platform to perform multiple common urologic procedures, namely upper urinary tract and extraperitoneal radical prostatectomies.
  - In September, a study was published which analyzed the outcomes of inguinal hernia repair procedures based on data from the Company's TRUST registry. According to the study, the Senhance System is a safe and doable platform to perform inguinal hernia repair procedures, and it can deliver high quality clinical outcomes related to patient recovery time, length of hospital stay, and postoperative pain.
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## **Portfolio Expansion**

### *Performance-Guided Surgery (PGS)*

PGS builds upon the foundation of Digital Laparoscopy by adding machine vision, augmented intelligence, and deep learning capabilities to help guide improved decision making, enriched collaboration, and enhanced predictability for all surgeons, independent of training or experience, to shift the promise of consistently superior surgery into practice.

Historical advances in surgery have largely focused on bringing tools and techniques into the OR to reduce the invasiveness of procedures and improve the execution of discrete tasks. Unlike many other industries, very little focus has been on improving the decision-making aspects of the surgical process, which is crucial in the high-pressure, highly variable situations which happen repeatedly during any surgery.

PGS is the first surgical paradigm focused on a holistic solution for the entire surgeon workflow to drive consistently superior outcomes. We believe PGS can deliver real-time clinical decision support to boost surgeon capabilities to perceive complex environments, make decisions, and perform the desired tasks with increased precision, safety, and efficiency to mitigate surgical errors and complications.

### *Expanded Global ISU Machine Vision Capabilities*

In September, the Company announced that it had received 510(k) clearance from the FDA for an expansion of machine vision capabilities on the previously cleared ISU. The ISU is utilized with the Senhance System which enables Digital Laparoscopy. The initial features of the ISU enable machine vision-driven control of the camera for a surgeon by responding to commands and recognizing certain objects and locations in the surgical field, and allow a surgeon to change the visualized field of view using the movement of their instruments. The newest ISU features expanded upon these capabilities and introduced more advanced features including: real-time 3D measurement, digital tagging, image enhancement, and enhanced camera control based on real-time data from anatomical structures while performing surgery. This is the first time any of these features will be clinically available in soft-tissue abdominal surgery.

### *Articulating Instrument Clearance*

In July, the Company announced that it had received 510(k) clearance for 5 mm articulating instruments, which offer better access to difficult-to-reach areas of the anatomy.

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#### *General Surgery Indication Expansion*

In March, the Company announced that it had received an additional FDA clearance for the Senhance Surgical System which allows for indication expansion in general surgery in the US.

#### *CE Mark for Intelligent Surgical Unit*

In January, the Company announced that it had received CE Mark approval for the ISU that enables machine vision capabilities on the Senhance System. This approval will provide Senhance Digital Laparoscopy programs in Europe access to this technology.

#### **Fourth Quarter and Full Year 2021 Revenue**

For the quarter ended December 31, 2021, the Company estimates preliminary unaudited revenue of approximately \$2.1 - \$2.5 million. For the full year, preliminary unaudited 2021 revenue is expected to be approximately \$7.9 - \$8.3 million, representing revenues from the sale of three Senhance Systems, system leasing, and related revenues from instruments and accessories, and services.

#### **Balance Sheet**

As of December 31, 2021, the Company had preliminary unaudited cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of approximately \$135.8 million, and there were approximately 235.2 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 System and our preliminary 2021 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 2022; whether final 2021 fourth quarter and full year revenue will meet expectations; whether the momentum we have generated will drive accelerated adoption of the Senhance System and whether we will continue to make progress towards on the promise of Performance-Guided Surgery; whether Performance Guided Surgery can deliver real-time clinical decision support to boost surgeon capabilities to perceive complex environments, make decisions, and perform the desired tasks with increased precision, safety, and efficiency to mitigate surgical errors and complications; whether we can continue to increase Senhance System placements and sales, and whether we can continue to add foundational sites and receive regulatory clearances and approvals that we seek. 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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