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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

May 11, 2021  
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:

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.

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## Item 2.02 Results of Operations and Financial Condition

On May 11, 2021, Asensus Surgical, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the first quarter ended March 31, 2021. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on May 11, 2021, following the issuance of the press release referred to above, the Company conducted a conference call to discuss the reported operating and financial results for the first quarter ended March 31, 2021. The Company had issued a press release on April 29, 2021 to announce the scheduling of the conference call. A copy of the transcript of the conference call is furnished herewith as Exhibit 99.2.

The information included herein and in Exhibit 99.1 and Exhibit 99.2 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	<a href="#">Press release dated May 11, 2021</a>
99.2	<a href="#">May 11, 2021 conference call transcript</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: May 13, 2021

**ASENSUS SURGICAL, INC.**

/s/ Shameze Rampertab

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Shameze Rampertab

Executive Vice President and Chief Financial Officer

## Asensus Surgical, Inc. Reports Operating and Financial Results for the First Quarter 2021

May 11, 2021

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- 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 announced its operating and financial results for the first quarter 2021.

### Recent Highlights

- Signed two lease agreements with hospitals to install Senhance® Surgical Systems
- A hospital completed the first buyout of a previously leased Senhance Surgical System
- Made FDA 510(k) submission for articulating instruments
- Published results from the first milestone study comparing health economic outcomes versus another robotic system as well as traditional laparoscopy
- Received expanded 510(k) clearance for general surgery indication
- Received CE Mark for the Intelligent Surgical Unit™(ISU™), enabling clinical use of machine vision capabilities in Europe
- Announced partnering arrangement with Amsterdam Skills Centre to launch Senhance surgical training center in the Netherlands
- Strengthened balance sheet through equity financings, extending cash runway into 2024

“We were pleased with our performance during the first quarter and with our strong start to the year. We acknowledge the pandemic around the world is still having impacts, but I'm encouraged by the signs of recovery this quarter,” said Anthony Fernando, President and CEO of Asensus Surgical. “We submitted for 510(k) clearance for articulating instruments, received FDA clearance for general surgery, saw strong procedure volume trends including the utilization of the ISU, announced a new training center in the EU, raised significant funds, finalized our name change and rebranding, and, subsequent to the quarter end, signed two Senhance system lease agreements. Our ability to deliver results while also advancing our technology pipeline during these times is proof to the capabilities and broad applicability of Senhance.”

### Name Change and Rebranding

On February 23, 2021, the Company announced that it changed its corporate name to Asensus Surgical, Inc. The name change reflects the company's broader vision of shaping the future of surgery by integrating computer vision and machine learning with surgical robotics. Effective March 5, 2021, the company's ticker symbol was changed to ASXC.

### Upcoming 2021 Milestones

For the full year 2021, the Company continues to expect to install 10 - 12 new Senhance Surgical Systems.

During the second quarter of 2021, the Company expects to achieve the following regulatory milestones:

- File for FDA 510(k) clearance for the next wave of ISU features
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During the second half of 2021, the Company expects to publish clinical papers in peer reviewed journals on the following subjects:

- Health economic evidence comparing Senhance, robotics and laparoscopy in General Surgery and Gynecology

### **Commercial and Clinical Update**

Thus far in 2021, the Company has signed two new agreements with two hospitals in Europe, and expects both of these new programs to be initiated in the second quarter. In addition, a hospital in Asia purchased a previously leased Senhance system at the end of the lease term.

During the first quarter, over 500 procedures were performed globally using the Senhance Surgical System, an increase of 3% over the first quarter of 2020.

On January 19, 2021, the Company announced it received CE Mark approval for the ISU that enables machine vision capabilities on the Senhance Surgical System. This approval will provide Senhance digital laparoscopic programs in Europe access to this new technology, ushering them to the forefront of surgical innovation utilizing augmented intelligence.

On February 18, 2021, the Company agreed to team with the Amsterdam Skills Centre (ASC) in the Netherlands for surgical training. This site will serve surgeons and staff throughout Europe with basic and advanced training on the Senhance Surgical System. The ASC will also provide Asensus Surgical with a world-class facility to engage European surgeons in technology and clinical development studies.

On March 3, 2021, the Company announced it received an additional FDA clearance for the Senhance Surgical System which allows for indication expansion in general surgery in the United States.

On April 15, 2021, the first milestone study comparing health economic outcomes of the Senhance System versus another robotic system, as well as traditional laparoscopy was published in The International Journal of Medical Robotics and Computer Assisted Surgery in April. According to the study, Senhance was less than half the cost of procedures performed on another robotic platform and was comparable to traditional laparoscopically assisted vaginal hysterectomy costs for certain gynecologic procedures. The study also found that case times for Senhance and other robotic systems were similar.

In May 2021, the Company submitted for FDA 510(k) clearance of articulating instruments for the Senhance Surgical System technology platform.

### **First Quarter Financial Results**

For the three months ended March 31, 2021, the Company reported revenue of \$2.1 million as compared to revenue of \$0.6 million in the three months ended March 31, 2020. Revenue in the first quarter of 2021 included \$1.3 million in Senhance system revenue, \$0.4 million in instruments and accessories, and \$0.4 million in services.

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, or a Lease Buyout. Systems revenue consisted of one Lease Buyout and revenue from multiple lease arrangements.

For the three months ended March 31, 2021, total net operating expenses were \$14.4 million, as compared to \$16.0 million in the three months ended March 31, 2020.

For the three months ended March 31, 2021, net loss was \$17.3 million, or \$0.08 per share, as compared to a net loss of \$17.0 million, or \$0.59 per share, in the three months ended March 31, 2020.

For the three months ended March 31, 2021, the adjusted net loss was \$12.2 million, or \$0.06 per share, as compared to an adjusted net loss of \$12.0 million, or \$0.41 per share in the three months ended March 31, 2020, after adjusting for the following charges: amortization of intangible assets, change in fair value of contingent consideration, change in fair value of warrant liabilities, restructuring and other charges, and deemed dividend related to beneficial conversion feature of preferred stock, all of which are non-cash charges. Adjusted net loss is a non-GAAP financial measure. See the reconciliation from GAAP to Non-GAAP Measures below.

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## **Balance Sheet Updates**

On January 14 and February 1, 2021, the Company closed two separate equity financings respectively, totaling approximately \$111 million in gross proceeds in aggregate, which, along with other capital obtained from warrant exercises and an ATM offering, is expected to extend the cash runway into 2024.

The Company had cash and cash equivalents and restricted cash of approximately \$166.4 million as of March 31, 2021.

## **Conference Call**

Asensus Surgical, Inc. will host a conference call on Tuesday, May 11, 2021, at 4:30 PM ET to discuss its first quarter 2021 operating and financial results. To listen to the conference call on your telephone, please dial 1-855-327-6837 for domestic callers and 1-631-891-4304 for international callers, and reference conference ID 10014229 approximately ten minutes prior to the start time. To access the live audio webcast or archived recording, use the following link <https://ir.asensus.com/events-and-presentations>. The replay will be available on the Company's website.

## **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).

## **Non-GAAP Measures**

The adjusted net loss and adjusted net loss per share presented in this press release are non-GAAP financial measures. The adjustments relate to amortization of intangible assets, change in fair value of contingent consideration, change in fair value of warrant liabilities, and for 2020, restructuring and other charges, and deemed dividend related to beneficial conversion feature of preferred stock. These financial measures are presented on a basis other than in accordance with U.S. generally accepted accounting principles ("Non-GAAP Measures"). In the tables that follow under "Reconciliation of Non-GAAP Measures," we present adjusted net loss and adjusted net loss per share, reconciled to their comparable GAAP measures. These items are adjusted because they are not operational or because these charges are non-cash or non-recurring and management believes these adjustments are meaningful to understanding the Company's performance during the periods presented. These Non-GAAP Measures should be considered a supplement to, not a substitute for, or superior to, the corresponding financial measures calculated in accordance with GAAP.

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## Forward-Looking Statements

This press release includes statements relating to the current market development and operational plans for the Senhance Surgical System, as well as 2021 first quarter results and plans for 2021. 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 are able to install 10-12 new Senhance Surgical Systems in 2021, whether we will file for FDA 510(k) clearance for the next generation ISU features in the second quarter of 2021, whether we will publish clinical papers in peer reviewed journals related to health economic evidence comparing Senhance, robotics and laparoscopy in General Surgery and Gynecology, whether we can manage our cash flow efficiently, whether we can manage the continuing impact of the COVID-19 pandemic on our business, whether we can meet the operational and regulatory goals we have set forth for 2021 and whether our cash on hand will be sufficient to meet our anticipated cash needs into 2024. For a discussion of the risks and uncertainties associated with Asensus Surgical's business, please review our filings with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K for the year ended December 31, 2020, which we filed with the SEC on March 11, 2021. 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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**Asensus Surgical, Inc.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
(in thousands except per share amounts)  
(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2021</b>	<b>2020</b>
Revenue:		
Product	\$ 1,704	\$ 242
Service	379	358
Total revenue	2,083	600
Cost of revenue:		
Product	2,380	913
Service	732	825
Total cost of revenue	3,112	1,738
Gross loss	(1,029)	(1,138)
Operating Expenses:		
Research and development	4,215	3,934
Sales and marketing	3,053	4,253
General and administrative	3,992	3,349
Amortization of intangible assets	2,867	2,564
Change in fair value of contingent consideration	257	1,056
Restructuring and other charges	—	858
Total Operating Expenses	14,384	16,014
Operating Loss	(15,413)	(17,152)
Other Expense, net:		
Change in fair value of warrant liabilities	(1,981)	(155)
Interest income	52	27
Interest expense	(7)	—
Other expense, net	(29)	(15)
Total Other Expense, net	(1,965)	(143)
Loss before income taxes	(17,378)	(17,295)
Income tax benefit	38	697
Net loss	(17,340)	(16,598)
Deemed dividend related to beneficial conversion feature of preferred stock	—	(412)
Net loss attributable to common stockholders	(17,340)	(17,010)
Comprehensive loss:		
Net loss	(17,340)	(16,598)
Foreign currency translation loss	(1,938)	(872)
Comprehensive loss	\$ (19,278)	\$ (17,470)
Net loss per common share attributable to common stockholders – basic and diluted	\$ (0.08)	\$ (0.59)
Weighted average number of shares used in computing net loss per common share – basic and diluted	204,992	28,906



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

	<u>March 31, 2021</u>	<u>December 31, 2020</u>
<b>Assets</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 165,245	\$ 16,363
Accounts receivable, net	2,306	1,115
Inventories	11,181	10,034
Other current assets	3,593	6,501
<b>Total Current Assets</b>	<u>182,325</u>	<u>34,013</u>
Restricted cash	1,149	1,166
Inventories, long-term	7,656	8,813
Property and equipment, net	9,179	10,342
Intellectual property, net	18,591	22,267
Net deferred tax assets	288	307
Operating lease right-of-use assets, net	4,234	1,164
Other long term assets	193	186
<b>Total Assets</b>	<u>\$ 223,615</u>	<u>\$ 78,258</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 2,327	\$ 1,965
Accrued expenses	3,830	6,301
Deferred revenue – current portion	892	789
Notes payable – current portion, net of debt discount	2,459	1,228
<b>Total Current Liabilities</b>	<u>9,508</u>	<u>10,283</u>
<b>Long Term Liabilities:</b>		
Contingent consideration	4,193	3,936
Notes payable – less current portion	356	1,587
Warrant liabilities	—	255
Noncurrent operating lease liabilities	3,640	628
<b>Total Liabilities</b>	<u>17,697</u>	<u>16,689</u>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity</b>		
Common stock \$0.001 par value, 750,000,000 shares authorized at March 31, 2021 and December 31, 2020; 232,716,797 and 116,231,072 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	233	116
Preferred stock, \$0.01 par value, 25,000,000 shares authorized, no shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	—	—
Additional paid-in capital	944,907	781,397
Accumulated deficit	(740,252)	(722,912)
Accumulated other comprehensive income	1,030	2,968
<b>Total Stockholders' Equity</b>	<u>205,918</u>	<u>61,569</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 223,615</u>	<u>\$ 78,258</u>

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Operating Activities:</b>		
Net loss	\$ (17,340)	\$ (16,598)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	802	570
Amortization of intangible assets	2,867	2,564
Stock-based compensation	1,786	1,923
Deferred tax benefit	(38)	(697)
Write down of inventory	122	—
Change in fair value of warrant liabilities	1,981	155
Change in fair value of contingent consideration	257	1,056
Changes in operating assets and liabilities:		
Accounts receivable	(1,608)	(340)
Inventories	(162)	(1,603)
Other current and long term assets	(21)	(76)
Accounts payable	242	509
Accrued expenses	(2,290)	(433)
Deferred revenue	128	83
Noncurrent operating lease liabilities	3,037	(130)
Net cash and cash equivalents used in operating activities	<u>(10,237)</u>	<u>(12,477)</u>
<b>Investing Activities:</b>		
Purchase of property and equipment	(395)	(2)
Net cash and cash equivalents (used in) provided by investing activities	<u>(395)</u>	<u>(2)</u>
<b>Financing Activities:</b>		
Proceeds from issuance of common stock, preferred stock and warrants under 2020 financing, net of issuance costs	—	13,525
Proceeds from issuance of common stock, net of issuance costs	129,322	11,212
Taxes paid related to net share settlement of vesting of restricted stock units	(214)	(33)
Proceeds from exercise of stock options and warrants	30,497	—
Net cash and cash equivalents provided by (used in) financing activities	<u>159,605</u>	<u>24,704</u>
Effect of exchange rate changes on cash and cash equivalents	(108)	(51)
Net increase in cash, cash equivalents and restricted cash	148,865	12,174
Cash, cash equivalents and restricted cash, beginning of period	17,529	10,567
Cash, cash equivalents and restricted cash, end of period	<u>\$ 166,394</u>	<u>\$ 22,741</u>
<b>Supplemental Schedule of Non-cash Investing and Financing Activities</b>		
Transfer of inventories to property and equipment	\$ —	\$ 1,958
Acquisition of property and equipment in accounts payable	\$ 191	\$ —
Reclass of warrant liability to common stock and additional paid-in-capital	\$ 2,236	\$ —
Lease liabilities arising from obtaining right-of-use assets	\$ 3,427	\$ —
Exchange of common stock for Series B Warrants	\$ —	\$ 2,470
Transfer of in-process research and development to intellectual property	\$ —	\$ 2,425
Conversion of preferred stock to common stock	\$ —	\$ 30

**Asensus Surgical, Inc.**  
**Reconciliation of Non-GAAP Measures**  
**Adjusted Net Loss and Net Loss per Share**  
(in thousands except per share amounts)  
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
<b>Net loss attributable to common stockholders (GAAP)</b>	\$ (17,340)	\$ (17,010)
<b>Adjustments</b>		
Amortization of intangible assets	2,867	2,564
Change in fair value of contingent consideration	257	1,056
Change in fair value of warrant liabilities	1,981	155
Restructuring and other charges	—	858
Deemed dividend related to beneficial conversion feature of preferred stock	—	412
<b>Adjusted net loss attributable to common stockholders (Non-GAAP)</b>	<b>\$ (12,235)</b>	<b>\$ (11,965)</b>

	Three Months Ended March 31,	
	2021	2020
<b>Net loss per share attributable to common stockholders (GAAP)</b>	\$ (0.08)	\$ (0.59)
<b>Adjustments</b>		
Amortization of intangible assets	0.01	0.09
Change in fair value of contingent consideration	0.00	0.04
Change in fair value of warrant liabilities	0.01	0.01
Restructuring and other charges	—	0.03
Deemed dividend related to beneficial conversion feature of preferred stock	—	0.01
<b>Adjusted net loss per share attributable to common stockholders (Non-GAAP)</b>	<b>\$ (0.06)</b>	<b>\$ (0.41)</b>

The non-GAAP financial measures for the three months ended March 31, 2021 and 2020 provide management with additional insight into the Company's results of operations from period to period without non-recurring and non-cash charges, and are calculated using the following adjustments:

- a) Intangible assets that are amortized consist of developed technology and purchased patent rights recorded at cost and amortized over 5 to 10 years.
- b) Contingent consideration in connection with the acquisition of the Senhance System in 2015 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 discounted cash flow model utilizing significant unobservable inputs including the probability of achieving each of the potential milestones 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 timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.
- c) The Company's Series B Warrants are measured at fair value using a simulation 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 volatility, holding cost and the risk-free interest rate for the term of the warrant. The warrant liability is revalued at each reporting period or upon exercise and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.
- d) Beginning in the fourth quarter of 2019 and continuing into the first quarter of 2020, we implemented a restructuring plan to reduce operating expenses as we continue the global market development of the Senhance platform. During the first quarter of 2020 our continued restructuring efforts resulted in \$0.9 million in severance costs due to headcount reduction.
- e) During the first quarter of 2020, the Company closed an underwritten public offering under which it issued, as part of units and the exercise of an over-allotment option, 25,367,646 Series C Warrants, each to acquire one share of Common Stock at an exercise price of \$0.68 per share, and 25,367,646 Series D Warrants, each to acquire one share of Common Stock at an exercise price of \$0.68 per share. The Company concluded that the Series C Warrants and Series D Warrants are considered equity instruments. The fair value of the Series C and Series D Warrants on the issuance date was determined using a Black-Scholes Merton model. The unit proceeds were then allocated to the Series A preferred stock, Series C Warrants, and Series D Warrants, respectively, based on their relative fair values. As a result, the Company determined that a beneficial conversion feature was created by the difference between the effective conversion price of the preferred stock of \$0.37 and the fair value of the Company's common stock as of the issuance date of \$0.42. The Company therefore recorded a beneficial conversion charge of \$0.4 million as an immediate charge to earnings available to common stockholders for the three months ended March 31, 2020.

**INVESTOR CONTACT:**

Mark Klausner or Mike Vallie, 443-213-0499

[invest@asensus.com](mailto:invest@asensus.com)

or

**MEDIA CONTACT:**

Kristin Schaeffer

CG Life

[kschaeffer@cglife.com](mailto:kschaeffer@cglife.com)

## **Exhibit 99.2**

Company: Asensus Surgical, Inc.

Conference Title: Q1 2021 Asensus Surgical, Inc. Earnings Call

Moderator: Mark Klausner, Westwicke Partners, Investor Relations  
Anthony Fernando, President and Chief Executive Officer  
Shameze Rampertab, Chief Financial Officer

Date: May 11, 2021

## **P R E S E N T A T I O N**

### **Operator**

Good afternoon, ladies and gentlemen, and welcome to the Asensus Surgical Inc.'s First Quarter 2021 Conference Call.

I would now like to turn the call over to Mr. Mark Klausner of Westwicke. Please go ahead.

### **Mark Klausner**

Thanks, Operator. Good afternoon, everyone, and thank you for joining us on today's call. On the call with me today are Anthony Fernando, President and Chief Executive Officer, and Shameze Rampertab, Chief Financial Officer.

Before we begin, I would like to caution listeners that certain information discussed by Management during this conference call, including any guidance provided, are forward-looking statements covered under the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. Actual results could differ materially from those stated or implied by our forward-looking statements due to risks and uncertainties associated with the company's business, including any impact from the COVID-19 pandemic.

The Company undertakes no obligation to update the information provided on this call. For a discussion of risks and uncertainties associated with Asensus Surgical's business, I encourage you to review the Company's filings with the Securities and Exchange Commission, including the 2020 Form 10-K filed in March 2021, and the Form 10-Q expected to be filed later today, and other filings we make with the SEC.

During this call, we will also present certain non-GAAP financial information related to adjusted net loss attributable to common shareholders and adjusted net loss per common share attributable to common stockholders. Management believes that these non-GAAP financial measures, taken in conjunction with U.S. GAAP financial measures, provide useful information for both Management and investors by excluding certain non-cash and other expenses that are not indicative of the Company's core operating results.

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Management uses non-GAAP measures to compare our performance relative to forecast and strategic plans, to benchmark our performance externally against competitors and for certain compensation decisions. Reconciliations from U.S. GAAP to non-GAAP results are presented in the tables accompanying our earnings release, which can be found in the Investor Relations section of our website.

It is now my pleasure to turn the call over to Asensus Surgical's President and Chief Executive Officer, Anthony Fernando.

**Anthony Fernando**

Thanks, Mark, and thank you, all, for joining us today.

On today's call, I will provide a brief summary and ask Shameze to review our financial performance, after which I will discuss our performance during the first quarter as well as our priorities for the rest of 2021 before turning to Q&A.

Before turning the call over to Shameze, I would like to provide an overview of our recent performance.

Overall, despite the continued headwinds from COVID impacting hospitals across the globe, we made significant progress towards a number of our goals for 2021. Subsequent to the end of the quarter, we signed two new lease agreements with hospitals in Europe, one of which we announced in a press release earlier this week, and the second, which will be announced upon installation later in the second quarter.

We also had our first lease buyout occur during the quarter, with a high-volume Senhance hospital in Japan, opting to purchase the system after having leased for just over a year. We believe this shows the value we bring to hospitals and is an early proof point that our business model around pricing and flexible economics is working.

In addition, we had a number of published clinical papers. One of the clinical papers compares health economic outcomes of the Senhance System versus another robotic system as well as traditional laparoscopy, which among other things pointed to very favorable cost per procedure as compared to the other robotic offering.

Lastly, we drove compelling procedure volumes in key geographies, with over 500 procedures completed globally. We are very proud of what we were able to accomplish, and look forward to continuing this momentum throughout 2021.

With that, I will turn the call over to Shameze for a financial update.

**Shameze Rampertab**

Thanks, Anthony.

Turning to the first quarter, for the three months ended March 31, 2021, the Company reported revenue of \$2.1 million as compared to revenue of \$0.6 million in the three months ended March 31, 2020.

Revenue in the first quarter of 2021 included \$1.3 million in system revenue, \$0.4 million in instruments and accessories, and \$0.4 million in services.

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, or a Lease Buyout. Systems revenue consisted of one Lease Buyout and revenue from multiple lease arrangements.

For the three months ended March 31, 2021, total operating expenses were \$14.4 million as compared to \$16.0 million in the three months ended March 31, 2020.

For the three months ended March 31, 2021, net loss attributable to common stockholders was \$17.3 million or \$0.08 per share as compared to net loss attributable to common stockholders of \$17.0 million or \$0.59 per share in the three months ended March 31, 2020.

For the three months ended March 31, 2021, the adjusted net loss attributable to common stockholders was \$12.2 million or \$0.06 per share as compared to an adjusted net loss of \$12.0 million or \$0.41 per share in the three months ended March 31, 2020.

Adjusted net loss is GAAP net loss adjusted for the following items: amortization of intangible assets, change in fair value of contingent consideration, change in fair value of warrant liabilities, and for 2020, restructuring and other charges, and a deemed dividend related to beneficial conversion feature of preferred stock, all of which are non-cash charges.

Adjusted net loss attributable to common stockholders is a non-GAAP financial measure. A reconciliation from GAAP to non-GAAP measures can be found in our earnings release.

Turning to the balance sheet, the Company had cash and cash equivalents and restricted cash of approximately \$166.4 million and working capital of \$172.8 million as of March 31, 2021, which is expected to extend the cash runway into 2024.

I'll turn the call back over to Anthony.

**Anthony Fernando**

Thanks, Shameze.

I will now provide an update on recent performance as well as the progress we have made on the key areas that we are focusing on in 2021. As a reminder, these are: first, the continued market development for the Senhance System, and second, expanding our portfolio and continuing the technological advancement of Senhance.

Starting with our market development efforts. It is crucial to our strategy that we continue to educate surgeons on the benefits of the Senhance System and then follow up with clinical data to support them.

At the beginning of the year, two clinical papers were published that were very important to us. The first paper compared health economic outcomes of the Senhance system versus another robotic system, as well as traditional laparoscopy, and was published in *The International Journal of Medical Robotics and Computer Assisted Surgery* in April. The study indicated that for certain gynecologic procedures, the Senhance system per procedure costs were less than half of the cost of comparable robotic procedures, and in line with Laparoscopically Assisted Vaginal Hysterectomy case costs. The study also showed case times between Senhance and the other robotic system were comparable.

In addition, a number of other papers were published both suggesting the safety and reproducibility of procedures utilizing the Senhance System, including a study on first use of Senhance in laparoscopic local gastrectomy for gastrointestinal stromal tumor, and a study focusing on European procedures in Urology, Abdominal, Thoracic, and Gynecologic Surgery.

We still expect to have our second milestone paper, which further analyzes clinical performance and economics in general surgery and gynecology when utilizing the Senhance System, will be completed during the first half of this year and published in the second half of 2021. As we continue to demonstrate real-world evidence that we are delivering clinical and surgical benefits, as well as provide good surgical outcomes at a lower procedure cost, we believe these publications could be a tailwind to accelerated Senhance system adoption.

The next segment of our market development effort is the growth of our global installed base, the acceleration of procedure volumes, and the increase in the number of foundational sites. As we said last quarter, our goal for 2021 is to have another 10 to 12 new Senhance systems installed.

System installs were and continue to be negatively impacted by COVID-19. We saw various geographies in the quarter still struggling with third and fourth waves of COVID-19. Specifically, the Netherlands, Germany, and Switzerland were effectively shut down for most of the quarter. Japan lifted its national state of emergency but still has local government restrictions in place. Even with some of the slowdowns, we believe we have a robust pipeline and remain confident in our system install goal for the year.

As I stated earlier, subsequent to the end of the first quarter, we signed two new lease agreements with hospitals in Europe which we expect to be installed during the second quarter.

Moving on to procedures. During the quarter we saw strong procedure volumes despite the continued elective procedure volume constraints caused by COVID, with over 500 cases completed. In both the U.S. and Asia, we saw strong volume growth over the first quarter of 2020, with volumes growing over 40% in Asia and growing over 60% in the U.S. This growth was largely driven by accelerating utilization of Senhance in a number of procedures within our existing installations, as well as the growth in procedures significantly outpacing the growth in new system installations year over year in both regions.



Europe continues to face strong COVID headwinds as the result of numerous country-wide lockdowns which persisted during the quarter. Even with these shutdowns impacting hospitals' ability to perform procedures, over 50% of the overall case volume was performed in Europe during the quarter.

On a global scale, a broad mix of procedures were performed across general, gynecology, and colorectal. The broad applicability of the system and the applicability of our digital laparoscopic platform is being validated in the case volumes.

Shifting to an update on our foundational sites. At the end of the quarter, we had 13 foundational sites, up from 11 at the start of 2021. As a reminder, foundational sites are hospitals that are performing or on track to perform clinical procedures with Senhance at an annualized rate of greater than 100 procedures per year. The fact that we have been able to increase the number of foundational sites including the continued uncertainty speaks volumes about the value proposition of the system and the ability of our team to support our customers as they ramp up utilization.

Another positive trend in our market development efforts is the early progress with the lease buyout. As you know from previous calls, all of the hospitals that installed a Senhance system in 2020 opted to utilize a leasing model. As part of these agreements, hospitals have the option to purchase the system at the end of the initial contract period. I am pleased to announce we had one lease buyout in the quarter, which is a foundational site located in Asia. This hospital leased the system for just over a year before exercising their option to buy the system. A hospital's willingness to convert a lease into a capital purchase demonstrates the value it sees in the Senhance digital laparoscopy program. This is an early proof point that the system's low cost per procedure and our flexibility around pricing models is working, even in the COVID environment. While lease buyouts are not a primary focus of ours, we do expect some additional conversions in 2021.

Now turning to our second initiative for the year, the continued portfolio expansion and technological advancement of the Senhance System. In the first quarter of 2021, we achieved a number of regulatory milestones.

First was the CE Marking of the initial version of the ISU which will provide Senhance digital laparoscopy programs in Europe access to this new technology.

Second was the FDA clearance of our expanded general surgery indication in the United States. With this clearance, the Senhance Surgical System can be utilized in over 2.7 million general surgical procedures performed in the U.S. annually. This is a major milestone and key to our future growth and clinical applicability of our technology.

Since the quarter's end, we have also made progress on our regulatory goals, stated on our last call, that we expect to achieve during the first half of 2021. The first being filing the submission for 510(k) clearance for articulating instruments, which we filed earlier this month. Adding articulation will widen the clinical utility and value of our platform technology to a broader number of surgeons.

The second goal was the submission for 510-K clearance for the next generation ISU which we expect to submit in the second quarter.

We have also made progress on other portfolio expanding tools and applications that enable the pursuit of our mission to improve the adoption of digital Laparoscopy and performance-guided surgery with Senhance. For example, during the COVID shutdown last year, we developed an independent product called Senhance Connect, a mobile, in-OR surgeon communication system. With Senhance Connect, we allow up to six clinical and product specialists to remotely interact, observe, and communicate with the clinical team in the OR throughout a surgical procedure via the system's encrypted virtual video capabilities. This enhanced intraoperative communication is accomplished through two key features of the Senhance Connect system.

First, the system enables multiple camera feeds from the OR, allowing participants from outside the OR to view the surgeon performing the procedure, view the Senhance console including the laparoscopic camera, and view the system, including the patient-side view of the surgical team. In addition, the system allows for two-way voice-based dialog between the Surgeon and the participants outside the OR. This allows for real time, on demand, verbal communication during the course of the surgical procedure.

Secondly, with the use of the touchscreen monitor, the Senhance Connect system allows users on both ends of the conversation to annotate points of interest on the display, to better communicate and illustrate surgical approaches when using Senhance.

The Senhance Connect platform enables Asensus clinical specialists to access the OR without physically being present, and also allows external clinicians to call in and lend their expertise for an optimal surgical outcome.

The Senhance Connect System has not only been useful for surgeon and surgical team support but has also proven to be a valuable tool in training. The ability to observe cases remotely provides surgeons more opportunities to educate themselves on Senhance without disrupting the operating room. Currently this system is being piloted at a few sites in the U.S., Europe and Japan and we plan to bring the Senhance Connect to a greater number of accounts across these regions in the second half of 2021.

Next, I will highlight Performance-Guided Surgery developments. We have received good feedback on the use of the ISU, the initial application of Performance-Guided Surgery, thus far. We have seen high utilization of the ISU with over 100 procedures being performed across just two sites in the U.S. and Europe. This is especially exciting given the fact that the European site was only installed three months ago. Feedback has been great so far and we are working to get the ISU rolled out to our foundational sites worldwide in the second half of 2021, including multiple sites in Japan.

To support continued demand, we have added multiple training facilities in key geographies. We launched a training center in Japan in the third quarter of 2020, and in February of 2021, we announced an agreement to launch a new surgical training center in Amsterdam. At the Japanese training center in Saitama, we were able to generate a very strong cadence of surgeon training during the back half of 2020, which continued into the early part of 2021. This momentum has been interrupted by COVID-related shutdowns in the region, but we expect that as those restrictions are lifted, that the Saitama training center will help drive new surgeon adoption and support new hospital installations.

At the new center in Amsterdam, there have been a number of surgeon trainings held over a relatively short period of time during what has turned out to be a very challenging European situation due to the variety of shutdowns across a number of countries. Despite all of this, interest remains very high for both training centers, and believe they will both help to facilitate the accelerated adoption of Senhance in their respective regions.

As it relates to the balance of 2021, because we operate in a variety of geographies which are in various stages of resurgence or recovery, it is difficult to predict how our operations will be impacted. However, we continue to expect that as we progress through the year, we will see an increase in case volumes as elective procedures are more widely performed. We also continue to expect for new system installations to become less challenging as our commercial teams gain broader access to hospitals as restrictions are lifted and hospital staff have more bandwidth to devote attention to non-COVID-related matters.

In summary, off the back of a successful 2020, we are very pleased with the progress we have made in the first quarter of 2021. During the quarter, we submitted for 510(k) clearance for articulated instruments, received FDA clearance for general surgery, saw good utilization of the ISU, announced a new training center in the EU, significantly strengthened the balance sheet, and rebranded the Company. We are more confident than ever in the opportunity ahead for the business and our shareholders, thanks to our strategy, execution, and cash on hand.

I want to thank our entire organization for their tireless effort during these uncertain times and we believe we are well positioned to achieve our mission to digitize the interface between the surgeon and patient to pioneer a new era of Performance-Guided Surgery.

With that, I would like to open the line for questions.

### **Operator**

Thank you. We will now begin the question-and-answer session. To join the question queue you may press star then one on your telephone key pad. You will hear a tone acknowledging your request. If you are using a speaker phone, please pick up your handset before pressing any keys. To withdraw your question please press star then two. Once again, to join the question queue please press star then one now. We will pause for a moment as callers join the queue.

Our first question comes from RK of H.C. Wainwright. Please go ahead.

### **Ramakanth Swayampakula**

Thank you. Good afternoon, Anthony and Shameze.

**Anthony Fernando**

Hi, RK.

**Ramakanth Swayampakula – H.C. Wainwright & Co. – Managing Director**

A couple of quick questions. Actually, it's fantastic to note that there was one buyout in the—in Japan, especially in this environment and it looks like that happens to be a foundation site as well, which is fantastic. I remember you telling me that Japan is a place where laparoscopy is used to a large extent. Just so that we understand a little bit more, what are the dynamics in play for this center to decide to go and do the buyout and what drove them to make a decision? Obviously, it looks like they've used this system for about a year at best.

**Anthony Fernando**

Sure, RK. Okay. With respect to this buyout, and as you said, you're correct, Japan has a very broad skill base of laparoscopies. Also, remember that the Japan healthcare system is very conscious about cost and it goes to speak with this hospital as well. They enter into this lease agreement and used the system for about a year, and performed well over 100 cases and proved to themselves that the economics work. The per procedure cost is significantly lower compared to other robotic platforms. Therefore, they decided that this was something that they wanted to purchase and expand into other specialties as well. I think it's really the proof that when they have the system and they have surgeons using it, it just significantly increases their confidence and they know what they're getting.

**Ramakanth Swayampakula**

Very good. Then, you've talked, I think, in the press release, I saw that there were about 500 procedures that were performed during the first quarter. Is there any way we can get some more granularity on these procedures? Just trying to figure out whether these are the typical hernia closure procedures or they're more complicated than that, just so that we have an idea, if they're more complicated, do they help on the cost efficiency better? I'm just trying to understand if there's a linkage between those two or not?

**Anthony Fernando**

RK, I think for—what I can say is that I think these procedures are spread across gynecology, general surgery, and even within general surgery, to a very good extent into the colorectal space, and then there are some pediatric cases as well. If you think about all of these cases, I wouldn't say they're just simple procedures. They are a pretty broad spectrum of simple-complex cases. I don't quite have the breakdown with me right now. But that's something that we can try to provide in a little bit more granularity offline.

**Ramakanth Swayampakula**

Thank you. One last question, on the number of foundational sites, it's good to see that there is a growth from 11 to 13 by the end of the first quarter. I think at some point you had stated how many foundational sites you would like to see in 2021? I don't remember that number. But, in general, do you see this as a start of a much bigger number that you would get to by the end of the year, because if you talk to people, at least in the United States, they seem to be feeling comfortable that we're coming to the end of—we're seeing the light at the end of the COVID tunnel, but what is your expectations as we progress through the year?

**Anthony Fernando**

Yes. RK, I think, the thing is it's—there's still a lot of uncertainty, whether it's in Japan, Europe, or the U.S. about case volumes that definitely interest and the fact that we were able to get two more sites on track for the year to be at a foundation level, that's a good sign and a positive sign. Obviously our goal is to keep increasing that, but it's very difficult to predict how things are going to turn out. U.S., definitely I agree with you. We are seeing some positive momentum, and Europe and Japan, I wouldn't quite say that yet. From our point of view, the goal is to keep increasing that number, so that we get majority of our sites performing at that level, so that we can improve adoption systematically. That's pretty much what we can say for now, given the uncertainty. I think once we come out of this, we'll be able to be more committed about the numbers there.

**Ramakanth Swayampakula**

Perfect. Thank you very much. Good luck to you and Shameze and talk to you soon.

**Anthony Fernando**

Thank you, RK.

**Operator**

This concludes the question-and-answer session. I would like to turn the conference back over to Anthony Fernando for any closing remarks.

**Anthony Fernando**

Thank you again for your interest in Asensus Surgical and we look forward to updating you on our progress on our next quarterly call. Thank you.

**Operator**

This concludes today's conference call. You may disconnect your lines. Thank you for participating and have a pleasant day.