

**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**

**August 8, 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 2.02 Results of Operations and Financial Condition**

On August 8, 2022, Asensus Surgical, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the second quarter ended June 30, 2022. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on August 8, 2022, 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 second quarter ended June 30, 2022. The Company had issued a press release on July 26, 2022 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 August 8, 2022</a>
99.2	<a href="#">August 8, 2022 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: August 11, 2022

**ASENSUS SURGICAL, INC.**

By: /s/ Shameze Rampertab

Shameze Rampertab

Executive Vice President and Chief Financial Officer

## Asensus Surgical, Inc. Reports Operating and Financial Results for the Second Quarter 2022

RESEARCH TRIANGLE PARK, N.C.--(GLOBE NEWSWIRE)--August 8, 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 announced its operating and financial results for the second quarter 2022.

### Recent Highlights

- Over 670 procedures were performed globally during the quarter, representing growth of 34% over the prior year quarter, including 77% growth in the EMEA region
- Continued the development of Performance-Guided Surgery capabilities which will enable surgeons to deliver better patient outcomes
- The Company had cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of approximately \$103.8 million at June 30, 2022

“We delivered yet another strong quarter of global Senhance® System utilization growth and made great progress towards the ongoing development of our digital surgery platform with the Intelligent Surgical Unit™ (ISU™) as we seek to make Performance-Guided Surgery (PGS) a reality,” said Anthony Fernando, Asensus Surgical President and CEO. “Our goal is to enable surgeons to perform safer, more predictable, and better quality procedures. By delivering real-time, data-driven clinical intelligence and guidance, Senhance and PGS will revolutionize surgery, and most importantly, help to improve patient outcomes.”

### Digital Surgery Portfolio Expansion

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

The Company continues to expand the utilization and applicability of the 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 late 2022. 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.

Through the evolution of the ISU, the Senhance System provides surgeons with real-time intraoperative digital tools, which represent the initial components of Performance-Guided Surgery. These tools can ultimately allow surgeons to perform better, more predictable surgery regardless of their skill level or experience.

#### *Articulating Instrument Launch*

The Company continues to expect a full scale commercial launch of 5mm Articulating Instruments in the second half of the year, which is currently in a pilot launch in the U.S. These instruments offer better access to difficult-to-reach areas of the anatomy by providing two additional degrees of freedom.

#### *U.S. Pediatric Clearance*

The Company continues to expect to submit its 510(k) application for pediatric clearance in the U.S. during the second half of 2022. Senhance System’s unique combination of the 3mm instrumentation with 5mm camera scope combined with haptic feedback make it a unique robotic assisted laparoscopic solution for pediatric surgeries.

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## Market Development

### *Procedure Volumes*

In the second quarter, surgeons performed over 670 procedures utilizing the Senhance System, representing a 34% increase over the second quarter of 2021, and a 3% increase sequentially over the first quarter of 2022. This growth was primarily driven by a 77% increase in procedures in the EMEA region.

When a procedure is performed with a Senhance System, the Company is able to collect robust data, including surgical video. Over time, the accumulation of this digital surgical data library will enable the Company to generate powerful clinical insights that will fuel the development of Performance-Guided Surgery capabilities to help surgeons reduce surgical variability and drive consistently superior surgical outcomes.

### *Clinical Registry (TRUST)*

The Company is leveraging 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. The Company expects to continue to grow this body of clinical data to support its commercial strategy as well as help to facilitate an increasing number of high-quality clinical publications demonstrating the value of Senhance and Performance-Guided Surgery.

### *Clinical Validation*

During the quarter, there were six peer-reviewed clinical papers published providing further support for the clinical utility of the Senhance System across a variety of surgical specialties.

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

### *New Program Initiations*

During the second quarter, the Company announced one Senhance installation, in the EMEA region, at the University Hospital Tübingen in Germany.

In addition, the Company has received two additional system orders which have not yet been installed. This includes the system announced on August 4, 2022, which was sold to the Company's distribution partner, which will be installed at a hospital in the Commonwealth of Independent States (CIS).

For the full year 2022, the Company now expects to initiate 8 - 10 new Senhance Surgical Systems.

## Second Quarter Financial Results

For the three months ended June 30, 2022, the Company reported revenue of \$1.0 million as compared to revenue of \$1.1 million in the three months ended June 30, 2021. Revenue in the second quarter of 2022 included \$0.3 million in lease revenue, \$0.3 million in instruments and accessories, and \$0.4 million in services.

For the three months ended June 30, 2022, total operating expenses were \$18.2 million, as compared to \$14.8 million, in the three months ended June 30, 2021.

For the three months ended June 30, 2022, net loss was \$19.6 million, or \$0.08 per share, as compared to a net loss of \$13.2 million, or \$0.06 per share, in the three months ended June 30, 2021.

Adjusted net loss is a non-GAAP financial measure. See the reconciliation of GAAP to Non-GAAP Measures below. For the three months ended June 30, 2022, the adjusted net loss was \$17.3 million, or \$0.07 per share, as compared to an adjusted net loss of \$12.7 million, or \$0.05 per share in the three months ended June 30, 2021, after adjusting for the following charges: amortization of intangible assets, change in fair value of contingent consideration, property and equipment impairment, gain on extinguishment of debt, and change in fair value of warrant liabilities, all of which are non-cash charges.

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## Balance Sheet Updates

The Company had cash, cash equivalents, short-term and long-term investments, excluding restricted cash of approximately \$103.8 million as of June 30, 2022.

## Conference Call

Asensus Surgical, Inc. will host a conference call on Monday, August, 8, 2022, at 4:30 PM ET to discuss its second quarter 2022 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 10019864 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).

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## Forward-Looking Statements

This press release includes statements relating to the Senhance System and our 2022 second quarter 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, including whether we can make Performance-Guided Surgery a reality; whether the Senhance System and Performance Guided Surgery will revolutionize surgery and help to improve patient outcomes; whether we will be able to expand the utilization and applicability of the ISU globally and whether we will receive CE Mark approval for expanded machine vision capabilities in Europe in late 2022; whether we will undertake a full scale commercial launch of 5mm Articulating Instruments in the second half of 2022; whether we will submit a 510(k) application for pediatric clearance in the U.S. during the second half of 2022; whether the accumulation of a digital surgical data library will give the Company the ability to generate powerful clinical insights that will enable the development of Performance-Guided Surgery capabilities to help surgeons reduce surgical variability and drive consistently superior surgical outcomes; whether we will continue to grow the Trust Registry data to support its commercial strategy; and whether we will initiate 8-10 new Senhance Surgical Systems placements in 2022. 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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**Asensus Surgical, Inc.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
(in thousands, except per share amounts)  
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
Product	\$ 254	\$ 363	\$ 601	\$ 1,726
Service	424	406	732	785
Lease	316	333	727	674
Total revenue	<u>994</u>	<u>1,102</u>	<u>2,060</u>	<u>3,185</u>
Cost of revenue:				
Product	883	1,003	1,259	2,678
Service	646	636	1,141	1,002
Lease	818	708	1,770	1,779
Total cost of revenue	<u>2,347</u>	<u>2,347</u>	<u>4,170</u>	<u>5,459</u>
Gross loss	<u>(1,353)</u>	<u>(1,245)</u>	<u>(2,110)</u>	<u>(2,274)</u>
Operating Expenses:				
Research and development	7,253	4,089	13,681	8,304
Sales and marketing	3,602	3,562	7,321	6,615
General and administrative	4,992	3,848	10,525	7,840
Amortization of intangible assets	2,533	2,862	5,203	5,729
Change in fair value of contingent consideration	(598)	478	(752)	735
Property and equipment impairment	432	—	432	—
Total Operating Expenses	<u>18,214</u>	<u>14,839</u>	<u>36,410</u>	<u>29,223</u>
Operating Loss	<u>(19,567)</u>	<u>(16,084)</u>	<u>(38,520)</u>	<u>(31,497)</u>
Other Income (Expense):				
Gain on extinguishment of debt	—	2,847	—	2,847
Change in fair value of warrant liabilities	—	—	—	(1,981)
Interest income	260	79	515	131
Interest expense	(141)	(5)	(341)	(12)
Other expense, net	(86)	(7)	(232)	(36)
Total Other Income (Expense), net	<u>33</u>	<u>2,914</u>	<u>(58)</u>	<u>949</u>
Loss before income taxes	<u>(19,534)</u>	<u>(13,170)</u>	<u>(38,578)</u>	<u>(30,548)</u>
Income tax (expense) benefit	<u>(85)</u>	<u>(2)</u>	<u>(169)</u>	<u>36</u>
Net loss	<u>(19,619)</u>	<u>(13,172)</u>	<u>(38,747)</u>	<u>(30,512)</u>
Comprehensive loss:				
Net loss	(19,619)	(13,172)	(38,747)	(30,512)
Foreign currency translation (loss) gain	(1,713)	472	(2,363)	(1,466)
Unrealized loss on available-for-sale investments	(144)	—	(696)	—
Comprehensive loss	<u>\$ (21,476)</u>	<u>\$ (12,700)</u>	<u>\$ (41,806)</u>	<u>\$ (31,978)</u>
Net loss per common share attributable to common stockholders – basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.06)</u>	<u>\$ (0.16)</u>	<u>\$ (0.14)</u>
Weighted average number of shares used in computing net loss per common share – basic and diluted	<u>236,505</u>	<u>233,250</u>	<u>236,201</u>	<u>219,199</u>

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

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
<b>Assets</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 10,844	\$ 18,129
Short-term investments, available-for-sale	83,360	80,262
Accounts receivable, net	699	749
Inventories	8,451	8,634
Prepaid expenses	2,927	3,255
Employee retention tax credit receivable	1,147	1,311
Other current assets	1,134	957
<b>Total Current Assets</b>	<u>108,562</u>	<u>113,297</u>
Restricted cash	1,290	1,154
Long-term investments, available-for-sale	9,581	37,435
Inventories, net of current portion	7,258	7,074
Property and equipment, net	9,389	10,971
Intellectual property, net	4,122	9,892
Net deferred tax assets	244	288
Operating lease right-of-use assets, net	4,747	5,348
Other long-term assets	2,157	1,014
<b>Total Assets</b>	<u>\$ 147,350</u>	<u>\$ 186,473</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 3,849	\$ 3,448
Accrued employee compensation and benefits	3,127	3,559
Accrued expenses and other current liabilities	1,617	1,617
Operating lease liabilities – current portion	579	683
Deferred revenue	510	543
<b>Total Current Liabilities</b>	<u>9,682</u>	<u>9,850</u>
<b>Long Term Liabilities:</b>		
Contingent consideration	1,619	2,371
Noncurrent operating lease liabilities	4,610	5,006
<b>Total Liabilities</b>	<u>15,911</u>	<u>17,227</u>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity</b>		
Common stock \$0.001 par value, 750,000,000 shares authorized at June 30, 2022 and December 31, 2021; 236,620,415 and 235,218,552 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	237	235
Preferred stock, \$0.01 par value, 25,000,000 shares authorized, no shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	958,646	954,649
Accumulated deficit	(824,121)	(785,374)
Accumulated other comprehensive loss	(3,323)	(264)
<b>Total Stockholders' Equity</b>	<u>131,439</u>	<u>169,246</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 147,350</u>	<u>\$ 186,473</u>

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

	<b>Six Months Ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
<b>Operating Activities:</b>		
Net loss	\$ (38,747)	\$ (30,512)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	1,720	1,585
Amortization of intangible assets	5,203	5,729
Amortization of discounts and premiums on investments, net	444	—
Stock-based compensation	4,328	3,628
Gain on extinguishment of debt	—	(2,847)
Deferred tax expense (benefit)	169	(36)
Bad debt expense	9	—
Change in inventory reserves	(567)	288
Property and equipment impairment	432	—
Loss on disposal of property and equipment	97	—
Change in fair value of warrant liabilities	—	1,981
Change in fair value of contingent consideration	(752)	735
Changes in operating assets and liabilities:		
Accounts receivable	(8)	127
Inventories	(1,933)	(1,687)
Operating lease right-of-use assets	409	(2,970)
Prepaid expenses	189	517
Other current and long-term assets	(1,169)	2,660
Accounts payable	524	679
Accrued expenses	(284)	(1,428)
Deferred revenue	(4)	14
Operating lease liabilities	(290)	3,052
Net cash and cash equivalents used in operating activities	<u>(30,230)</u>	<u>(18,485)</u>
<b>Investing Activities:</b>		
Purchase of available-for-sale investments	(17,792)	—
Proceeds from maturities of available-for-sale investments	41,408	—
Purchase of property and equipment	(443)	(700)
Net cash and cash equivalents provided by (used in) investing activities	<u>23,173</u>	<u>(700)</u>
<b>Financing Activities:</b>		
Proceeds from issuance of common stock, net of issuance costs	—	130,314
Taxes paid related to net share settlement of vesting of restricted stock units	(349)	(1,041)
Proceeds from exercise of stock options and warrants	18	30,835
Net cash and cash equivalents (used in) provided by financing activities	<u>(331)</u>	<u>160,108</u>
Effect of exchange rate changes on cash and cash equivalents	239	(329)
Net (decrease) in cash, cash equivalents and restricted cash	(7,149)	140,594
Cash, cash equivalents and restricted cash, beginning of period	19,283	17,529
Cash, cash equivalents and restricted cash, end of period	<u>\$ 12,134</u>	<u>\$ 158,123</u>
<b>Supplemental Disclosure for Cash Flow Information:</b>		
Cash paid for leases	\$ 549	\$ 539
Cash paid for taxes	\$ 65	\$ 50
<b>Supplemental Schedule of Non-cash Investing and Financing Activities:</b>		
Transfer of inventories to property and equipment	\$ 724	\$ 1,243
Acquisition of property and equipment in accounts payable	\$ —	\$ 67
Reclass of warrant liability to common stock and additional paid-in-capital	\$ —	\$ 2,236
Lease liabilities arising from obtaining right-of-use assets	\$ —	\$ 3,461

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
<b>Net loss attributable to common stockholders (GAAP)</b>	\$ (19,619)	\$ (13,172)	\$ (38,747)	\$ (30,512)
<b>Adjustments</b>				
Amortization of intangible assets	2,533	2,862	5,203	5,729
Change in fair value of contingent consideration	(598)	478	(752)	735
Property and equipment impairment	432	—	432	—
Gain on extinguishment of debt	—	(2,847)	—	(2,847)
Change in fair value of warrant liabilities	—	—	—	1,981
<b>Adjusted net loss attributable to common stockholders (Non-GAAP)</b>	<u>\$ (17,252)</u>	<u>\$ (12,679)</u>	<u>\$ (33,864)</u>	<u>\$ (24,914)</u>

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
<b>Net loss per share attributable to common stockholders (GAAP)</b>	\$ (0.08)	\$ (0.06)	\$ (0.16)	\$ (0.14)
<b>Adjustments</b>				
Amortization of intangible assets	0.01	0.02	0.02	0.03
Change in fair value of contingent consideration	0.00	0.00	0.00	0.00
Property and equipment impairment	0.00	—	0.00	—
Gain on extinguishment of debt	—	(0.01)	—	(0.01)
Change in fair value of warrant liabilities	—	—	—	0.01
<b>Adjusted net loss per share attributable to common stockholders (Non-GAAP)</b>	<u>\$ (0.07)</u>	<u>\$ (0.05)</u>	<u>\$ (0.14)</u>	<u>\$ (0.11)</u>

The non-GAAP financial measures for the three and six months ended June 30, 2022 and 2021, provide management with additional insight into the Company's results of operations from period to period without non-cash charges 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 Monte-Carlo simulation utilizing significant unobservable inputs including the probability of achieving each of the potential milestones, revenue volatility, EURO to USD exchange rate, 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) Property and equipment impairment associated with returned Senhance Systems under operating leases that are not expected to generate future cash flows sufficient to recover their net book value.
- d) During the second quarter of 2021, the Company received notification from the U.S. Small Business Administration that the principal amount of its Paycheck Protection Program loan of \$2.8 million and related interest had been forgiven. Gain on extinguishment of debt of \$2.8 million was recognized for the three and six months ended June 30, 2021, in the consolidated statement of operations and comprehensive loss.
- e) 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.

**INVESTOR CONTACT:**

Mark Klausner or Mike Vallie, 443-213-0499

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

**OR**

**MEDIA CONTACT:**

Lauren Stredler, 847-271-6891

CG Life

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

Asensus Surgical, Inc. Q2 2022 Earning Call Transcript

**Corporate Participants:**

**Mark Klausner**, *Westwicke Partners*

**Anthony Fernando**, *President and Chief Executive Officer*

**Shameze Rampertab**, *Chief Financial Officer*

**Presentation:**

**Mark Klausner**

Good afternoon, everyone, and thank you for joining us for the Asensus Surgical second quarter 2022 business and financial update conference 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 and other geopolitical factors beyond our control. The company undertakes no obligation to update the information provided on this call or discussion of risks and uncertainties associated with the Asensus Surgical business, I encourage you to review the company's filings with the Securities and Exchange Commission, including the 2021 Form 10-K filed in February 2022 and the Form 10-Q expected to be filed later today, and any 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 stockholders and the adjusted net loss per common share attributable to common stockholders. Management believes that these non-GAAP financial measures taken in conjunction with US GAAP financial measures provide useful information for both management and investors by excluding certain noncash and other expenses that are not indicative of the company's core operating results. 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 US 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 an overview of our recent accomplishments and then ask Shameze to review our financial performance, after which I will discuss our performance during the second quarter as well as our priorities for the rest of 2022 before turning to Q&A.

Before turning the call over to Shameze, I would like to provide an overview of our recent performance. Similar to many companies with surgical procedure businesses, we experienced a number of macro headwinds during the quarter. We have continued to see procedure volumes be negatively impacted by hospital staffing shortages and inflationary pressures. Despite those headwinds, we delivered a strong 34% year over year increase in Senhance case volumes, largely a result of significant growth in our European sites. This performance continues to validate the utility of Senhance among surgeons across a variety of geographies and surgical specialities, and continues to feed the Augmented Intelligence development engine which will help deliver the intelligent capabilities of Performance Guided Surgery.

We also experienced disruptions to our commercial efforts, as hospital staffing, capital purchasing trends, supply chain challenges, and the ongoing conflict in Eastern Europe impacted our ability to place new systems during the quarter. Even with this, we have installed one system year to date and continue to be encouraged by the development of our pipeline, with two additional system orders on our books that we expect to be installed within the next few months.

During the second quarter, we attended the Society of Robotic Surgery Conference, or SRS, at the end of June, where we had several presentations on the clinical performance of Senhance and our vision for Performance-Guided surgery. Additionally, Dr. Amit Trevidi, the Chair of Surgery at Hackensack Meridian Health Pascack Valley Medical Center, led a breakfast symposium in which he described his successful experience with the ISU performing sleeve gastrectomies and his overall experience with Performance-Guided Surgery in Bariatrics, as he has performed over 300 cases using the Senhance system.

In July, we attended the 30th International Congress of the European Association for Endoscopic Surgery, or EAES, in Kraków, Poland. We participated in “Meet the Expert” sessions throughout the event in which our team shared clinical insights and demonstrated the features of the Senhance System.

These were both great opportunities to show the impressive capabilities that the Senhance System and the ISU have to offer.

As it is only one of two approved multi-port systems in the US, the Senhance system offers truly unique capabilities, such as haptic feedback, 3mm instrumentation, and the ISU, the industry’s only digital Augmented Intelligence platform available for use.

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

**Shameze Rampertab**

Thanks, Anthony.

Turning to the second quarter, for the three months ended June 30, 2022, the company reported revenue of \$1.0 million as compared to revenue of \$1.1 million in the three months ended June 30, 2021. Revenue in the second quarter of 2022 included \$0.3 million in lease revenue, \$0.3 million in instruments and accessories, and \$0.4 million in services.

For the three months ended June 30, 2022, total operating expenses were \$18.2 million as compared to \$14.8 million in the three months ended June 30, 2021.

For the three months ended June 30, 2022, net loss attributable to common stockholders was \$19.6 million or \$0.08 per share as compared to net loss attributable to common stockholders of \$13.2 million or \$0.06 per share in the three months ended June 30, 2021.

For the three months ended June 30, 2022, the adjusted net loss attributable to common stockholders was \$17.3 million or \$0.07 per share as compared to an adjusted net loss of \$12.7 million or \$0.05 per share in the three months ended June 30, 2021.

Adjusted net loss is GAAP net loss adjusted for the following items: amortization of intangible assets, change in fair value of contingent consideration, property and equipment impairment, gain on extinguishment of debt, and change in fair value of warrant liabilities, all of which are non-cash charges.

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

Turning to the balance sheet, the company had cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of approximately \$103.8 million and working capital of \$98.9 million as of June 30, 2022.

I would now like to turn the call back over to Anthony.

### **CEO Conclusion - Anthony Fernando**

Thanks, Shameze.

I would now like to provide an update on recent performance as well as the progress we have made on the key focus areas for 2022. As a reminder, those are: First, the continued market development of the Senhance System, and second the ongoing development of our product portfolio and continuing the technological advancement of Senhance.

Starting with market development. This year we continue to expect to have 2-3 papers published over the course of the rest of the year. These peer reviewed studies are vital for providing real world data on how the Senhance platform, the ISU, and all of the features of Senhance can benefit surgeons and patients across a wide variety of surgical specialties. In the second quarter, we had six new publications bringing the total for the year to 10. One key publication based on a literature review specifically focused on robotic applications for pediatric surgery which placed Senhance in high regard, particularly with 3mm instruments. This review identified 36 different publications that suggested robotically-assisted surgery was a viable alternative for pediatric procedures. These reviewed papers assessed a variety of criteria to determine the success of robotically assisted pediatric urology and general surgical procedures, including operating time, success rate, complications, length of stay, cost, and learning curves. This paper provides insights on the advantages of the Senhance system with smaller pediatric patients as the 3mm fully-reusable instruments tend to be more precise. We are very pleased with the results of this paper, as this is valuable data that can support the importance of receiving US pediatric clearance.

Other key studies include one which noted the short learning curve and low cost per procedure using Senhance for radical prostatectomy procedures in Taiwan, and the second regarding colorectal procedures in Japan.

As we continue developing our list of clinical publications, we have also continued to leverage our growing real-world clinical data through our clinical registry. Our TRUST registry, the industry's largest robotic-assisted laparoscopic registry continues to grow in size and scale. We remain focused on leveraging the data accumulated to facilitate studies and publications which highlight the real-world benefits of Senhance.

As we have mentioned in the past, one of our focuses is providing surgeons the opportunity to participate in training sessions at one of our six centers located in Europe, the United States, and Japan. We continue to work to drive increased volumes of surgeons through these centers on a regular basis.

We have implemented a variety of tools to create a holistic training environment focused on getting surgeons up to speed and performing Senhance procedures quickly. These tools include the Asensus Surgical Learning Academy, which is our distance learning portal that provides surgeons with access to abundant interactive educational resources throughout the Senhance learning pathway, such as extensive interactive online training modules that build foundational knowledge of the Senhance System in preparation for hands-on training, procedural mapping guides that accelerate learning through knowledge sharing by Senhance clinical experts, quick reference guides to increase operating room efficiency, and a surgical video archive of Senhance procedures for continuing education. Other tools that we are leveraging are our mobile surgical simulator, which is designed to enhance surgeon skill level with the Senhance interface in a simulated environment, Senhance Connect, a multi-site digital video collaboration solution that enables virtual real-time best practice sharing among Senhance users from the operating room, and global training centers located in the US, Europe, and Japan. We believe these tools, in aggregate, will allow us to continue to facilitate the adoption of Senhance by surgeons across the globe and provide clinical intelligence through our Performance-Guided Surgery framework to assist surgeons in performing consistently superior surgery.

The next segment of our market development efforts is the expansion of our global footprint, including the growth of our installed base, the acceleration of procedure volumes and the increase in the number of foundational sites.

Beginning with new program initiations. The second quarter was again challenging as we continued to experience headwinds as a result of the conflict in Eastern Europe as well as ongoing supply chain issues. As a result of the conflict in Ukraine and surrounding areas, we made the decision to re-focus our commercial efforts on other regions, in particular Western Europe, and have seen positive traction since making that shift. We installed one system during the quarter, at University Hospital Tübingen, in Germany. In addition to that installation, we also have signed agreements with two hospitals, both of which we expect to be installed in the coming months. This includes one system that was purchased by our distribution partner in the month of August, and the system set to be installed in the CIS region in the near term. We are seeing positive momentum in the build out of our pipeline, in particular in Europe and Japan, and continue to work to generate demand for the platform globally.

Given the macro headwinds at play, and the impact they had on our first half performance, we have revisited our expectations for new system initiations globally, and now expect 8-10 for the year. Despite these near term volatility caused by a confluence of factors, we remain confident in our ability to drive the adoption of Senhance on a global scale over the long term.

Now, turning to procedure volumes. We have continued to see very strong procedure volume trends, up 34% over the second quarter of 2021 and 3% sequentially. With over 670 procedures performed in the quarter, the total for the first half of the year is over 1300 procedures. Volume trends were strongest in Europe, and overall general surgery had the most procedures throughout all geographies. Despite macro headwinds in the US, we were pleased to see sequential growth with impressive utilization trends.

We have also seen some of our systems reach significant milestones this quarter. At Evangelisches Krankenhaus in Wesel, Germany, Dr. Vivianda Menke and Dr. Olaf Hansen hit significant strong procedure volume milestones completing over 500 general and colorectal cases. We also saw a number of surgeons and hospitals hit the 100-procedure mark, including Dr. Steven McCarus at AdventHealth in Winter Park in Florida and Saitama Medical University reached their 100th colorectal case.

Turning to the expansion of our product portfolio, we are excited to build upon our accomplishments and reach additional regulatory milestones that will further develop the Senhance System and broaden its applicability.

We continue to expect the commercial launch of 5mm Articulating Instruments in the second half of this year, which is currently in a pilot launch in the U.S and Europe. Articulating instruments offer better access to “difficult-to-reach” or “around-the-corner” areas of the anatomy by providing two additional degrees of freedom. By allowing surgeons to manipulate the tip of the instrument in a wrist-like manner, they are often more easily able to perform certain tasks while at the same time reducing the pressure placed on the port where the instrument is inserted into the surgical field. By offering articulating instruments, the applicability of Senhance is expanded to those surgeons who view articulating instruments as critical.

In the second half of 2022, we also expect to submit our 510(k) application for pediatric clearance in the U.S. following strong early clinical utilization in Europe and increasing demand from U.S. surgeons. This will broaden the applicability of the Senhance System’s unique combination of the 3mm instrumentation with 5mm camera scope combined with haptic feedback to benefit more patients.

We continue to expand the utilization and applicability of the Intelligent Surgical Unit™ or ISU™ globally, and expect to receive CE Mark approval for expanded machine vision capabilities in Europe in late 2022.

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 have been made available in soft-tissue abdominal surgery, and can ultimately allow surgeons to perform better, more predictable surgery regardless of their skill level or experience.

In order to harness the power of data, we are continuing to invest in the development of our cloud and data management capabilities. We are currently partnering with hospitals and other institutions to work towards the compilation of a critical mass of surgical data, aided by the roll out of the ISU across our installed base which will provide a tremendous amount of surgical insight. The build out of this dataset has been somewhat slowed as a result of supply chain delays, which have delayed the expanded use of the ISU. The build out of this capability remains a top priority and we are continuing to push to roll out the ISU as quickly as possible.

We remain incredibly excited about the future of Asensus and the opportunity that exists for Senhance to revolutionize how soft tissue abdominal surgery is performed. Despite the challenging macro environment, we continue to make good progress towards the development of Performance-Guided Surgery and its advanced intelligent capabilities while at the same time accelerating the utilization of Senhance on a daily basis across the globe. I want to thank our employees whose dedication and ingenuity have allowed us to drive meaningful innovation and ultimately deliver better outcomes for surgeons, hospitals, and patients.

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

**Operator**

The first question is from RK Ramakanth from H.C. Wainwright. Please go ahead.

**RK Ramakanth**

Thank you. This is RK from H.C. Wainwright, and good afternoon, Anthony and Shameze.

It looks like a pretty decent quarter, considering everything I just said. So I just want to understand a little bit more about your confidence of ability to install eight to 10 devices for the year. If you can remind us, how many have been installed to date, and which regions are you concentrating and working on for the next set of installations for the year?

**Anthony Fernando**

Hi, RK. Let me try to answer that.

Currently we've installed one new system in Germany, and, like we said, we have two on the books that will get installed in the coming months, and once they get installed, we will obviously share the sites and all the details associated with each of those. For the rest of the year, I think the pipeline remains pretty good. As you guys have seen repeatedly, we had very good traction in Europe. I would think that Europe is going to lead the charge in terms of installed for the rest of the year, ended up pretty healthy pipeline there, and also Japan and the U.S. They both have pretty good pipelines, and we expect to see new installations in all three regions, but would primarily be led by Western Europe.

**RK Ramakanth**

Perfect. Then on the procedures, as you said, you have greater than 1,300 procedures in the first half of the year. Certainly that is tracking well. Based on what you are seeing on the procedures, I'm just trying to understand how to connect the dots between the procedures, and the revenue for them, for the rest of the year.

**Anthony Fernando**

I think the connectivity is really dependent on the type of arrangement that we have. Because if it's somewhat of a leasing arrangement, then a certain volume of procedures are part of the leasing arrangement, and anything additional would generate additional revenue. But then there are many systems that were purchased prior to our leasing arrangements, so those obviously have a very nice revenue stream coming from consumables and also the service agreement. It's going to be a mix between the consumables, service revenue, and then the leasing revenues from current systems, and then also the new systems that we place as part of the rest of the remaining months of the year.

**RK Ramakanth**

Thanks for that, Anthony, last question from me, on the articulating instruments. Obviously, that's a feature which I believe surgeons really like. Then you make such betterments on the Senhance system. Is there a way how you monitor both, obviously it's the utility, but also how it attracts new clients or new needs for additional information? I'm just trying to have an understanding of the ROI of some of these investments you continuously do on Senhance.

**Anthony Fernando**

Yes, RK. If I understood your question correctly, with when we talk about articular instrument, this has been a request of several surgeons, and based on that request is why we developed this instrument. We know there is a strong pull from the market for this, and then we are hoping that we will be able to see an increase in adoption of these instruments and acceleration of procedure growth at the institutions. We are pretty close to all the sites, so we have a pretty good idea of the level of adoption and acceleration of the procedures being used by each of the surgeons. Not only the current surgeons, but we also think that once we add articulation, it'll even increase the level of confidence for additional surgeons at the existing hospitals who might also join to do cases on Senhance. There's a two-pronged approach here: one providing tools for the existing surgeon community, and then also trying to attract newer surgeons at the existing hospitals, and obviously new hospitals as well.

**RK Ramakanth**

Thank you. Thanks for taking all my questions.

**Anthony Fernando**

Thank you, RK.

**Operator**

This concludes today's question-and-answer session. I would like to turn the conference back over to Anthony Fernando. Pardon me, there's now another question, from Ross Osborn from Cantor Fitzgerald. Please go ahead.

**Ross Osborn**

Hi. Congrats on the progress made during the quarter, and thanks for taking my questions.

I guess starting out with regards to the system, placements are the deepest and placement in the quarter and the two announced orders. Could you provide a little more color on how long the sales process took from initiating those conversations until the orders are placed? Then also, if possible, what attracted those buyers to the Senhance system relative to competitors?

**Anthony Fernando**

I think it's a varying timeline. We've had some that are relatively long, especially going through certain tender processes could take north of 12 months or four quarters, and there are others that convert within the same quarter, so I think we have the full spectrum of the time it takes to convert something to an order.

On what's attractive, I think there are a few things. One is the fact that it's a laparoscopic tool, so the learning curve is relatively small and short, and it's a very familiar interface for the laparoscopic surgeons, and also some other features that we offer in terms of haptic feedback, the use of three-millimeter instrumentation. Those tend to be things that are attractive. Then also not to mention the digital features that we offer with the intelligence surgical unit. That's a unique proposition for some of the surgeons. They are very keen on these digital features and being able to do more and be able to see the potential of what they can do for them. So that's been yet another point. The third is the economics. I think we've continued to show the economic value from a per procedure point of view, and that remains. So we have publications, we have data from some of the institutions that we are able to share with other institutions, and they talk amongst themselves as well and compare notes on costs, so that's also another attractor. Those factors put together is what's driving some of these new sites to be convinced that Senhance is the right choice for them.

**Ross Osborn**

Great, understood. Then I guess outside of the extended ISU capabilities, what else is the company doing to drive performance-guided surgery?

**Anthony Fernando**

Yes. So on the performance guide surgery front, it's a two-factor thing. One's the technology that's continuing to evolve and develop, and then at the same time, even organizationally, we're re-aligning ourselves. We've just created a new medical affairs function. We brought in a seasoned general surgeon to be part of the team as the Vice President of Medical Affairs so that we can converge this innovative technology and also put things together between the technology clinical data in order to optimize the procedure-specific solution. If technology alone is not enough, so at the same time we are evolving and adopting the organization to be able to provide value and then make it clear to be able to define the solution, and also train the surgeons and develop all the different techniques to derive value. That's what we're doing also to drive performance-guided surgery on both fronts, externally and internally being able to support it.

**Ross Osborn**

Sounds great. Thanks again for taking my questions, and congrats on the progress.

**Anthony Fernando**

Thank you, Ross.

**Operator**

There are no further questions. I'll now hand the call back over to Anthony Fernando for any closing remarks.

**Closing - 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.