

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

FORM 8-K

CURRENT REPORT

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

**November 10, 2022
Date of Report (date of earliest event reported)**

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

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

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

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

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

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

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

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

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

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

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

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On November 10, 2022, Asensus Surgical, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the third quarter ended September 30, 2022. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on November 10, 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 third quarter ended September 30, 2022. The Company had issued a press release on October 31, 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	Press release dated November 10, 2022
99.2	November 10, 2022 conference call transcript
104	Cover Page Interactive Data File (formatted in inline XBRL)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 14, 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 Third Quarter 2022

RESEARCH TRIANGLE PARK, N.C.--(GLOBE NEWSWIRE)--November 10, 2022-- Asensus Surgical, Inc. (NYSE American: ASXC), a medical device company that is digitizing the interface between the surgeon and the patient to pioneer a new era of Performance-Guided Surgery™, today announced its operating and financial results for the third quarter 2022.

Recent Highlights

- Over 1,900 procedures were performed globally during the nine months ended September 30, 2022, representing growth of 27% over the prior year
- Five new Senhance program initiations year to date, 3 in Germany, 1 in Japan, 1 in CIS region
- Submitted FDA 510(k) application for pediatric indication in the U.S.
- Received the Society of Laparoscopic & Robotic Surgeons 2022 Innovation of the Year award for the Intelligent Surgical Unit™(ISU™)
- The Company had cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of approximately \$88.3 million at September 30, 2022

“We are very pleased with what we have accomplished this quarter, with impressive utilization metrics, a growing base of clinical evidence highlighting the benefits of the Senhance system and the ISU, and the growth of our installed base,” said Anthony Fernando, Asensus Surgical President and CEO. “As we have made great progress towards the ongoing development of Performance-Guided Surgery and its suite of digital capabilities, we look forward to continuing to progress the platform to enable safer, more consistent surgery - resulting in better outcomes for hospitals and patients alike.”

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. The expanded machine vision capabilities have both U.S. FDA 510(k) clearance and Japanese PMDA approval.

This filing included a review of the entire Senhance System platform, and if successful, would represent one of the first robotic surgical systems to be approved through the new, more rigorous MDR process.

Articulating Instrument Launch

These instruments are currently in a pilot launch in the U.S. and Europe, and the Company continues to expect a full scale commercial launch by the end of 2022. Articulating Instruments offer better access to difficult-to-reach areas of the anatomy by providing two additional degrees of freedom.

U.S. Pediatric Regulatory Submission

The Company submitted its 510(k) application for pediatric clearance in the U.S. during the third quarter of 2022. The 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.

Market Development

Procedure Volumes

During the first nine months of 2022, over 1,900 procedures have been completed utilizing the Senhance System, a 27% increase over the same period in 2021. In the third quarter, surgeons performed over 600 procedures, representing an 18% increase over the third quarter of 2021. This growth was primarily driven by strong utilization trends as a result of an expanded installed base and a growth in new surgeon users at existing installations as well as a broader market recovery.

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 continues 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 the Senhance System and Performance-Guided Surgery, with over 2,000 patients enrolled to date. The registered procedures consist of approximately 67% general surgery, including abdominal and thoracic, 15% GYN, and 18% urology.

Clinical Validation

During the quarter, there were three 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.

During the quarter, the Company received the Society of Laparoscopic & Robotic Surgeons 2022 Innovation of the Year award for the ISU. Each year, The Society of Laparoscopic & Robotic Surgeons recognizes the most innovative products that have a multidisciplinary application in minimally invasive surgery.

New Program Initiations

During the third quarter, the Company announced four Senhance System initiations:

- Evangelical Hospital Goettingen-Weende in Göttingen, Germany
- Saiseikai Shiga Hospital in Ritto, Japan
- The Clinic for General and Visceral Surgery at the St. Bernhard Hospital in Kamp-Lintfort, Germany
- A hospital in the Commonwealth of Independent States (CIS) region

Subsequent to the end of the third quarter, the Company announced one additional Senhance System initiation, bringing the year to date total to five:

- The Dr. von Hauner Children's Hospital at the Ludwig Maximilians University of Munich, located in Munich, Germany.

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

Third Quarter Financial Results

For the three months ended September 30, 2022, the Company reported revenue of \$2.6 million as compared to revenue of \$2.6 million in the three months ended September 30, 2021. Revenue in the third quarter of 2022 included \$1.2 million in system revenue, \$0.3 million in lease revenue, \$0.8 million in instruments and accessories, and \$0.3 million in services.

For the three months ended September 30, 2022, total operating expenses were \$17.2 million, as compared to \$16.7 million, in the three months ended September 30, 2021.

For the three months ended September 30, 2022, net loss was \$18.9 million, or \$0.08 per share, as compared to a net loss of \$16.1 million, or \$0.07 per share, in the three months ended September 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 September 30, 2022, the adjusted net loss was \$16.9 million, or \$0.07 per share, as compared to an adjusted net loss of \$14.3 million, or \$0.06 per share in the three months ended September 30, 2021, after adjusting for the following charges: amortization of intangible assets, change in fair value of contingent consideration, and employee retention tax credit, all of which are non-cash charges.

Balance Sheet Updates

The Company had cash, cash equivalents, short-term and long-term investments, excluding restricted cash of approximately \$88.3 million as of September 30, 2022.

Conference Call

Asensus Surgical, Inc. will host a conference call on Thursday, November 10, 2022, at 4:30 PM ET to discuss its third quarter 2022 operating and financial results. To listen to the conference call on your telephone, please dial 1-866-652-5200 for domestic callers and 1-412-317-6060 for international callers, and reference conference ID 10171489 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 at <https://ir.asensus.com/events-and-presentations>.

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. 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. For more information, visit www.asensus.com.

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Forward-Looking Statements

This press release includes statements relating to the Senhance System and our 2022 third 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 the Company's platform to enable safer, more consistent surgery resulting in better outcomes for hospitals and patients alike; whether the Company will receive CE Mark approval for expanded machine vision capabilities in Europe in late 2022; whether the Company's articulating instruments will undergo a full scale commercial launch by the end of 2022; whether the Company will receive a pediatric clearance for the Senhance Surgical System from the FDA; whether the Company's TRUST clinical registry is the largest multi-specialty robotic-assisted laparoscopic registry in the industry and whether the Company will continue to grow the Trust registry data to support its commercial strategy; 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.

Asensus Surgical, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
Product	\$ 1,964	\$ 1,922	\$ 2,565	\$ 3,651
Service	335	395	1,067	1,180
Lease	264	254	991	925
Total revenue	<u>2,563</u>	<u>2,571</u>	<u>4,623</u>	<u>5,756</u>
Cost of revenue:				
Product	3,057	1,993	4,316	4,671
Service	365	342	1,506	1,344
Lease	982	1,015	2,752	2,794
Total cost of revenue	<u>4,404</u>	<u>3,350</u>	<u>8,574</u>	<u>8,809</u>
Gross loss	<u>(1,841)</u>	<u>(779)</u>	<u>(3,951)</u>	<u>(3,053)</u>
Operating Expenses:				
Research and development	6,741	4,469	20,422	12,773
Sales and marketing	3,615	3,551	10,936	10,166
General and administrative	4,853	5,557	15,378	13,397
Amortization of intangible assets	2,398	2,804	7,601	8,533
Change in fair value of contingent consideration	(416)	278	(1,168)	1,013
Property and equipment impairment	—	—	432	—
Total Operating Expenses	<u>17,191</u>	<u>16,659</u>	<u>53,601</u>	<u>45,882</u>
Operating Loss	<u>(19,032)</u>	<u>(17,438)</u>	<u>(57,552)</u>	<u>(48,935)</u>
Other Income (Expense), net:				
Gain on extinguishment of debt	—	—	—	2,847
Change in fair value of warrant liabilities	—	—	—	(1,981)
Interest income	291	122	806	253
Interest expense	(99)	(65)	(440)	(77)
Employee retention tax credit	—	1,311	—	1,311
Other (expense) income, net	(29)	33	(261)	(3)
Total Other Income (Expense), net	<u>163</u>	<u>1,401</u>	<u>105</u>	<u>2,350</u>
Loss before income taxes	<u>(18,869)</u>	<u>(16,037)</u>	<u>(57,447)</u>	<u>(46,585)</u>
Income tax (expense) benefit	(55)	(32)	(224)	4
Net loss	<u>(18,924)</u>	<u>(16,069)</u>	<u>(57,671)</u>	<u>(46,581)</u>
Comprehensive loss:				
Net loss	(18,924)	(16,069)	(57,671)	(46,581)
Foreign currency translation loss	(1,655)	(931)	(4,018)	(2,397)
Unrealized gain (loss) on available-for-sale investments	86	(53)	(610)	(53)
Comprehensive loss	<u>\$ (20,493)</u>	<u>\$ (17,053)</u>	<u>\$ (62,299)</u>	<u>\$ (49,031)</u>
Net loss per common share attributable to common stockholders – basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.07)</u>	<u>\$ (0.24)</u>	<u>\$ (0.21)</u>
Weighted average number of shares used in computing net loss per common share – basic and diluted	<u>236,713</u>	<u>234,337</u>	<u>236,373</u>	<u>224,300</u>

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

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 13,870	\$ 18,129
Short-term investments, available-for-sale	72,481	80,262
Accounts receivable, net	2,250	749
Inventories	9,035	8,634
Prepaid expenses	3,713	3,255
Employee retention tax credit receivable	1,147	1,311
Other current assets	1,034	957
Total Current Assets	<u>103,530</u>	<u>113,297</u>
Restricted cash	1,107	1,154
Long-term investments, available-for-sale	1,937	37,435
Inventories, net of current portion	3,441	7,074
Property and equipment, net	9,145	10,971
Intellectual property, net	1,529	9,892
Net deferred tax assets	227	288
Operating lease right-of-use assets, net	4,799	5,348
Other long-term assets	2,938	1,014
Total Assets	<u>\$ 128,653</u>	<u>\$ 186,473</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 3,637	\$ 3,448
Accrued employee compensation and benefits	3,868	3,559
Accrued expenses and other current liabilities	1,320	1,617
Operating lease liabilities – current portion	662	683
Deferred revenue	357	543
Total Current Liabilities	<u>9,844</u>	<u>9,850</u>
Long Term Liabilities:		
Contingent consideration	1,203	2,371
Noncurrent operating lease liabilities	4,630	5,006
Total Liabilities	<u>15,677</u>	<u>17,227</u>
Commitments and Contingencies		
Stockholders' Equity		
Common stock \$0.001 par value, 750,000,000 shares authorized at September 30, 2022 and December 31, 2021; 236,783,315 and 235,218,552 shares issued and outstanding at September 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 September 30, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	960,676	954,649
Accumulated deficit	(843,045)	(785,374)
Accumulated other comprehensive loss	(4,892)	(264)
Total Stockholders' Equity	<u>112,976</u>	<u>169,246</u>
Total Liabilities and Stockholders' Equity	<u>\$ 128,653</u>	<u>\$ 186,473</u>

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

	Nine Months Ended September 30,	
	2022	2021
Operating Activities:		
Net loss	\$ (57,671)	\$ (46,581)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	2,481	2,416
Amortization of intangible assets	7,601	8,533
Amortization of discounts and premiums on investments, net	556	65
Stock-based compensation	6,361	6,589
Gain on extinguishment of debt	—	(2,847)
Deferred tax expense (benefit)	224	(4)
Change in inventory reserves	386	377
Bad debt expense	9	—
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	(1,168)	1,013
Changes in operating assets and liabilities:		
Accounts receivable	(1,735)	113
Inventories	(535)	(1,941)
Operating lease right-of-use assets	237	(3,174)
Prepaid expenses	(693)	1,220
Employee retention tax credit receivable	164	(1,311)
Other current and long-term assets	(2,123)	2,098
Accounts payable	449	1,376
Accrued expenses	236	(588)
Deferred revenue	(139)	(81)
Operating lease liabilities	(53)	3,259
Net cash and cash equivalents used in operating activities	<u>(44,884)</u>	<u>(27,487)</u>
Investing Activities:		
Purchase of available-for-sale investments	(25,588)	(88,232)
Proceeds from maturities of available-for-sale investments	67,702	—
Purchase of property and equipment	(904)	(838)
Net cash and cash equivalents provided by (used in) investing activities	<u>41,210</u>	<u>(89,070)</u>
Financing Activities:		
Proceeds from issuance of common stock, net of issuance costs	—	130,361
Taxes paid related to net share settlement of vesting of restricted stock units	(350)	(1,058)
Proceeds from exercise of stock options and warrants	18	30,838
Net cash and cash equivalents (used in) provided by financing activities	<u>(332)</u>	<u>160,141</u>
Effect of exchange rate changes on cash and cash equivalents	(300)	(181)
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>(4,306)</u>	<u>43,403</u>
Cash, cash equivalents and restricted cash, beginning of period	19,283	17,529
Cash, cash equivalents and restricted cash, end of period	<u>\$ 14,977</u>	<u>\$ 60,932</u>
Supplemental Disclosure for Cash Flow Information:		
Cash paid for leases	\$ 729	\$ 781
Cash paid for taxes	\$ 79	\$ 63
Supplemental Schedule of Non-cash Investing and Financing Activities:		
Transfer of inventories to property and equipment	\$ 1,293	\$ 2,156
Reclass of warrant liability to common stock and additional paid-in-capital	\$ —	\$ 2,236
Lease liabilities arising from obtaining right-of-use assets	\$ 316	\$ 3,857

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss attributable to common stockholders (GAAP)	\$ (18,924)	\$ (16,069)	\$ (57,671)	\$ (46,581)
Adjustments				
Amortization of intangible assets	2,398	2,804	7,601	8,533
Change in fair value of contingent consideration	(416)	278	(1,168)	1,013
Property and equipment impairment	—	—	432	—
Gain on extinguishment of debt	—	—	—	(2,847)
Change in fair value of warrant liabilities	—	—	—	1,981
Employee retention tax credit	—	(1,311)	—	(1,311)
Adjusted net loss attributable to common stockholders (Non-GAAP)	<u>\$ (16,942)</u>	<u>\$ (14,298)</u>	<u>\$ (50,806)</u>	<u>\$ (39,212)</u>

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss per share attributable to common stockholders (GAAP)	\$ (0.08)	\$ (0.07)	\$ (0.24)	\$ (0.21)
Adjustments				
Amortization of intangible assets	0.01	0.01	0.03	0.04
Change in fair value of contingent consideration	0.00	0.01	0.00	0.01
Property and equipment impairment	—	—	0.00	—
Gain on extinguishment of debt	—	—	—	(0.01)
Change in fair value of warrant liabilities	—	—	—	0.01
Employee retention tax credit	—	(0.01)	—	(0.01)
Adjusted net loss per share attributable to common stockholders (Non-GAAP)	<u>\$ (0.07)</u>	<u>\$ (0.06)</u>	<u>\$ (0.21)</u>	<u>\$ (0.17)</u>

The non-GAAP financial measures for the three and nine months ended September 30, 2022 and 2021, which provide management with additional insight into the Company's results of operations from period to period without 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 7 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 nine months ended September 30, 2021, in the consolidated statement of operations and comprehensive loss.
- e) The Company's Series B Warrants were measured at fair value using a simulation model which took 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 was revalued upon exercise and the final change in fair value was recognized in the first quarter of 2021.
- f) During the third quarter of 2021, the Company submitted a refund for incurred employee payroll taxes of \$1.3 million under the Employee Retention Tax Credit provision as part of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). A corresponding tax credit receivable of \$1.3 million was recorded on the condensed consolidated balance sheet at September 30, 2021.

INVESTOR CONTACT:

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OR

MEDIA CONTACT:

Isabella Rodriguez, 708-833-1572
CG Life
irodriguez@cglife.com

ASXC Third Quarter 2022 Earnings Call Transcript**Mark Klausner**

Good afternoon, everyone, and thank you for joining us for the Asensus Surgical third 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. For a 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 U.S. 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 financial 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.

With that, 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. Today, I will begin with discussing our recent performance and events, then Shameze will review our financial results. Following that, I will go over our third quarter performance and priorities for the balance of 2022 before turning to Q&A.

Now, I would like to provide an overview of our recent performance. We are pleased to see an accelerated expansion of the Senhance system installed base this quarter with four new system initiations; two in Germany, one in Japan, and one in the CIS region. Subsequent to the end of the third quarter, we announced an additional system placement in Germany, bringing the year-to-date total to five system initiations.

We remain focused on increasing awareness of Senhance and educating the surgical community on its benefits by leveraging industry events. In September, we received The Society of Laparoscopic & Robotic Surgeons, or SLS, 2022 Innovation of the Year award for our Intelligent Surgical Unit, or ISU. Each year, SLS recognizes the most innovative products that have a multidisciplinary application in minimally invasive surgery. We are incredibly proud of our team's commitment to enhancing clinical performance and very excited that the clinical community sees the tremendous value the ISU brings to the OR.

We also participated in the 12th European Society of Pediatric Endoscopic Surgeons' Annual Congress in Barcelona, Spain in late September. Dr. Hamit Cakir, a pediatric surgeon at Maastricht University Medical Center in the Netherlands gave an insightful presentation during the Robotics Masterclass focused on his success in pediatric procedures using Senhance.

As we continue to seek to drive global adoption, we recently moved into a new office in the heart of Tokyo, Japan, with a new showroom and state of the art training facility. This is very exciting as we have grown our installed base over the last few years in Japan and have seen great momentum with our clinical efforts in the country.

As Japan is the number one laparoscopy market and the number two robotics market, we have seen that surgeons are eager to adopt our digital laparoscopic technology, and we will continue to partner with new hospitals in order to facilitate these innovative procedures with the Senhance system. We have continued to add talent across our senior leadership team as we work to drive developments of Performance-Guided Surgery and accelerate the adoption of Senhance globally. Following the addition of a new Vice President of medical affairs and professional education, we recently appointed a new Vice President of Global Marketing to bolster our efforts to drive awareness of the platform among surgeons and hospital administrators.

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

Shameze Rampertab

Thanks, Anthony. Turning to the third quarter, for the three months ended September 30, 2022, the company reported revenue of \$2.6 million as compared to revenue of \$2.6 million in the three months ended September 30, 2021. Revenue in the third quarter of 2022 included \$1.2 million in system revenue, \$0.3 million in lease revenue, \$0.8 million in instruments and accessories, and \$0.3 million in services.

For the three months ended September 30, 2022, total operating expenses were \$17.2 million as compared to \$16.7 million in the three months ended September 30, 2021.

For the three months ended September 30, 2022, net loss attributable to common stockholders was \$18.9 million or \$0.08 per share as compared to net loss attributable to common stockholders of \$16.1 million or \$0.07 per share in the three months ended September 30, 2021.

For the three months ended September 30, 2022, the adjusted net loss attributable to common stockholders was \$16.9 million or \$0.07 per share as compared to an adjusted net loss of \$14.3 million or \$0.06 per share in the three months ended September 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, and employee retention tax credit, 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 and is posted on our website.

Turning to the balance sheet, the company had cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of approximately \$88.3 million and working capital of \$93.7 million as of September 30, 2022.

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

Anthony Fernando

Thanks, Shameze.

I would now like to provide an update on progress we have made towards our key focus areas for 2022.

Starting with market development. As we have mentioned in the past, 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 third quarter, we had three new publications bringing the total for the year to 13.

These publications highlighted Senhance's capabilities, workflow-effectiveness, and cost-effectiveness across multiple procedure specialties, as well as the unique clinical benefits of Senhance's haptic feedback.

This growing list of publications is vital for supporting the breadth of research that proves the benefits of the Senhance system with real world data. As a reminder, all of these clinical publications can be found under the clinical resources section of our website.

As we continue to develop our list of clinical publications, we have also continued to leverage our growing real-world clinical data through our clinical registry. Our TRUST registry, which we believe is the industry's largest robotic-assisted laparoscopic registry, continues to grow in size and scale, with over 2,000 patients enrolled to date. The registered patients consist of approximately 67% general surgery, including abdominal and thoracic, 15% GYN, and 18% urology procedures. We remain focused on leveraging the data accumulated to facilitate studies and publications which highlight the real-world benefits of Senhance.

In October, a TRUST Registry Investigator Meeting was held in Amsterdam, and was hosted by Professor Willeke of St. Marien Hospital in Siegen, Germany. The meeting was an opportunity for the key investigators who are participating in the registry to come together with the goal of collaborating on upcoming opportunities to share the incredible data that has been collected thus far. We are very excited about the data our registry is accumulating, and the opportunities this research provides for validating the importance of the Senhance system and ultimately helping to improve surgical outcomes and efficiencies.

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.

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, this quarter, we had four new program initiations, with one additional initiation since the end of the third quarter.

Evangelical Hospital Goettingen-Weende of Göttingen, Germany completed their installation of the Senhance system, and became the seventh Senhance hospital in Germany. This system has been placed within their general surgery department at the hospital. Saiseikai Shiga Hospital in Ritto, Japan has leased a Senhance system, similarly to be used in laparoscopic general surgery. Most recently, the Clinic for General and Visceral Surgery at the St. Bernhard Hospital in Kamp-Lintfort, Germany initiated their Senhance program and our fourth system in the quarter, was sold to our distribution partner, and placed in a hospital in the CIS region. All of these sites are great opportunities for the Senhance system to deliver benefit to their practice and patients.

In November, we had another German placement, bringing the total Senhance programs initiated to nine in this region. This system will be installed at the Dr. von Hauner Children's Hospital at the Ludwig Maximilians University of Munich, located in Munich, Germany. We are very excited to announce this will be the first ever Senhance installation to be completely dedicated to pediatric procedures.

As the Senhance system is the only robotic-assisted surgical system in the world to provide fully reusable 3-millimeter instruments as well as haptic feedback, it is well positioned to help surgeons deliver better, more predictable outcomes on smaller patients. Senhance's digital fulcrum and tremor filtration can minimize traumatic forces exerted by instruments on the abdominal wall. The combination of these two features creates an optimal micro laparoscopic working environment for the surgeon. Its advanced minimally-invasive instrumentation, innovative safety features, and novel clinical intelligence capabilities helps reduce invasiveness and surgical variability, especially in complex pediatric surgery.

With these new program initiations, our year-to-date total is now at five. Japan and Germany continue to expand into very important geographic areas for our growing installed base, and are the second and third largest markets for medical devices in the world. This validates our assumption that the more surgeons in an area have in-person, hands-on access to a Senhance system, the greater the adoption becomes. We are excited to see these two thriving areas continue to expand going forward.

Looking ahead, we continue to expect 8-10 new system initiations for the year. As we head into the final quarter of 2022, we remain confident in our ability to drive the adoption of Senhance on a global scale over the long term based on the quality of our customer pipeline.

Now, turning to procedure volumes. We have continued to see very strong procedure volume trends, with over 1,900 Senhance procedures completed as of September 30th across multiple geographies and specialties, with a 27% increase over 2021. In the quarter, procedure volumes increased 18% year over year.

We remain focused on increasing procedure volumes across a wide variety of surgical specialties. When a case is performed with a Senhance system, we have the ability to collect system data and surgical video. As we continue to accumulate a rich digital library of surgical data, we have the ability to generate powerful clinical insights that will enable Performance-Guided Surgery to help surgeons reduce surgical variability and drive consistently superior outcomes in their procedures.

In the United States, we saw accelerated utilization trends and adoption rates as hospitals appear to have returned to more normalized volumes and a typical operating environment. In addition, we continue to see an increasing number of surgeons using Senhance. Importantly, during the quarter we saw multiple existing hospital customers expand from a single surgeon user, to multiple surgeon users, which points to the clinical value that both the surgeons and hospitals are seeing from Senhance.

Despite some slowdowns due to European holiday seasonality, we continue to see expansion of the installed base driving high procedure volumes and expect to see more installations in Europe in the coming quarters.

In Asia, we have seen some COVID related headwinds resulting in a slower rebound in procedure volumes than in other geographies. We expect to see these sites recover now as the COVID circumstances appear to be improving, and we continue to see more hospitals in the region seek to install new Senhance systems.

We have also seen some of our systems reach significant milestones this quarter. Dr. Narimantas Samalavičius and his team at Klaipeda University Hospital, in Lithuania, completed their 750th case with the Senhance Surgical System.

Turning to our portfolio expansion efforts. We are excited to continue to build upon our recent accomplishments and achieve additional regulatory milestones that will further develop the Senhance system and broaden its applicability.

We have recently submitted 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, and we look forward to providing you updates regarding a potential clearance in 2023. We believe the Senhance system's combination of 3mm instrumentation and advanced safety features including haptic feedback make it uniquely optimized for pediatric patients who to this point have not been able to benefit from the capabilities of robotics with 5mm and 3mm instruments.

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 by the end of the year.

Importantly, this filing through the new European MDR pathway included a review of the entire platform. If successful, the Senhance platform will be one of the early robotic surgical systems to be approved through the new, more rigorous MDR process, a significant achievement which speaks to the quality of the platform and our organization's expertise in regulatory processes across the globe.

We continue to expect the commercial launch of 5mm Articulating Instruments in the final months of this year.

We are happy to announce that we recently received Japanese PMDA approval for Thoracic laparoscopic procedures with Senhance. In 2019, the Senhance Surgical System was first approved by the Ministry of Health, Labor and Welfare, or MHLW, for use in laparoscopy for general surgery, gynecology and urology.

Now, with additional 19 thoracic procedures, the system is approved for a total of 126 procedures in Japan with reimbursement. This is a meaningful approval as it expands our already wide indications, including general surgery, gynecology, and urology in adults and pediatrics. This approval for the use of Senhance in Japan to mirror that of our CE Mark indications, makes Senhance more broadly applicable to hospitals, surgeons, and patients in that region. We are very excited for this expansion of the Senhance system, and seeing surgeons and hospitals benefit from the breadth of Senhance's applicability.

We are very pleased with the progress we have made this past quarter towards our goals, and further advancing the development of Performance-Guided Surgery and its advanced intelligent capabilities. As we head into the final quarter of the year, we remain committed to increasing system utilization and growing our installed base even further. I am very proud of the work our Asensus team has done so far this year, and would like to take a moment to thank them for their consistent dedication to innovation, and ultimately driving safer and more reliable outcomes for surgeons, hospitals, and patients.

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

Q&A

Operator

Our first question comes from Ross Osborn from Cantor Fitzgerald. Please go ahead.

Question – Ross Osborn

Hi, congrats on the progress meets in the quarter. Starting off, you installed four systems during the third quarter and you've announced one post quarter. You need three more to hit the bottom end of your guidance. What level of comfort do you have in hitting your target, or stated otherwise, how far along are you in conversations with hospitals to achieve your reiterated guidance?

Response – Anthony Fernando

Yeah Ross, I think with the question, as we've stated before, the pipeline has been developing over a relatively long period of time, and we do have the pipeline to hit the guidance numbers. I think we are in relatively mature stages of conversations, and it's more about timing of when. due to various reasons some that are local to the hospital, where they have certain criteria and timing, and others are financial related, but I believe that the pipeline is very robust, and we hope to hit the guidance between the coming 1.5 months as we close out the year.

Question – Ross Osborn

Sounds great. Then, switching to articulating instrument. Can you help us quantify what the transition from pilot to full commercial launch entails? Just curious to hear what that acceleration looks like.

Response – Anthony Fernando

It's making the instruments available and the systems compatible with those articulated instruments. We have to go through a certain upgrade pathway for the system and also make sure that the hospitals understand the use of the new instrumentation. We are in that transition process now of making sure that the instruments are compatible with the systems and getting more sites up and running. I think very soon before the end of this year, when we talked about the upcoming full commercial launch where we will start to see a ramp up of clinical usage of these systems starting in the U.S. initially and then moving to Europe once we get our final approval of the system changes in Europe. I think we're getting very close to seeing that ramp up, and once we do launch, the customer has the choice of saying, okay, what kind of instruments do they want to use, do they want to use the straight instrument or do they want to use the articulated instrument? But, we should be ready with sites that are up and running and make compatible to start using these instruments here in the coming weeks and months.

Question – Ross Osborn

Okay perfect. Then last one for me. You touched on this in your prepared remarks, but it is an important part of the story. Would you be able to provide a little bit more color on your clinical data development and publication efforts during the quarter and what we can expect to see going forward? Maybe, key takeaways from the three published studies?

Response – Anthony Fernando

Yes. There are good takeaways, Ross, especially when you have a sizeable registry and actively engaged investigators. There's a whole slew of data, so they are looking at this data to say what are we seeing, what trends are we seeing, and what more do we need to focus on. And the areas that you can see is the efficiency track where they are looking at how fast they can get the case times to be equal or better than laparoscopy, and we have seen some of that come to play. Also, another piece is looking at the cost, saying how close in terms of cost are we in comparing laparoscopy and Senhance. Then, also looking at the clinical outcomes. The clinical outcomes part, I would say that work stream is just beginning because we need a good volume of data in order to start comparing Senhance clinical outcomes versus laparoscopy in this case. It's coming along. I think there's two tracks of this, one, leveraging the data in the Trust registry, and the other, investigator led work that's ongoing on a pretty continuous basis to further investigate benefits and opportunities for further improving the clinical outcome. It's a very big part for us and for us, the goal really is to use real world evidence now that we have 40 plus systems installed, trying to work with high volume sites to be able to generate data and produce real world evidence that we can use for getting other sites interested and leveraging the benefits of the Senhance system.

Response – Ross Osborn

Great. Thank you for taking my questions and congrats again on the progress.

Response – Anthony Fernando

Thank you, Ross.

Operator

The next question comes from Jennifer Sadeghi from H.C. Wainwright. Please go ahead.

Question – Jennifer Sadeghi

Hi, this is Jennifer Sadeghi from H.C. Wainwright. Thank you for taking your questions and congratulations on your recent announcement of the submission of the 510(k) for pediatric clearance in the U.S., as well the ninth hospital in Germany poised to be able to utilize the Senhance system. I understand this program will be the first dedicated to the utilization of Senhance in an exclusively pediatric population. I was wondering if you could give some additional color on this new indication, maybe on some of the timelines and expectations going forward? Any details would be appreciated.

Response – Anthony Fernando

Hi Jennifer. Thanks for the question. As you know, we've had pediatric approval in Europe, and we currently are in a few hospitals performing pediatric cases. What we recently announced was a very unique hospital because they acquired the system and partnered with us to primarily focus on pediatric cases. That's really exciting for us to see that, and it is the first time that we are seeing one hospital that just engaged with us just to focus on pediatrics. With respect to the FDA submission, so we submitted this about a month ago and the timelines are somewhat variable. I couldn't give you an exact timeline, but I would think that in the first half of 2023 is what we would expect to hear back. But it's hard for me to give you a very specific timeline, but I would say in the first half is a reasonable assumption for seeking clearance.

Response – Jennifer Sadeghi

Great. Thank you so much for the additional color and I will put myself back on the queue.

Response – Anthony Fernando

Thank you, Jennifer.

Operator

There are no more questions in the queue. This concludes our question and answer session. I would like to turn the conference back over to Anthony Fernando, Asensus Surgical's President and CEO, 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 for joining.

Operator

Conference has now concluded. Thank you for attending today's presentation. You may now disconnect.