
**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**

**February 28, 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:

<u>Title of each class</u>	<u>Trading symbol</u>	<u>Name of each exchange on which registered</u>
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 February 28, 2022, Asensus Surgical, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2021. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on February 28, 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 fourth quarter and full year ended December 31, 2021. The Company had issued a press release on February 22, 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 February 28, 2022
99.2	February 28, 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: March 2, 2022

ASENSUS SURGICAL, INC.

/s/ Shameze Rampertab

Shameze Rampertab

Executive Vice President and Chief Financial Officer

Asensus Surgical, Inc. Reports Operating and Financial Results for the Fourth Quarter and Full Year 2021

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--February 28, 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 fourth quarter and full year 2021.

Fourth Quarter Highlights

- Over 500 procedures were performed globally during the quarter, representing growth of 30% over the fourth quarter 2020
- Six Senhance Surgical Programs were initiated during the quarter
- Fourth quarter revenue of \$2.5 million

Year-End Highlights

- Over 2,100 procedures performed globally, representing 44% growth compared to 2020
- 10 Senhance Surgical Programs were initiated
- Received four regulatory clearances:
 - FDA 510(k) clearance for expansion of machine vision capabilities for the Intelligent Surgical Unit™ (ISU™)
 - FDA 510(k) clearance for articulating instruments
 - Expanded FDA 510(k) clearance for general surgery indication
 - CE Mark approval for the ISU
- Full year 2021 revenue of \$8.2 million, representing growth of 159% over the prior year
- The Company had cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of approximately \$135.8 million at December 31, 2021

"Despite the macro headwinds that persisted throughout the year, we were able to significantly grow our active installed base, drive the highest procedure volumes in Senhance's commercial history, and make great strides with the development and expansion of our portfolio. We continue to believe that there is a critical need to elevate the way surgery is performed globally by bringing clinical intelligence to the OR, and the growth we achieved in 2021 validates the clinical utility Senhance delivers to surgeons and hospitals," said Anthony Fernando, Asensus Surgical President and CEO. "As we look towards 2022, we expect to continue to drive the global adoption of Senhance through our market development and portfolio expansion efforts while at the same time focusing on the ongoing development of the platform's innovative digital capabilities to deliver on the promise of Performance-Guided Surgery."

Upcoming 2022 Milestones

For the full year 2022, the Company expects to initiate 10 - 12 new Senhance Surgical Systems.

During the second half of 2022, the Company expects to achieve the following commercial and regulatory milestones:

- Full scale commercialization of articulating instruments globally
- File a 510(k) for FDA clearance of Senhance for pediatric indication
- Receive CE Mark for expanded machine vision capabilities for the ISU

Market Development

2021 Senhance Program Initiations

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

During the fourth quarter of 2021, the Company initiated six programs, one in the US, three in EMEA, and two in Asia.

Procedure Volumes

In 2021, surgeons performed over 2,100 procedures utilizing the Senhance System, representing a 44% increase over the previous year. Compared to 2020, US-based procedure volumes increased 95%, EMEA increased 42%, and Asia increased 18%. These procedures included general surgery, gynecology, urology, bariatric, and colorectal surgical cases.

Clinical Validation

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

Portfolio Expansion

Performance-Guided Surgery (PGS)

As an organization, the Company's goal is to revolutionize the way surgery is performed. The fact that there are complications with one in five surgeries is unacceptable, and, more importantly, avoidable. The Company is helping to unlock clinical intelligence and capabilities to reduce surgical variability and the complications associated with it. PGS builds upon the foundation of Digital Laparoscopy by adding machine vision, augmented intelligence, and deep learning capabilities. These capabilities shift the promise of consistently superior surgery into practice regardless of a surgeon's experience or skill level by guiding improved decision making, enriching collaboration, and enhancing predictability.

Expanded Global ISU Machine Vision Capabilities

In September 2021, the Company announced that it had received 510(k) clearance from the FDA for an expansion of machine vision capabilities on the previously cleared ISU. The ISU is utilized with the Senhance System which enables Digital Laparoscopy. The initial features of the ISU enable machine vision-driven control of the camera for a surgeon by responding to commands and recognizing certain objects and locations in the surgical field, and allow a surgeon to change the visualized field of view using the movement of their instruments. The newest ISU features expanded upon these capabilities and introduced more advanced features including: real-time 3D measurement, digital tagging, image enhancement, and enhanced camera control based on real-time data from anatomical structures while performing surgery. This is the first time any of these features will be clinically available in soft-tissue abdominal surgery.

Articulating Instrument Clearance

In July 2021, the Company announced that it had received 510(k) clearance for 5mm articulating instruments, which offer better access to difficult-to-reach areas of the anatomy.

General Surgery Indication Expansion

In March 2021, the Company announced that it had received an additional FDA clearance for the Senhance Surgical System which allows for indication expansion in general surgery in the US.

CE Mark for Intelligent Surgical Unit

In January 2021, the Company announced that it had received CE Mark approval for the ISU that enables machine vision capabilities on the Senhance System. This approval will provide Senhance Digital Laparoscopy programs in Europe access to this technology.

Fourth Quarter Financial Results

For the three months ended December 31, 2021, the Company reported revenue of \$2.5 million as compared to revenue of \$1.1 million in the three months ended December 31, 2020. Revenue in the fourth quarter of 2021 included \$1.7 million in system revenue, \$0.5 million in instruments and accessories, and \$0.3 million in services.

For the three months ended December 31, 2021, total operating expenses were \$15.9 million, as compared to \$14.2 million, in the three months ended December 31, 2020.

For the three months ended December 31, 2021, net loss was \$15.9 million, or \$0.07 per share, as compared to a net loss of \$13.8 million, or \$0.13 per share, in the three months ended December 31, 2020.

Adjusted net loss is a non-GAAP financial measure. See the reconciliation of GAAP to Non-GAAP Measures below. For the three months ended December 31, 2021, the adjusted net loss was \$15.7 million, or \$0.07 per share, as compared to an adjusted net loss of \$9.7 million, or \$0.9 per share in the three months ended December 31, 2020, after adjusting for the following charges: amortization of intangible assets, change in fair value of contingent consideration, change in fair value of warrant liabilities, and restructuring and other charges, 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 \$135.8 million as of December 31, 2021.

Conference Call

Asensus Surgical, Inc. will host a conference call on Monday, February 28, 2022, at 4:30 PM ET to discuss its fourth quarter and fiscal year 2021 operating and financial results. To listen to the conference call on your telephone, please dial 1-855-327-6837 for domestic callers and 1-631-891-4304 for international callers, and reference conference ID 10017809 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. 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.

Forward-Looking Statements

This press release includes statements relating to the Senhance System and our 2021 results. These statements and other statements regarding our future plans and goals constitute "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control and which may cause results to differ materially from expectations and include whether we will be able to continue to progress our strategic plan in 2022, including achieving our commercial and regulatory milestones; whether the growth we achieved in 2021 validates the clinical utility the Senhance System delivers to surgeons and hospitals; whether we can continue to drive the global adoption of Senhance through our market development and portfolio expansion efforts while at the same time focusing on the ongoing development of the platform's innovative digital capabilities to deliver on the promise of Performance-Guided Surgery; whether we will initiate 10-12 new Senhance Surgical Systems placements in 2022; whether we can continue to increase Senhance System placements and sales; and whether we can continue to add foundational sites and receive regulatory clearances and approvals that we seek. For a discussion of the risks and uncertainties associated with the Company's business, please review our filings with the Securities and Exchange Commission (SEC). You are cautioned not to place undue reliance on these forward-looking statements, which are based on our expectations as of the date of this press release and speak only as of the origination date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
Revenue:				
Product	\$ 2,136	\$ 620	\$ 6,712	\$ 1,612
Service	340	488	1,520	1,563
Total revenue	2,476	1,108	8,232	3,175
Cost of revenue:				
Product	1,457	(99)	7,974	2,254
Service	830	691	3,122	2,912
Total cost of revenue	2,287	592	11,096	5,166
Gross profit (loss)	189	516	(2,864)	(1,991)
Operating Expenses:				
Research and development	6,575	3,752	19,348	16,621
Sales and marketing	3,229	2,774	13,395	13,064
General and administrative	5,926	3,712	19,323	14,137
Amortization of intangible assets	2,721	2,837	11,254	10,801
Change in fair value of contingent consideration	(2,578)	1,154	(1,565)	2,924
Restructuring and other charges	—	(8)	—	851
Total Operating Expenses	15,873	14,221	61,755	58,398
Operating Loss	(15,684)	(13,705)	(64,619)	(60,389)
Other Income (Expense):				
Gain on extinguishment of debt	—	—	2,847	—
Change in fair value of warrant liabilities	—	(130)	(1,981)	(336)
Interest income	337	2	590	35
Interest expense	(293)	(19)	(370)	(19)
Employee retention tax credit	—	—	1,311	—
Other expense, net	(12)	(67)	(15)	(119)
Total Other Income (Expense), net	32	(214)	2,382	(439)
Loss before income taxes	(15,652)	(13,919)	(62,237)	(60,828)
Income tax (expense) benefit	(229)	130	(225)	1,516
Net loss	(15,881)	(13,789)	(62,462)	(59,312)
Deemed dividend related to beneficial conversion feature of preferred stock	—	—	—	(412)
Deemed dividend related to conversion of preferred stock into common stock	—	—	—	(299)
Net loss attributable to common stockholders	(15,881)	(13,789)	(62,462)	(60,023)
Comprehensive loss:				
Net loss	(15,881)	(13,789)	(62,462)	(59,312)
Foreign currency translation (loss) gain	(588)	2,147	(2,985)	4,338
Unrealized loss on available-for-sale investments	(194)	—	(247)	—
Comprehensive loss	\$ (16,663)	\$ (11,642)	\$ (65,694)	\$ (54,974)
Net loss per common share attributable to common stockholders – basic and diluted	\$ (0.07)	\$ (0.13)	\$ (0.28)	\$ (0.85)
Weighted average number of shares used in computing net loss per common share – basic and diluted	234,851	103,783	226,960	70,809

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

	<u>December 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 18,129	\$ 16,363
Short-term investments, available-for-sale	80,262	—
Accounts receivable, net	749	1,115
Inventories	8,634	10,034
Prepaid expenses	3,255	3,535
Employee retention tax credit receivable	1,311	—
Other current assets	957	2,966
Total Current Assets	<u>113,297</u>	<u>34,013</u>
Restricted cash	1,154	1,166
Long-term investments, available-for-sale	37,435	—
Inventories, net of current portion	7,074	8,813
Property and equipment, net	10,971	10,342
Intellectual property, net	9,892	22,267
Net deferred tax assets	288	307
Operating lease right-of-use assets, net	5,348	1,164
Other long-term assets	1,014	186
Total Assets	<u>\$ 186,473</u>	<u>\$ 78,258</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 3,448	\$ 1,965
Accrued expenses	5,176	5,615
Operating lease liabilities – current portion	683	686
Deferred revenue	543	789
Notes payable – current portion, net of debt discount	—	1,228
Total Current Liabilities	<u>9,850</u>	<u>10,283</u>
Long Term Liabilities:		
Contingent consideration	2,371	3,936
Noncurrent operating lease liabilities	5,006	628
Notes payable, less current portion	—	1,587
Warrant liabilities	—	255
Total Liabilities	<u>17,227</u>	<u>16,689</u>
Commitments and Contingencies		
Stockholders' Equity		
Common stock \$0.001 par value, 750,000,000 shares authorized at December 31, 2021 and 2020; 235,218,552 and 116,231,072 shares issued and outstanding at December 31, 2021 and 2020, respectively	235	116
Preferred stock, \$0.01 par value, 25,000,000 shares authorized, no shares issued and outstanding at December 31, 2021 and 2020, respectively	—	—
Additional paid-in capital	954,649	781,397
Accumulated deficit	(785,374)	(722,912)
Accumulated other comprehensive income	(264)	2,968
Total Stockholders' Equity	<u>169,246</u>	<u>61,569</u>
Total Liabilities and Stockholders' Equity	<u>\$ 186,473</u>	<u>\$ 78,258</u>

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

	Years Ended December 31,	
	2021	2020
Operating Activities:		
Net loss	\$ (62,462)	\$ (59,312)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	2,857	2,898
Amortization of intangible assets	11,254	10,801
Amortization of discounts and premiums on investments, net	409	—
Stock-based compensation	9,429	7,911
Gain on extinguishment of debt	(2,847)	—
Deferred tax expense (benefit)	225	(1,516)
Bad debt expense	144	—
Change in inventory reserves	(492)	(3,034)
Change in fair value of warrant liabilities	1,981	336
Change in fair value of contingent consideration	(1,565)	2,924
Changes in operating assets and liabilities:		
Accounts receivable	174	(447)
Inventories	(611)	(4,164)
Operating lease right-of-use assets	(4,254)	1,106
Prepaid expenses	146	824
Employee retention tax credit receivable	(1,311)	—
Other current and long-term assets	902	366
Accounts payable	1,614	(1,758)
Accrued expenses	(475)	(2,219)
Deferred revenue	(229)	(105)
Operating lease liabilities	4,452	(1,203)
Other long-term liabilities	—	(83)
Net cash and cash equivalents used in operating activities	<u>(40,659)</u>	<u>(46,675)</u>
Investing Activities:		
Purchase of available-for-sale investments	(122,330)	—
Proceeds from maturities of available-for-sale investments	4,030	—
Purchase of property and equipment	(1,368)	(3)
Net cash and cash equivalents used in investing activities	<u>(119,668)</u>	<u>(3)</u>
Financing Activities:		
Proceeds from issuance of common stock, preferred stock and warrants under 2020 financing, net of issuance costs	—	13,478
Proceeds from issuance of common stock, net of issuance costs	131,929	33,847
Proceeds from notes payable, net of issuance costs	—	2,815
Taxes paid related to net share settlement of vesting of restricted stock units	(1,063)	(36)
Payment of contingent consideration	—	(74)
Proceeds from exercise of stock options and warrants	30,839	3,340
Net cash and cash equivalents provided by financing activities	<u>161,705</u>	<u>53,370</u>
Effect of exchange rate changes on cash and cash equivalents	376	270
Net increase in cash, cash equivalents and restricted cash	1,754	6,962
Cash, cash equivalents and restricted cash, beginning of period	17,529	10,567
Cash, cash equivalents and restricted cash, end of period	<u>\$ 19,283</u>	<u>\$ 17,529</u>

	Years Ended	
	December 31,	
	2021	2020
Supplemental Disclosure for Cash Flow Information:		
Cash paid for taxes	\$ 170	\$ 82
Supplemental Schedule of Non-cash Investing and Financing Activities:		
Transfer of inventories to property and equipment	\$ 3,244	\$ 8,113
Right-of-use assets recognized related to new lease obligations	\$ 5,119	\$ —
Reclass of warrant liability to common stock and additional paid-in-capital	\$ 2,236	\$ —
Exchange of common stock for Series B Warrants	\$ —	\$ 2,470
Transfer of in-process research and development to intellectual property	\$ —	\$ 2,425
Deemed dividend related to beneficial conversion feature of preferred stock	\$ —	\$ 412
Deemed dividend related to conversion of preferred stock into common stock	\$ —	\$ 299
Conversion of preferred stock to common stock	\$ —	\$ 79

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 December 31,		Years Ended December 31,	
	2021	2020	2021	2020
Net loss attributable to common stockholders (GAAP)	\$ (15,881)	\$ (13,789)	\$ (62,462)	\$ (60,023)
Adjustments				
Amortization of intangible assets	2,721	2,837	11,254	10,801
Change in fair value of contingent consideration	(2,578)	1,154	(1,565)	2,924
Change in fair value of warrant liabilities	—	130	1,981	336
Restructuring and other charges	—	(8)	—	851
Gain on extinguishment of debt	—	—	(2,847)	—
Employee retention tax credit	—	—	(1,311)	—
Deemed dividend related to beneficial conversion feature of preferred stock	—	—	—	412
Deemed dividend related to conversion of preferred stock into common stock	—	—	—	299
Adjusted net loss attributable to common stockholders (Non-GAAP)	<u>\$ (15,738)</u>	<u>\$ (9,676)</u>	<u>\$ (54,950)</u>	<u>\$ (44,400)</u>

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
Net loss per share attributable to common stockholders (GAAP)	\$ (0.07)	\$ (0.13)	\$ (0.28)	\$ (0.85)
Adjustments				
Amortization of intangible assets	0.01	0.03	0.05	0.15
Change in fair value of contingent consideration	(0.01)	0.01	(0.01)	0.04
Change in fair value of warrant liabilities	—	—	0.01	—
Restructuring and other charges	—	—	—	0.01
Gain on extinguishment of debt	—	—	(0.01)	—
Employee retention tax credit	—	—	—	—
Deemed dividend related to beneficial conversion feature of preferred stock	—	—	—	0.01
Deemed dividend related to conversion of preferred stock into common stock	—	—	—	0.01
Adjusted net loss per share attributable to common stockholders (Non-GAAP)	<u>\$ (0.07)</u>	<u>\$ (0.09)</u>	<u>\$ (0.24)</u>	<u>\$ (0.63)</u>

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

- a) Intangible assets that are amortized consist of developed technology and purchased patent rights recorded at cost and amortized over 5 to 10 years.
 - b) Contingent consideration in connection with the acquisition of the Senhance System in 2015 is recorded as a liability and is the estimate of the fair value of potential milestone payments related to business acquisitions. Contingent consideration is measured at fair value using a Monte-Carlo simulation utilizing significant unobservable inputs including the probability of achieving each of the potential milestones, revenue volatility, and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.
 - c) The Company's Series B Warrants are measured at fair value using a simulation model which takes into account, as of the valuation date, factors including the current exercise price, the expected life of the warrant, the current price of the underlying stock, its expected volatility, holding cost and the risk-free interest rate for the term of the warrant. The warrant liability is revalued at each reporting period or upon exercise and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.
 - d) Beginning in the fourth quarter of 2019 and continuing into the first quarter of 2020, we implemented a restructuring plan to reduce operating expenses as we continue the global market development of the Senhance platform. During the first quarter of 2020, the Company continued the restructuring efforts with additional headcount reductions, which resulted in \$0.9 million in severance costs in the year ended December 31, 2020.
 - e) During the second quarter of 2021, the Company received notification from the U.S. Small Business Administration (the "SBA") that the principal amount of its Paycheck Protection Program loan ("PPP loan") of \$2.8 million and related interest had been forgiven. Gain on extinguishment of debt of \$2.8 million was recognized for the year ended December 31, 2021, in the consolidated statement of operations and comprehensive loss.
 - 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 consolidated balance sheet at December 31, 2021.
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g) During the first quarter of 2020, the Company closed an underwritten public offering under which it issued, as part of units and the exercise of an over-allotment option, 25,367,646 Series C Warrants, each to acquire one share of Common Stock at an exercise price of \$0.68 per share, and 25,367,646 Series D Warrants, each to acquire one share of Common Stock at an exercise price of \$0.68 per share. The Company concluded that the Series C Warrants and Series D Warrants are considered equity instruments. The fair value of the Series C and Series D Warrants on the issuance date was determined using a Black-Scholes Merton model. The unit proceeds were then allocated to the Series A preferred stock, Series C Warrants, and Series D Warrants, respectively, based on their relative fair values. As a result, the Company determined that a beneficial conversion feature was created by the difference between the effective conversion price of the Series A preferred stock of \$0.37 and the fair value of the Company's common stock as of the issuance date of \$0.42. The Company therefore recorded a beneficial conversion charge of \$0.4 million as an immediate charge to loss available to common stockholders for the year ended December 31, 2020. Upon conversion of the Series A preferred stock to common stock, an additional deemed dividend of \$0.3 million was recorded as an immediate charge to loss available to common stockholders for the year ended December 31, 2020.

INVESTOR CONTACT:

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MEDIA CONTACT:

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CG Life
kschaeffer@cglife.com

C O R P O R A T E P A R T I C I P A N T S

Mark Klausner, *Westwicke Partners*

Anthony Fernando, *President and Chief Executive Officer*

Shameze Rampertab, *Chief Financial Officer*

C O N F E R E N C E C A L L P A R T I C I P A N T S

Swayampakula Ramakanth, *H.C. Wainwright & Co.*

Ross Osborn, *Cantor Fitzgerald & Co.*

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

Operator

Welcome to the Asensus Surgical, Inc. Fourth Quarter and Fiscal Year 2021 Financial and Operating Results Conference Call.

The conference is being recorded.

I would now like to turn the conference over to Mark Klausner from Westwicke. Please go ahead.

Mark Klausner

Good afternoon, everyone, and thank you for joining us for the Asensus Surgical Fourth Quarter and Full Year 2021 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 business, I encourage you to review the Company's filings with the Securities and Exchange Commission, including the 2021 Form 10-K expected to be filed later today and other filings we make with the SEC.

During this call, we will also present certain non-GAAP financial information related to adjusted net loss attributable to common 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 measures to compare our performance relative to forecast and strategic plans that benchmark our performance externally against competitors and for certain compensation decisions. Reconciliations from U.S. GAAP to non-GAAP results are presented in the tables accompanying our earnings release, which can be found in the Investor Relations section of our website.

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

Anthony Fernando

Thanks, Mark.

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 priorities for 2022 before turning to Q&A.

While 2021 continued to be challenging with the macro headwinds associated with COVID, including hospital restrictions, staffing shortages and supply chain issues, we accomplished a tremendous amount throughout the year. We expanded our installed base by approximately 33%, drove a 44% increase in procedure volumes, made great strides in the development of the Senhance Surgical System and increased revenues by approximately 150% compared to 2020.

We finished the year on a high note. During the fourth quarter, we had six new Senhance programs initiated and saw procedure volumes increase by approximately 30% versus the prior year fourth quarter.

Along those lines, I would like to provide a more detailed update on recent performance and the progress we have made on our key focus areas over this past year. As a reminder, these are, first, the continued market development for the Senhance System; and second, expanding our portfolio and continuing the technological advancement of Senhance.

Starting with our market development efforts. It is crucial to our strategy that we continue to raise awareness of Senhance and follow up with health economic relevance data to support its adoption. As we mentioned in the past, we expected to have a number of key clinical papers published throughout 2021. During the year, we had 21 peer-reviewed manuscripts published, the most significant of which was in April. This publication in the *International Journal of Medical Robotics and Computer Assisted Surgery* was the first to compare health economic outcomes of Senhance versus another robotic system as well as traditional laparoscopy. The study indicated that for certain gynecologic procedures, the Senhance System per procedure cost were less than half of the cost of comparable robotic procedures and in line with traditional laparoscopically assisted vaginal hysterectomy case cost.

The study also showed case times between Senhance and the other robotic system were comparable. We continue to believe that the development of data related to the variety of benefits offered by Senhance allows for greater adoption by surgeons in the future.

The next segment of our market development efforts is the growth of our global installed base and the acceleration of procedure volumes. During the fourth quarter, six Senhance programs were initiated, bringing the total to 10 programs for 2021, which was in line with our guidance for the year.

Now turning to procedure volumes. In 2021, over 2,100 procedures were performed, representing the highest annual procedure volume total since the inception of Senhance, which points to the continued momentum we have generated. Importantly, we saw growth across each of our key geographies during the year, with the U.S. growing 95%, the EMEA region growing 42% and Asia growing 18% compared to 2020.

During the fourth quarter, over 500 procedures were performed using Senhance, representing an increase of approximately 30% over the previous year quarter. In addition to the continued growth in utilization, we are very encouraged by the continued broadening of the types of procedures being performed with Senhance. During the year, general surgery made up 40% of case volumes, with gynecology, urology, bariatric and colorectal procedures making up the remaining 60%. This is important as it points to the fact that Senhance continues to be utilized across the most common high-volume specialties within soft tissue abdominal surgery.

Now turning to our second initiative for the year: the continued portfolio expansion and technological advancement of the Senhance System. We reached two key regulatory milestones as we received 510(k) clearance for the expanded capabilities of the Intelligent Surgical Unit, or ISU, which will allow us to grow its capabilities with the Senhance System, as well as 510(k) clearance for five-millimeter articulating instruments, which will improve the dexterity of our instrument platform, offering better access to difficult-to-reach areas of the anatomy. We also received CE Mark for the initial version of the ISU and expanded the U.S. indications for use of the Senhance System to include general surgery.

Another technological development milestone during 2021 was the launch of Senhance Connect. This is a mobile, in-OR surgeon communication system. With Senhance Connect, up to six clinical and product specialists can remotely interact, observe and communicate with the clinical team in the OR throughout a surgical procedure from anywhere on the globe. It has proven to be a valuable tool that we have quickly been able to roll out over the course of the year, and utilization has continued to grow as more surgeons have interacted with the technology.

We are very proud of what we were able to accomplish in 2021, but also equally as proud of what we have been able to accomplish since late in 2019 when I stepped into the role of CEO and we implemented our market development strategy. Since this time, we have routinely delivered on the milestones we have set out to achieve on a quarterly and yearly basis, and the cumulative results have been very encouraging.

First, we have more than doubled the size of our installed base around the world. Second, we have more than doubled the number of procedures performed. And third, we have rapidly accelerated the volume of clinical data related to Senhance being published, with more than 30% of all publications on the platform happening in the last 12 months.

Given the macro headwinds that have impacted health care systems globally throughout the last two years, our ability to achieve these feats is an even more validating outcome. We have generated real momentum during 2020 and 2021, capped off by a very strong fourth quarter, and we look forward to accelerating that momentum as we move to 2022.

Before turning the call over to Shameze to review our financial performance, I want to thank everybody within the Asensus organization as well as our customers and partners for their extraordinary commitment during the year. Without their dedication and efforts, we would not be where we are today.

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

Shameze Rampertab

Thanks, Anthony.

Turning to the fourth quarter. For the three months ended December 31, 2021, the Company reported revenue of \$2.5 million as compared to revenue of \$1.1 million in the three months ended December 30, 2020. Revenue in the fourth quarter of 2021 included \$1.7 million in system revenue, \$0.5 million in instruments and accessories, and \$0.3 million in services.

For the three months ended December 31, 2021, total operating expenses were \$15.9 million as compared to \$14.2 million in the three months ended December 31, 2020.

For the three months ended December 31, 2021, net loss attributable to common stockholders was \$15.9 million, or \$0.07 per share, as compared to net loss attributable to common stockholders of \$13.8 million, or \$0.13 per share, in the three months ended December 31, 2020.

For the three months ended December 31, 2021, the adjusted net loss attributable to common stockholders was \$15.7 million, or \$0.07 per share, as compared to an adjusted net loss of \$9.7 million, or \$0.09 per share, in the three months ended December 31, 2020.

Adjusted net loss is GAAP net loss adjusted for the following items: amortization of intangible assets, change in fair value of contingent consideration, change in fair value of warrant liabilities and restructuring and other charges, all of which are noncash charges. Adjusted net loss attributable to common stockholders is a non-GAAP financial measure. 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 \$135.8 million, working capital of \$103.4 million as of December 31, 2021.

I'll turn the call back over to Anthony.

Anthony Fernando

Thanks, Shameze.

I would now like to provide our perspectives on 2022.

In 2021, we generated significant momentum and put ourselves in a great position to drive the broad adoption of Senhance. With the addition of a number of key clinical publications that support and validate the benefits of Senhance and the continued technological development of the platform, we were able to drive a material 33% expansion of our installed base and a record Senhance procedure volumes, which grew 44% year over year.

In 2022, we look to drive increased awareness of the platform, have impactful data published that reinforces the clinical benefits Senhance brings to patients, surgeons and hospitals, and expand the capabilities of the platform, all with the goal of facilitating increased adoption and utilization across the globe.

In terms of what to expect from us in the near term, our focus areas for 2022 are the continued market development of the Senhance System and the ongoing development of our portfolio. Starting with market development.

The primary goals of our market development activities are the growth of our global installed base and the acceleration of procedure volumes. In order to drive widespread adoption, we need to inform and educate our potential customer base of the benefits of Senhance and then follow up with clinical data to support our claims in order to further demonstrate the value of the Senhance System. During the year, we will continue to work to publish additional peer-reviewed papers that focus on the clinical, economic and workflow benefits of digital laparoscopy performed with Senhance as compared to traditional laparoscopy and also showcase how digital technology and real-time clinical intelligence can be helpful to surgeons and patients.

A tool we will continue to leverage to increase awareness of Senhance and educate the surgical community on its benefits is participation in major surgical meetings and congresses across our key geographies. During 2022, we hope to have a podium presence at most of the major congresses and industry events in the U.S., Europe and Japan. 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.

Turning to the growth in our installed base. Our goal for 2022 is to add an additional 10 to 12 new system initiations globally. Similar to last year, we continue to focus on the acceleration of global procedure volumes. With the substantially larger installed base and the potential for lessening COVID headwinds during the year, as well as the recent expansion of our portfolio, we believe we can continue to scale the volumes of procedures being performed with Senhance as well as the variety of procedures being performed on a daily basis.

In support of our efforts to drive system utilization, we have continued to invest in surgeon training and medical education. We have implemented a variety of tools to create a holistic training environment focused on getting surgeons up to speed and performing Senhance procedures rapidly. These tools feature 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 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-video digital collaboration solution that enables virtual real-time best practice sharing amongst enhanced surgeon users from the operating room; and global training centers located in the U.S., 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.

As we continue to emphasize the training and onboarding of new surgeon users and focus on increased utilization, we expect to see growth in the number of foundational sites during the year. As a reminder, foundational sites are hospitals that are performing, or are on track to perform, more than 100 procedures on an annualized basis. While we expect COVID to continue to impact case volumes during the first half of 2022, resulting in lumpy utilization within specific hospitals and regions, we are confident the number of foundational sites will expand as we progress through the year.

Turning to the expansion of our product portfolio. We are excited to continue building upon our accomplishments in 2021 as we seek to further develop the Senhance System technologically and broaden its applicability. In 2022, we are focused on a number of key milestones.

First, the full-scale commercial launch of five-millimeter articulating instruments. These instruments are currently in a pilot launch in the U.S., during which we are optimizing the functionality to provide the incremental dexterity that surgeons have been looking for. We expect broader adoption following a full commercial launch globally during the second half of the year.

Our second portfolio initiative is to seek pediatric clearance in the U.S. With the combination of three-millimeter instrumentation with a five-millimeter camera scope and haptic feedback, Senhance is uniquely positioned to bring these benefits of digital laparoscopy to pediatrics in a way that no other platform on the market can by offering a revolutionary and unmatched reduction in invasiveness. We have seen strong early clinical utilization in Europe and demand from the U.S.-based surgeons. In response to this, we decided to pursue a pediatric indication in the U.S. and intend to submit a 510(k) application during the second half of the year.

Lastly, we are seeking to continue to expand the applicability of the ISU globally. Following the U.S. and Japanese regulatory approvals, early feedback from surgeons have been excellent. The newest ISU features introduced more advanced features such as 3D measurement, digital tagging, image enhancement and enhanced camera control based on real-time data from the anatomical structures while performing surgery. We believe we are the first and only system to offer these additional features to surgeons, giving them real-time intraoperative digital tools, which, to this point, they have never had access to. In addition, we are pursuing a CE Mark approval for expanded machine vision capabilities in Europe, which we expect to receive in late 2022.

With the expanded ISU capabilities approved in the U.S. and Japan, and with Europe to follow, we plan to aggressively expand the utilization of the ISU throughout our global installed base as quickly as possible.

The commercial rollout of the ISU is our first significant technological push into what we call Performance-Guided Surgery. As it stands today, Senhance has significant advantages over traditional laparoscopy and other robotic platforms, but we have a more ambitious vision for the level of clinical intelligence Senhance can bring to the health care system.

As an organization, our goal is to revolutionize the way surgery is performed. The fact that there are complications with one in five surgeries is unacceptable and, more importantly, avoidable. As we build out Performance-Guided Surgery, we are helping unlock clinical intelligence and capabilities to reduce surgical variability, and the complications associated with it. We are pioneering a new standard of surgery with digital solutions that can greatly increase predictability and surgical proficiencies regardless of surgeon's skills or experience.

We've made good progress towards developing some of the foundational components of Performance-Guided Surgery, including the ISU and Senhance Connect. During the year, we will continue to take steps towards the development of evolutionary capabilities, leveraging the ISU, which will allow us to deliver on the promise of Performance-Guided Surgery. We believe that the future of surgery is data driven and our ability to collect, analyze and extract insights from data is a foundational component of our strategy.

In order to harness the power of that data, we are investing to further develop our cloud and data management capabilities. In addition, we will leverage our growing installed base while at the same time partnering with hospitals and other institutions to work towards the compilation of a critical mass of surgical data. Using this data and our analytics capabilities, we will be able to build the surgical infrastructure of the future, enabling surgeons and hospitals to deliver better, more consistent outcomes.

As we look ahead to the future, we are very excited about the position we are in to take advantage of the tremendous opportunity that exists to elevate surgery in ways that matter. We generated significant momentum during 2021, and we look forward to building upon that momentum to advance the capabilities of Senhance, making progress towards the promise of Performance-Guided Surgery and increasing the global adoption of Senhance.

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

Operator

The first question comes from Swayampakula Ramakanth with H.C. Wainwright. Please go ahead.

Swayampakula Ramakanth

Thank you. This is RK from H.C. Wainwright. (Multiple speakers). Congratulations. Certainly, you got off '22 at a very high note. I can see that.

As you said, in the fourth quarter, you had like greater than 500 procedures. So coming off of that, with whatever amount of detail you could provide, how is the last 60 days or so looking in terms of procedure volume? And how should we think about '22?

Anthony Fernando

Thanks, RK, for the question.

With respect to cases, I think we are seeing a pretty steady volume, and the goal is obviously to continue to grow significantly during the course of the year. But the unfortunate part, it is hard to be pretty predictable from month to-month or quarter to-quarter in terms of volume, because there's still some level of fluctuation at certain sites, whether it's COVID or other staff shortages, etc.

I think you could expect to see a continued growth in volume in terms of cases. And I would also say that maybe earlier in the year it might be smaller numbers in terms of growth, but hoping to get caught up in the middle to the latter part of the year.

Swayampakula Ramakanth

Perfect. My second question, you're expecting 10 to 12 system initiations during '22 at the same time you are also wanting to file the 510(k) for the pediatric indication. So I'm assuming this does not take into account what you could gain from the pediatric market. So for us to understand the market itself, is there something called a pediatric market in the sense is there a certain number of hospitals that specifically want admission for pediatrics? And what work do you need to do before even you can file the 510(k)?

Anthony Fernando

Sure, RK.

I think, again, it depends on geography. If you look at Europe where we are now, several hospitals have different departments or some institutions that are primarily focused on women's health, and pediatrics is kind of part of that women's health group. And in the U.S., obviously, again, there are some independent pediatrics, but otherwise, it's a different unit or a surgical unit within some hospitals.

There is a need for pediatrics, because not many pediatric cases are done using robotics for several reasons. And then that's the reason that we saw in Europe there was very good interest. Given that we had three-millimeter instruments, couple that with haptic feedback, and then also using a five-millimeter scope; in Europe, surgeons thought that it's going to be a really good solution. And then there were some preliminary publication on that as well. And that kind of got picked up by some of the U.S. surgeons also expressing interest in inquiring about if they could have that solution.

I wouldn't say that there's a very large market in comparison to that population, but there is a relatively significant opportunity there, especially because there's no solution that caters to the pediatric patient population offering some direct-line benefits. We believe that with the instrumentation that we have, haptic feedback, that this will be a very appropriate and suitable solution for that population, and thus be able to be a good solution for them.

We do think there is an opportunity there. In Europe, we're already there. Then in the U.S., we kind of do the same in focusing on either institutions that only do pediatrics, or other hospitals that also have a pediatric department.

Swayampakula Ramakanth

Perfect. Thank you, thank you very much for taking the question.

Anthony Fernando

Thanks, RK.

Operator

The next question comes from Ross Osborn with Cantor Fitzgerald. Please go ahead.

Ross Osborn

Hi. Good afternoon. Thanks for taking my questions. Congratulations on a productive 2021.

Starting off, would you guys maybe just discuss the financial impact from Russia's invasion of Ukraine, just given your presence in both countries? And then as a follow-up, how do you see outright sales for sale and leasebacks evolving this year given what is hopefully going to be a more normal operating environment?

Anthony Fernando

Hi, Ross. Thanks for the question.

Starting with Russia and Ukraine, I think, yes, we do have a presence there. And again, the impact, obviously there's going to be an impact. But to what extent, it's not being quite determined yet. So we'll have to wait and see how everything pans out. But those were two focus areas of last year going into that area. That's one.

What was the second part of your question, if you don't mind repeating, please?

Ross Osborn

Just how you see the sale of your systems in terms of outright sales versus the sale and leaseback strategy. Do you see it returning to more outright sales given hospital budgets, hopefully, coming back this year as COVID headwinds subside?

Anthony Fernando

Yes. Ross, I think we would see both. I think in some of the distributor countries, and even some of the Eastern European countries, I think direct sale is something we have seen, and I think we'll continue to see that. And in our direct markets, obviously, a lease and then a lease conversion is something that we'll also see.

I think even in the Western European and other direct markets, I think there are some preferences in some countries to prefer to buy versus a lease. So I think we're going to see a mix, but we're really focusing on the leasing opportunity. It's a flexibility that we are trying to bring to offer in order to move through the capital process faster and more effectively compared to going through different committees, etc., to trying to get Capex approved versus trying to go through the lease process in order to begin the program. And then while the program is ongoing and they see the value, then it becomes even easier.

I think we're going to see a mix. And I would say that that might be slightly changed to having slightly more sales, direct sales compared to leases, but I wouldn't be surprised if it just continues to be leases and then convert as well.

Ross Osborn

Okay. Great. That makes sense. And then just lastly for me. I noticed supply chains, you had a bit of headwinds you started seeing in the fourth quarter. Given we're two months in 2022, have you seen the supply chains improve at all?

Anthony Fernando

Actually, we've not seen improvement, I would say. I mean, we've had some challenges on the semiconductor front and also some challenges on the plastics, medical grade plastics front as well. So those continue, but at the same time, we found alternate ways to move through them in trying to get us some more time. So we've not seen a very clear improvement, I would say. We're still kind of working through those challenges, but kind of found alternate means to uproot it.

Ross Osborn

Got it. Thanks for taking my questions. Congrats again on 2021.

Anthony Fernando

Thank you, Ross.

Operator

That concludes our question-and-answer session for today. I will now turn the call back to Anthony Fernando for 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.

Operator

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