



Asensus Surgical, Inc. Reports Operating and Financial Results for the Fourth Quarter and Full Year 2022

March 2, 2023

RESEARCH TRIANGLE PARK, N.C., March 02, 2023 (GLOBE NEWSWIRE) -- 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™ (PGS), today announced its operating and financial results for the fourth quarter and full year 2022.

As the Company hosted an Investor Day on Tuesday, February 21, 2023 during which an in-depth review of the business was provided, the Company will not be hosting an earnings conference call in conjunction with this earnings release.

Recent Highlights

- In February 2023, unveiled plans for the LUNA™ Surgical System, its next generation digital surgery platform
- In February 2023, announced the intention to collaborate with KARL STORZ on developing next-generation instrumentation and an agreement in which KARL STORZ intends to sell the Company's Intelligent Surgical Unit™ (ISU™) as a standalone device
- In February 2023, announced a multi-year collaboration with Google Cloud to further expand the capabilities of the Company's Performance-Guided Surgery framework enabled through the ISU
- In January 2023, received CE Mark for expanded machine vision capabilities within the ISU, including 3D measurement, digital tagging, image enhancement, and enhanced camera control

Fourth Quarter Highlights

In line with the preliminary results released on January 9, 2023, the Company announced:

- Over 840 surgical procedures were performed globally during the quarter, representing growth of over 29% compared to the fourth quarter 2021
- Five Senhance® Surgical Programs were initiated during the quarter, including two in Germany, two in Japan, and one in the CIS region
- Fourth quarter revenue of \$2.5 million

Full Year Highlights

- Over 3,100 surgical procedures were performed globally, representing growth of over 29% compared to 2021
- In 2022, nine Senhance Surgical Programs were initiated, in-line with guidance of 8-10 systems
- Full year 2022 revenue of \$7.1 million
- The Company had cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of approximately \$74.4 million at December 31, 2022

"2022 was an exciting year for the company. We continued to see strong adoption and utilization trends as more surgeons across the globe were performing procedures using Senhance, and we made significant progress in the development and launch of cutting-edge digital surgical capabilities to help surgeons perform better, more consistent surgery," said Anthony Fernando, Asensus Surgical President and CEO. "As we look to the future, we are incredibly excited about the opportunity we have to revolutionize patient care through Performance-Guided Surgery. By introducing the most advanced robotics platforms in combination with novel clinical intelligence being bolstered by leading cloud computing power, we believe we can reduce surgical variability and help surgeons achieve better outcomes, regardless of their skill level or geographic location."

Upcoming 2023 Milestones

For the full year 2023, the Company expects to initiate 10 - 12 new Senhance programs.

During the first half of 2023, the Company expects to achieve the following regulatory milestone:

- FDA clearance of Senhance Surgical System for pediatric indication

During the second half of 2023, the Company expect to achieve the following developmental milestones:

- Integrated system testing for LUNA Surgical System
- Preclinical evaluation for LUNA Surgical System
- Standalone ISU final testing

2023 Investor Day

On February 21, 2023, the Company hosted an Investor Day. Based on its clinical and commercial experience to date, the Company introduced an integrated Digital Surgery solution comprising a next generation surgical platform and instruments, real-time intraoperative clinical intelligence and a secure cloud platform to apply machine learning to deliver clinical insights. This Digital Surgery solution will enable the Company's vision of Performance-Guided Surgery.

A link to a video replay of the event can be found [HERE](#).

LUNA, the Company's Next Generation Digital Surgery Platform

Designed based on the feedback received from over 10,000 digital laparoscopic procedures performed with the Senhance System, the LUNA Surgical System is the Company's next generation digital surgery platform. Through a combination of advanced minimally invasive instrumentation, the first ever digital interface between the surgeon and the console, and industry-leading clinical intelligence tools, we believe LUNA is poised to revolutionize the way surgery is performed.

The LUNA Surgical System is under development, and not currently available for use.

KARL STORZ Collaboration Agreement

The Company previously announced that it had entered into a Memorandum of Understanding with KARL STORZ VentureONE Pte. Ltd. (KARL STORZ), a new wholly owned subsidiary of KARL STORZ SE & Co. KG. As part of this agreement, KARL STORZ intends to market and sell Asensus' Intelligent Surgical Unit as a standalone device together with their IMAGE1 S™ Imaging system and OR1™ integration solution. The companies also intend to work together on the integration of the ISU into KARL STORZ's laparoscopic vision systems and jointly collaborate on developing next-generation instrumentation to be used with Asensus and KARL STORZ surgical platforms.

New Intelligent Surgical Unit Capabilities Announced

In January 2023, the Company received CE Mark for an expansion of machine vision capabilities on the previously cleared ISU. This approval included a review of the Senhance Surgical System platform, making Senhance one of the first robotic surgical systems to be approved through the new, more rigorous EU Medical Device Regulation, or MDR, process. These expanded ISU capabilities are now commercially available across all of the Company's key geographies, including the European Union, Japan, and the U.S.

In February 2023, the Company announced incremental features sets which are now under development, including an analytical feature set, a safety feature set, and a training and education set.

Google Cloud Collaboration

Asensus Surgical previously announced that it agreed on a multi-year strategic collaboration with Google Cloud to integrate Google Cloud's secure cloud data architecture and machine learning technologies to further expand the capabilities of the Asensus Surgical's Performance-Guided Surgery framework enabled through the ISU. Google's secure cloud data architecture will capture this data and Asensus will enable customer access portals and performance dashboards for surgeons and hospitals. Google's machine learning technologies will be utilized to analyze the data and discern clinical intelligence that can be utilized by surgeons and hospitals in addition to continuously improving the software in the ISU to provide better intra-operative clinical insight.

Articulating Instrument Launch

These instruments were commercially launched in the U.S., Japan and Europe, in the fourth quarter 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 U.S. FDA 510(k) application for pediatric clearance in the U.S. during the third quarter of 2022. The Senhance System's unique combination of 3mm instrumentation with a 5mm camera scope combined with haptic feedback make it a unique robotic assisted laparoscopic solution for pediatric surgeries. The Company expects to receive FDA 510(k) clearance during the first half of 2023.

Market Development

2022 Senhance Program Initiations

During the fourth quarter of 2022, the Company initiated five new Senhance Surgical System placements, two in Germany, two in Japan, and one in the CIS region, bringing the total number of new Senhance Surgical System placements to nine in 2022.

Procedure Volumes

Previously, the Company has used the terms "surgical procedure" and "surgical case" interchangeably to mean a single surgery. Following an analysis of the growing collection of Senhance surgical data, it was identified that it is becoming increasingly common that multiple surgical procedures are being performed during a single surgical case. As a result, the Company will now report the number of total surgical procedures completed. During 2023 we will provide data from similar periods in 2022 using the same methodology. As an example, in previous quarters, a surgical case where both a cholecystectomy (gallbladder removal) and an umbilical hernia repair were completed, it would have been counted as a single procedure. Under the revised definition, that example would be counted as two procedures.

In 2022, surgeons performed over 3,100 surgical procedures utilizing the Senhance System, representing a 29% increase over the 2,400 surgical procedures performed in the previous year. These procedures included general surgery, gynecology, urology, colorectal, pediatric, and bariatric surgical cases.

Fourth Quarter Financial Results

For the three months ended December 31, 2022, the Company reported revenue of \$2.5 million as compared to revenue of \$2.5 million in the three months ended December 31, 2021. Revenue in the fourth quarter of 2022 included \$1.3 million in system revenue, \$0.4 million in lease revenue, \$0.5 million in instruments and accessories, and \$0.3 million in services.

For the three months ended December 31, 2022, total operating expenses were \$18.3 million, as compared to \$15.9 million, in the three months ended December 31, 2021.

For the three months ended December 31, 2022, net loss was \$17.9 million, or \$0.08 per share, as compared to a net loss of \$15.9 million, or \$0.07 per share, in the three months ended December 31, 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 December 31, 2022, the adjusted net loss was \$16.7 million, or \$0.07 per share, as compared to an adjusted net loss of \$15.7 million, or \$0.07 per share in the three months ended December 31, 2021, after adjusting for the following charges: amortization of intangible assets, change in fair value of contingent consideration, and property and equipment impairment, 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 \$74.4 million as of December 31, 2022.

The Company intends to file its Annual Report on Form 10-K for the fiscal year ended December 31, 2022 on or about March 2, 2023, with the Securities and Exchange Commission. The Company expects that the audited financial statements that will be included in the filing will contain statements regarding management's assessment of the Company's ability to continue as a going concern, and a going concern qualification in the audit opinion from its independent registered public accounting firm. This announcement is made pursuant to NYSE American Company Guide Sections 401(h) and 610(b), which require public announcement of the receipt of an audit opinion containing a going concern paragraph.

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. Based upon the foundations of Digital Laparoscopy and the Senhance Surgical System, the Company is developing the LUNA Surgical System, a next generation robotic and instrument system as a foundation of its Digital Surgery solution. These systems will be powered by the Intelligent Surgical Unit 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. The Senhance Surgical System is 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. To learn more about Performance-Guided Surgery, Digital Laparoscopy with the Senhance Surgical System and the new LUNA System visit www.asensus.com.

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Forward-Looking Statements

This press release includes statements relating to Asensus Surgical, the LUNA Surgical System, the Senhance Surgical System and our 2022 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 revolutionize patient care through Performance-Guided Surgery, whether our robotics platforms in combination with novel clinical intelligence can reduce surgical variability and help surgeons achieve better outcomes, whether we will be able to initiate 10-12 new Senhance Surgical Systems in 2023, whether, in the first half of 2023, we will be able to achieve FDA clearance of the Senhance Surgical System for a pediatric indication, whether, in the second half of 2023, we will be able to achieve developmental milestones: integrating system testing for the LUNA Surgical System, preclinical evaluation for the LUNA Surgical System and standalone ISU final testing, whether the LUNA Surgical System will revolutionize the way surgery is performed, whether the collaboration between Asensus Surgical and Google Cloud will be successful and whether definitive agreements will be successfully negotiated and lead to a successful collaboration between Asensus Surgical and Karl Storz. 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		Years Ended	
	December 31,		December 31,	
	2022	2021	2022	2021
Revenue:				
Product	\$ 1,762	\$ 1,748	\$ 4,327	\$ 5,399
Service	306	340	1,373	1,520
Lease	396	388	1,387	1,313
Total revenue	<u>2,464</u>	<u>2,476</u>	<u>7,087</u>	<u>8,232</u>
Cost of revenue:				
Product	987	1,070	5,303	5,741
Service	668	453	2,174	1,799
Lease	643	764	3,395	3,556
Total cost of revenue	<u>2,298</u>	<u>2,287</u>	<u>10,872</u>	<u>11,096</u>
Gross loss	<u>166</u>	<u>189</u>	<u>(3,785)</u>	<u>(2,864)</u>
Operating Expenses:				
Research and development	8,520	6,575	28,942	19,348
Sales and marketing	3,820	3,229	14,756	13,395
General and administrative	4,794	5,926	20,172	19,323
Amortization of intangible assets	107	2,721	7,708	11,254
Change in fair value of contingent consideration	53	(2,578)	(1,115)	(1,565)
Property and equipment impairment	999	—	1,431	—
Total Operating Expenses	<u>18,293</u>	<u>15,873</u>	<u>71,894</u>	<u>61,755</u>
Operating Loss	<u>(18,127)</u>	<u>(15,684)</u>	<u>(75,679)</u>	<u>(64,619)</u>
Other Income (Expense), net:				
Gain on extinguishment of debt	—	—	—	2,847
Change in fair value of warrant liabilities	—	—	—	(1,981)
Interest income	335	337	1,141	590
Interest expense	30	(293)	(410)	(370)
Employee retention tax credit	—	—	—	1,311
Other expense, net	(34)	(12)	(295)	(15)
Total Other Income (Expense), net	<u>331</u>	<u>32</u>	<u>436</u>	<u>2,382</u>
Loss before income taxes	<u>(17,796)</u>	<u>(15,652)</u>	<u>(75,243)</u>	<u>(62,237)</u>
Income tax expense	<u>(94)</u>	<u>(229)</u>	<u>(318)</u>	<u>(225)</u>
Net loss	<u>(17,890)</u>	<u>(15,881)</u>	<u>(75,561)</u>	<u>(62,462)</u>
Comprehensive loss:				
Net loss	(17,890)	(15,881)	(75,561)	(62,462)
Foreign currency translation loss	2,151	(588)	(1,867)	(2,985)
Unrealized gain (loss) on available-for-sale investments	353	(194)	(257)	(247)
Comprehensive loss	<u>\$ (15,386)</u>	<u>\$ (16,663)</u>	<u>\$ (77,685)</u>	<u>\$ (65,694)</u>
Net loss per common share attributable to common stockholders – basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.07)</u>	<u>\$ (0.32)</u>	<u>\$ (0.28)</u>
Weighted average number of shares used in computing net loss per common share – basic and diluted	<u>236,843</u>	<u>234,851</u>	<u>236,492</u>	<u>226,960</u>

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

	December 31,	December 31,
	2022	2021
Assets		
Current Assets:		
Cash and cash equivalents	\$ 6,329	\$ 18,129

Short-term investments, available-for-sale	64,195	80,262
Accounts receivable, net	2,256	749
Inventories	8,284	8,634
Prepaid expenses	3,584	3,255
Employee retention tax credit receivable	554	1,311
Other current assets	1,671	957
Total Current Assets	86,873	113,297
Restricted cash	1,141	1,154
Long-term investments, available-for-sale	3,865	37,435
Inventories, net of current portion	5,469	7,074
Property and equipment, net	9,542	10,971
Intellectual property, net	1,576	9,892
Net deferred tax assets	174	288
Operating lease right-of-use assets, net	4,950	5,348
Other long-term assets	2,463	1,014
Total Assets	\$ 116,053	\$ 186,473
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 3,348	\$ 3,448
Accrued employee compensation and benefits	4,508	3,559
Accrued expenses and other current liabilities	1,293	1,617
Operating lease liabilities – current portion	800	683
Deferred revenue	465	543
Total Current Liabilities	10,414	9,850
Long Term Liabilities:		
Contingent consideration	1,256	2,371
Noncurrent operating lease liabilities	4,738	5,006
Total Liabilities	16,408	17,227
Commitments and Contingencies		
Stockholders' Equity		
Common stock \$0.001 par value, 750,000,000 shares authorized at December 31, 2022 and December 31, 2021; 236,895,440 and 235,218,552 shares issued and outstanding at December 31, 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 December 31, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	962,731	954,649
Accumulated deficit	(860,935)	(785,374)
Accumulated other comprehensive loss	(2,388)	(264)
Total Stockholders' Equity	99,645	169,246
Total Liabilities and Stockholders' Equity	\$ 116,053	\$ 186,473

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

	Years Ended	
	December 31,	
	2022	2021
Operating Activities:		
Net loss	\$ (75,561)	\$ (62,462)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	3,368	2,857
Amortization of intangible assets	7,708	11,254
Amortization of discounts and premiums on investments, net	565	409
Stock-based compensation	8,416	9,429
Gain on extinguishment of debt	—	(2,847)
Deferred tax expense	318	225

Change in inventory reserves	620	(492)
Bad debt expense	9	144
Property and equipment impairment	1,431	—
Loss on disposal of property and equipment	122	—
Change in fair value of warrant liabilities	—	1,981
Change in fair value of contingent consideration	(1,115)	(1,565)
Changes in operating assets and liabilities:		
Accounts receivable	(1,528)	174
Inventories	(2,302)	(611)
Operating lease right-of-use assets	232	(4,254)
Prepaid expenses	(450)	146
Employee retention tax credit receivable	757	(1,311)
Other current and long-term assets	(2,101)	902
Accounts payable	35	1,614
Accrued employee compensation and benefits	4,523	(859)
Accrued expenses	(3,955)	384
Deferred revenue	(55)	(229)
Operating lease liabilities	26	4,452
Net cash and cash equivalents used in operating activities	<u>(58,937)</u>	<u>(40,659)</u>
Investing Activities:		
Purchase of available-for-sale investments	(33,886)	(122,330)
Proceeds from maturities of available-for-sale investments	82,702	4,030
Purchase of property and equipment	<u>(1,279)</u>	<u>(1,368)</u>
Net cash and cash equivalents provided by (used in) investing activities	<u>47,537</u>	<u>(119,668)</u>
Financing Activities:		
Proceeds from issuance of common stock and warrants, net of issuance costs	—	131,929
Taxes paid related to net share settlement of vesting of restricted stock units	(350)	(1,063)
Proceeds from exercise of stock options and warrants	<u>18</u>	<u>30,839</u>
Net cash and cash equivalents (used in) provided by financing activities	<u>(332)</u>	<u>161,705</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(81)</u>	<u>376</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	(11,813)	1,754
Cash, cash equivalents and restricted cash, beginning of period	<u>19,283</u>	<u>17,529</u>
Cash, cash equivalents and restricted cash, end of period	<u>\$ 7,470</u>	<u>\$ 19,283</u>
Supplemental Disclosure for Cash Flow Information:		
Cash paid for leases	\$ 984	\$ 1,490
Cash paid for taxes	\$ 165	\$ 170
Supplemental Schedule of Non-cash Investing and Financing Activities:		
Transfer of inventories to property and equipment	\$ 2,693	\$ 3,244
Reclass of warrant liability to common stock and additional paid-in-capital	\$ —	\$ 2,236
Lease liabilities arising from obtaining right-of-use assets	\$ 577	\$ 5,119

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		Years Ended	
	December 31,		December 31,	
	2022	2021	2022	2021
Net loss attributable to common stockholders (GAAP)	\$ (17,890)	\$ (15,881)	\$ (75,561)	\$ (62,462)
Adjustments				
Amortization of intangible assets	107	2,721	7,708	11,254
Change in fair value of contingent consideration	53	(2,578)	(1,115)	(1,565)
Property and equipment impairment	999	—	1,431	—
Gain on extinguishment of debt	—	—	—	(2,847)

Change in fair value of warrant liabilities	—	—	—	1,981
Employee retention tax credit	—	—	—	(1,311)
Adjusted net loss attributable to common stockholders (Non-GAAP)	\$ (16,731)	\$ (15,738)	\$ (67,537)	\$ (54,950)

	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2022	2021	2022	2021
Net loss per share attributable to common stockholders (GAAP)	\$ (0.08)	\$ (0.07)	\$ (0.32)	\$ (0.28)

Adjustments

Amortization of intangible assets	—	0.01	0.03	0.05
Change in fair value of contingent consideration	—	(0.01)	(0.01)	(0.01)
Property and equipment impairment	0.01	—	0.01	—
Gain on extinguishment of debt	—	—	—	(0.01)
Change in fair value of warrant liabilities	—	—	—	0.01
Employee retention tax credit	—	—	—	—
Adjusted net loss per share attributable to common stockholders (Non-GAAP)	\$ (0.07)	\$ (0.07)	\$ (0.29)	\$ (0.24)

The non-GAAP financial measures for the three months and years ended December 31, 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 5 to 10 years.

b) Contingent consideration in connection with the acquisition of the Senhance System in 2015 is recorded as a liability and is the estimate of the fair value of potential milestone payments related to business acquisitions. Contingent consideration is measured at fair value using a Monte-Carlo simulation utilizing significant unobservable inputs including the probability of achieving each of the potential milestones, revenue volatility, EURO to USD exchange rate, and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.

c) Property and equipment impairment associated with returned Senhance Systems under operating leases and Senhance Systems currently under operating leases that are not expected to generate future cash flows sufficient to recover their net book value.

d) During 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 year ended December 31, 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 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").

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Source: Asensus Surgical, Inc.