



Asensus Surgical, Inc. Reports Operating and Financial Results for the First Quarter 2023

May 11, 2023

RESEARCH TRIANGLE PARK, N.C., May 11, 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™, today announced its operating and financial results for the first quarter 2023.

Recent Highlights

- 20% year-over-year growth in surgical procedures, with over 900 procedures performed globally during the quarter
- Surpassed 10,000 procedures on Senhance® Surgical System
- One Senhance Surgical Program was initiated during the quarter
- In March 2023, received FDA 510(k) clearance for an expanded indication to treat pediatric patients
- In January 2023, received CE Mark for an expansion of machine vision capabilities on the previously cleared Intelligent Surgical Unit™(ISU™) including 3D measurement, digital tagging, image enhancement, and enhanced camera control
- First quarter revenue of \$1.0 million
- The Company had cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of approximately \$57.4 million at March 31, 2023

"We are thrilled to report another quarter of strong procedure growth and progress in advancing our mission of Performance-Guided Surgery. The expansion of our pediatric indication into the U.S. is a significant milestone for our company, and we are excited to bring the benefits of our technology to a new patient population. Our continued increase in surgical procedures performed globally is a testament to the value our platform brings to surgeons and patients alike," said Anthony Fernando, Asensus Surgical President and CEO. "We remain on track to meet our milestones for the year, including the initiation of new Senhance programs, and the achievement of milestones for our LUNA™ Surgical System which is under development. As we look to the future, we remain focused on revolutionizing patient care through innovative surgical technology."

Upcoming 2023 Milestones

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

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

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

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 the LUNA System is poised to revolutionize the way surgery is performed.

The LUNA 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 the definitive agreements, KARL STORZ intends to market and sell

Asensus' ISU as a standalone device, and the companies intend to jointly collaborate on the development and integration of next-generation instrumentation. The agreement is progressing towards signing and will represent an important step expanding our commercial reach and development capabilities.

U.S. Pediatric Regulatory Clearance

The Company received U.S. FDA 510(k) clearance for pediatric surgeries in the U.S. during the first quarter of 2023. 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.

Market Development

Procedure Volumes

During the first quarter of 2023, there was a 20% increase in total surgical procedures completed utilizing the Senhance System over the same period in 2022. Strong utilization patterns brought on by an increased installed base, an increase of new surgeon users at existing installations, and a broader market recovery were the main drivers of this expansion.

2023 Senhance Program Initiations

During the first quarter of 2023, the Company initiated one new Senhance Surgical System placement in Japan.

Clinical Validation

During the quarter, [a peer reviewed paper](#) was published highlighting early experience of using the Senhance System in pediatric procedures in the United States. Conducted with IRB approval prior to 510(k) clearance, this study highlights the safety and feasibility of using Senhance System in pediatric cases. The surgical team successfully performed surgeries on eight patients ranging from four months to 16 years old, including procedures such as cholecystectomy, inguinal herniorrhaphy, orchidopexy, and exploration for suspected enteric duplication cyst. The successful use of the Senhance System in pediatric surgeries marks an important milestone for the Company in its ongoing mission to advance the field of surgical robotics.

Intelligent Surgical Unit (ISU) Collects Two Industry Awards on the Heels of Passing 10,000 Procedures on Senhance Surgical System

The Senhance System has passed the 10,000 worldwide procedures milestone and the Company recently received two prestigious industry awards. The first award comes from MedTech Breakthrough, where the ISU was named the "Best New Technology Solution" in the surgical category. This achievement is remarkable as the ISU competed against nearly 4,000 nominations from across the globe. This marks the third time Asensus has earned a MedTech Breakthrough win. The MedTech Breakthrough Awards program is an independent program devoted to honoring excellence in medical and health-related technology companies, products, services and people. The second award comes from Juniper Research's Future Digital Awards for Excellence in Digital Health Innovation, where the ISU has been honored as the "Best Medical Robotics Solution" and awarded the Platinum Winner title. The awards program recognizes organizations that have made outstanding contributions to their industry and are positioned to make a significant impact in the future.

First Quarter Financial Results

For the three months ended March 31, 2023, the Company reported revenue of \$1.0 million as compared to revenue of \$1.1 million in the three months ended March 31, 2022. Revenue in the first quarter of 2023 included \$0.5 million in lease revenue, \$0.3 million in instruments and accessories, and \$0.2 million in services.

For the three months ended March 31, 2023, total operating expenses were \$20.4 million, as compared to \$18.2 million, in the three months ended March 31, 2022.

For the three months ended March 31, 2023, net loss was \$22.2 million, or \$0.09 per share, as compared to a net loss of \$19.1 million, or \$0.08 per share, in the three months ended March 31, 2022.

Adjusted net loss is a non-GAAP financial measure. See the reconciliation of GAAP to Non-GAAP Measures below. For the three months ended March 31, 2023, the adjusted net loss was \$22.0 million, or \$0.09 per share, as compared to an adjusted net loss of \$16.6 million, or \$0.07 per share in the three months ended March 31, 2022, after adjusting for the following charges: amortization of intangible assets, and change in fair value of contingent consideration, both 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 \$57.4 million as of March 31, 2023.

Conference Call

To listen to the conference call on your telephone, please dial 1-844-826-3033 for domestic callers and 1-412-317-5185 for international callers, 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. 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, and digital laparoscopy with the Senhance Surgical System visit www.asensus.com.

Follow Asensus

Email Alerts: <https://ir.asensus.com/email-alerts>

LinkedIn: <https://www.linkedin.com/company/asensus-surgical-inc>

Twitter: <https://twitter.com/AsensusSurgical>

YouTube: <https://www.youtube.com/c/transenterix>

Vimeo: <https://vimeo.com/asxc>

Forward-Looking Statements

This press release includes statements relating to Asensus Surgical, and our 2023 first 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 meet our milestones for the year, including the initiation of 10-12 new Senhance programs and the development of the LUNA Surgical System; whether we will meet our 2023 second half milestones of integrated system testing for the LUNA Surgical System, preclinical evaluation for the LUNA Surgical System and Standalone ISU final testing; whether, once fully developed and cleared, the LUNA Surgical System will revolutionize the way surgery is performed; whether the Senhance System's unique combination of 3mm instrumentation with a 5mm camera scope with haptic feedback make it a unique robotic assisted laparoscopic solution for pediatric surgeries 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.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended	
	March 31,	
	2023	2022
Revenue:		
Product	\$ 293	\$ 347
Service	195	308
Lease	488	411
Total revenue	<u>976</u>	<u>1,066</u>
Cost of revenue:		
Product	1,225	375
Service	749	496
Lease	973	952
Total cost of revenue	<u>2,947</u>	<u>1,823</u>
Gross loss	<u>(1,971)</u>	<u>(757)</u>
Operating Expenses:		
Research and development	10,139	6,428
Sales and marketing	4,553	3,719
General and administrative	5,468	5,533
Amortization of intangible assets	112	2,670
Change in fair value of contingent consideration	105	(154)
Total Operating Expenses	<u>20,377</u>	<u>18,196</u>
Operating Loss	<u>(22,348)</u>	<u>(18,953)</u>
Other Expense, net:		
Interest income	439	255
Interest expense	—	(200)
Other expense, net	(218)	(146)
Total Other Income (Expense), net	<u>221</u>	<u>(91)</u>
Loss before income taxes	<u>(22,127)</u>	<u>(19,044)</u>
Income tax expense	(91)	(84)
Net loss	<u>(22,218)</u>	<u>(19,128)</u>

Comprehensive loss:		
Net loss	(22,218)	(19,128)
Foreign currency translation gain (loss)	550	(650)
Unrealized gain (loss) on available-for-sale investments	307	(552)
Comprehensive loss	<u>\$ (21,361)</u>	<u>\$ (20,330)</u>
Net loss per common share attributable to common stockholders – basic and diluted	\$ (0.09)	\$ (0.08)
Weighted average number of shares used in computing net loss per common share – basic and diluted	238,280	235,892

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

	<u>March 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 18,737	\$ 6,329
Short-term investments, available-for-sale	37,697	64,195
Accounts receivable, net	658	2,256
Inventories	8,844	8,284
Prepaid expenses	3,326	3,584
Employee retention tax credit receivable	554	554
Other current assets	1,740	1,671
Total Current Assets	<u>71,556</u>	<u>86,873</u>
Restricted cash	1,142	1,141
Long-term investments, available-for-sale	958	3,865
Inventories, net of current portion	5,198	5,469
Property and equipment, net	8,972	9,542
Intellectual property, net	1,506	1,576
Net deferred tax assets	171	174
Operating lease right-of-use assets, net	4,769	4,950
Other long-term assets	2,251	2,463
Total Assets	<u>\$ 96,523</u>	<u>\$ 116,053</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 4,972	\$ 3,348
Accrued employee compensation and benefits	3,391	4,508
Accrued expenses and other current liabilities	1,283	1,293
Operating lease liabilities – current portion	775	800
Deferred revenue	456	465
Total Current Liabilities	<u>10,877</u>	<u>10,414</u>
Long Term Liabilities:		
Contingent consideration	1,361	1,256
Noncurrent operating lease liabilities	4,568	4,738
Total Liabilities	<u>16,806</u>	<u>16,408</u>
Commitments and Contingencies		
Stockholders' Equity		
Common stock \$0.001 par value, 750,000,000 shares authorized at March 31, 2023 and December 31, 2022; 239,341,570 and 236,895,440 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	239	237

Preferred stock, \$0.01 par value, 25,000,000 shares authorized, no shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	964,162	962,731
Accumulated deficit	(883,153)	(860,935)
Accumulated other comprehensive income	(1,531)	(2,388)
Total Stockholders' Equity	<u>79,717</u>	<u>99,645</u>
Total Liabilities and Stockholders' Equity	\$ 96,523	\$ 116,053

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

	Three Months Ended	
	March 31,	
	2023	2022
Operating Activities:		
Net loss	\$ (22,218)	\$ (19,128)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	813	869
Amortization of intangible assets	112	2,670
Amortization of discounts and premiums on investments, net	(89)	215
Stock-based compensation	1,916	2,245
Deferred tax expense	91	84
Bad debt expense	—	177
Change in inventory reserves	(374)	(180)
Change in fair value of contingent consideration	105	(154)
Changes in operating assets and liabilities:		
Accounts receivable	1,607	25
Inventories	203	(1,440)
Operating lease right-of-use assets	187	197
Prepaid expenses	250	201
Other current and long-term assets	(27)	(487)
Accounts payable	1,608	74
Accrued employee compensation and benefits	(1,120)	(1,043)
Accrued expenses and other current liabilities	(93)	(107)
Deferred revenue	(13)	(1)
Operating lease liabilities	(206)	(160)
Net cash and cash equivalents used in operating activities	<u>(17,248)</u>	<u>(15,943)</u>
Investing Activities:		
Purchase of available-for-sale investments	(2,949)	(5,967)
Proceeds from maturities of available-for-sale investments	32,750	29,258
Purchase of property and equipment	(64)	(246)
Net cash and cash equivalents provided by investing activities	<u>29,737</u>	<u>23,045</u>
Financing Activities:		
Taxes paid related to net share settlement of vesting of restricted stock units	(488)	(348)
Proceeds from exercise of stock options and warrants	5	12
Net cash and cash equivalents used in financing activities	<u>(483)</u>	<u>(336)</u>
Effect of exchange rate changes on cash and cash equivalents	403	(45)
Net increase in cash, cash equivalents and restricted cash	12,409	6,721
Cash, cash equivalents and restricted cash, beginning of period	7,470	19,283
Cash, cash equivalents and restricted cash, end of period	<u>\$ 19,879</u>	<u>\$ 26,004</u>
Supplemental Disclosure for Cash Flow Information:		
Cash paid for leases	\$ 330	\$ 300
Cash paid for taxes	\$ 190	\$ 29
Supplemental Schedule of Non-cash Investing and Financing Activities:		
Transfer of inventories to property and equipment	\$ 112	\$ 160

Lease liabilities arising from obtaining right-of-use assets	\$	45	\$	—
--	----	----	----	---

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

	Three Months Ended March 31,	
	2023	2022
Net loss attributable to common stockholders (GAAP)	\$ (22,218)	\$ (19,128)
Adjustments		
Amortization of intangible assets	112	2,670
Change in fair value of contingent consideration	105	(154)
Adjusted net loss attributable to common stockholders (Non-GAAP)	\$ (22,001)	\$ (16,612)

	Three Months Ended March 31,	
	2023	2022
Net loss per share attributable to common stockholders (GAAP)	\$ (0.09)	\$ (0.08)
Adjustments		
Amortization of intangible assets	—	0.01
Change in fair value of contingent consideration	—	—
Adjusted net loss per share attributable to common stockholders (Non-GAAP)	\$ (0.09)	\$ (0.07)

The non-GAAP financial measures for the three months ended March 31, 2023 and 2022, 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.

INVESTOR CONTACT:

Mark Klausner or Mike Vallie
ICR Westwicke
invest@asensus.com
443-213-0499

MEDIA CONTACT:

Dan Ventresca
Matter Communications
AsensusPR@matternow.com
617-874-5488



Source: Asensus Surgical, Inc.