



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

November 14, 2023

RESEARCH TRIANGLE PARK, N.C., Nov. 14, 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 third quarter 2023.

Recent Highlights

- 17% growth in surgical procedures, with over 2,700 procedures performed globally year to date at September 30, 2023
- Two Senhance Surgical programs initiated in the quarter, with two programs initiated subsequent to the end of the third quarter, bringing the year-to-date total to five
- The Company had cash and cash equivalents and short-term investments, excluding restricted cash, of approximately \$33.1 million at September 30, 2023

"I'm pleased with the progress we've made and the strong foundation we are building for the future. We anticipate reaching important milestones in the upcoming quarters," said Anthony Fernando, Asensus Surgical President and CEO. "With the LUNA™ Surgical System program progressing as planned, our primary objective continues to be the completion of our preclinical evaluation planned for December this year with the full LUNA system. Additionally, we are excited to see notable traction in the pediatrics space, a testament to our commitment to advancing surgical technology for all patients and the unique features of the Senhance System."

2023 Milestones

During the third quarter of 2023, the Company achieved the following developmental milestones:

- Finalized manufacturing strategy with Flex for LUNA Surgical System
- Finalized strategic relationship with NVIDIA as our graphics hardware provider

During the last quarter of 2023, the Company continues to expect to achieve the following developmental milestones:

- Complete integrated system testing for our LUNA Surgical System
- Conduct preclinical evaluation for our LUNA Surgical System
- Finalize manufacturing partner for the updated Intelligent Surgical Unit™ (ISU™) platform

For the full year 2023, the Company now expects to initiate 8 - 10 new Senhance programs, revised from the previous estimate.

LUNA System

The LUNA System's development is in progress and is now entering the testing and evaluation phase before regulatory submissions. Preclinical evaluation is on track to be completed in December this year with seven U.S and European surgeons in attendance over a week long period to perform preclinical procedures on porcine models to confirm the performance of the LUNA system. Future milestones include freezing the system's design in early 2024, followed by verification and validation testing, and pilot manufacturing. The Company is confident in the regulatory pathway for the LUNA System. Ongoing communication with the FDA, along with strong in-house regulatory expertise and past successful submissions for the Senhance System, lead the Company to anticipate using a standard 510(k) pathway in the U.S., rather than the more complex de novo pathway. This streamlined approach is expected to apply globally, offering a quicker market entry compared to new entrants.

Market Development

Procedure Volumes

Year to date ended September 30, 2023, there was a 17% growth in procedures completed utilizing the Senhance System over the same period in 2022. The main drivers of this expansion were consistent utilization patterns brought on by an increased installed base and an increase of new

surgeon users at existing installations.

2023 Senhance Program Initiations

Year to date, the Company initiated five new Senhance Surgical System placements or sales, which consisted of two in Japan, one in Germany, one in the Commonwealth of Independent States (CIS) region, and one in the United States.

In August, the Company initiated a program with First Towakai Hospital, in their urology, gynecology, and gastroenterology departments. This initiation in Japan further strengthens the Company's presence in the region.

In July, Mayo Clinic Hospital, Saint Marys Campus, a leading U.S.-based hospital, became the first hospital in the United States to exclusively utilize the Senhance System for pediatric surgery. The system's specialized features, including augmented intelligence, machine learning, haptic feedback, and tailored instruments, make it exceptionally well-suited for pediatric procedures.

After the close of the third quarter, the Company placed one additional system and sold a second system.

Klinikum Idar-Oberstein Hospital in Germany, initiated a Senhance Surgical System in the Clinic for General, Visceral and Minimally Invasive Surgery. The second system was sold to the Company's distribution partner and is planned for installation in the Commonwealth of Independent States (CIS) region.

Third Quarter Financial Results

For the three months ended September 30, 2023, the Company reported revenue of \$1.1 million, as compared to revenue of \$2.6 million in the three months ended September 30, 2022. Revenue in the third quarter of 2023 included \$0.5 million in lease revenue, \$0.3 million in instruments and accessories, and \$0.3 million in services.

For the three months ended September 30, 2023, total operating expenses were \$18.5 million, as compared to \$17.2 million, in the three months ended September 30, 2022.

For the three months ended September 30, 2023, net loss was \$18.3 million, or \$0.07 per share, as compared to a net loss of \$18.9 million, or \$0.08 per share, in the three months ended September 30, 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 September 30, 2023, the adjusted net loss was \$15.6 million, or \$0.06 per share, as compared to the adjusted net loss of \$16.9 million, or \$0.07 per share in the three months ended September 30, 2022, after adjusting for the following non-cash charges: amortization of intangible assets, change in fair value of contingent consideration, and change in fair value of warrant liabilities.

Balance Sheet Updates

The Company had cash and cash equivalents and short-term investments, excluding restricted cash, of approximately \$33.1 million as of September 30, 2023.

In July, a registered direct offering was successfully completed, yielding approximately \$10 million in gross proceeds. The infusion of these funds is strategically earmarked to fortify working capital and contribute to ongoing research and development endeavors.

Based on the recent financing and our current operating plan, the Company anticipates that available cash will now sustain operations until the late second quarter of 2024.

Conference Call

To listen to the conference call on your telephone, please dial 1-888-886-7786 for domestic callers and 1-416-764-8658 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 are and 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.

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Forward-Looking Statements

This press release includes statements relating to Asensus Surgical, our 2023 third quarter results, and our plans for the remainder of 2023 and beyond. 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, based on our current cash and current operating plan, we will have sufficient available cash to sustain operations until the late second quarter of 2024 and whether we will be able to successfully complete financing sufficient to sustain our operations after that time, whether we will be able to achieve wider adoption of the Senhance System and optimizing its utilization, whether we will initiate 8-10 new Senhance programs during 2023, whether our LUNA System development efforts will continue on the anticipated timeline, whether our regulatory submissions for the LUNA System will be successful, and whether in the last quarter of 2023, we will complete integrated system testing for the LUNA Surgical System, conduct preclinical evaluation for the LUNA Surgical System and finalize a manufacturing partner for the ISU. 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		Nine Months Ended	
	September 30,		June 30,	
	2023	2022	2023	2022
Revenue:				
Product	\$ 301	\$ 1,964	\$ 892	\$ 2,565
Service	295	335	779	1,067
Lease	493	264	1,475	991
Total revenue	<u>1,089</u>	<u>2,563</u>	<u>3,146</u>	<u>4,623</u>
Cost of revenue:				
Product	1,171	3,057	4,008	4,316
Service	581	365	1,849	1,506
Lease	1,117	982	3,033	2,752
Total cost of revenue	<u>2,869</u>	<u>4,404</u>	<u>8,890</u>	<u>8,574</u>
Gross loss	<u>(1,780)</u>	<u>(1,841)</u>	<u>(5,744)</u>	<u>(3,951)</u>
Operating expenses:				
Research and development	9,290	6,741	28,409	20,422
Sales and marketing	4,138	3,615	13,140	10,936
General and administrative	4,571	4,853	15,163	15,378
Amortization of intangible assets	114	2,398	340	7,601
Change in fair value of contingent consideration	366	(416)	674	(1,168)
Property and equipment impairment	—	—	—	432
Total Operating Expenses	<u>18,479</u>	<u>17,191</u>	<u>57,726</u>	<u>53,601</u>
Operating Loss	<u>(20,259)</u>	<u>(19,032)</u>	<u>(63,470)</u>	<u>(57,552)</u>
Other income (expense), net:				
Change in fair value of warrant liabilities	2,278	—	2,278	—
Interest income	406	291	1,276	806
Interest expense	—	(99)	—	(440)
Other expense	(686)	(29)	(1,146)	(261)
Total Other Income, net	<u>1,998</u>	<u>163</u>	<u>2,408</u>	<u>105</u>
Loss before income taxes	<u>(18,261)</u>	<u>(18,869)</u>	<u>(61,062)</u>	<u>(57,447)</u>
Income tax expense	57	55	136	224
Net loss	<u>(18,318)</u>	<u>(18,924)</u>	<u>(61,198)</u>	<u>(57,671)</u>
Net loss per common share attributable to common stockholders – basic and diluted	<u>\$ (0.07)</u>	<u>\$ (0.08)</u>	<u>\$ (0.25)</u>	<u>\$ (0.24)</u>
Weighted average number of shares used in computing net loss per common share – basic and diluted	<u>256,184</u>	<u>236,713</u>	<u>244,744</u>	<u>236,373</u>
Comprehensive loss:				
Net loss	(18,318)	(18,924)	(61,198)	(57,671)

Foreign currency translation (loss) gain	(640)	(1,655)	84	(4,018)
Unrealized gain (loss) on available-for-sale investments	67	86	473	(610)
Comprehensive loss	<u>\$ (18,891)</u>	<u>\$ (20,493)</u>	<u>\$ (60,641)</u>	<u>\$ (62,299)</u>

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

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 21,699	\$ 6,329
Short-term investments, available-for-sale	11,420	64,195
Accounts receivable, net	662	2,256
Inventory, net	6,683	8,284
Prepaid expenses	4,174	3,584
Employee retention tax credit receivable	—	554
Other current assets	1,324	1,671
Total Current Assets	<u>45,932</u>	<u>86,873</u>
Restricted cash	1,615	1,141
Long-term investments, available-for-sale	—	3,865
Inventory, net of current portion	5,640	5,469
Property and equipment, net	9,237	9,542
Intellectual property, net	1,278	1,576
Deferred tax assets, net	150	174
Operating lease right-of-use assets, net	5,004	4,950
Other long-term assets	1,871	2,463
Total Assets	<u>\$ 70,727</u>	<u>\$ 116,053</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 4,526	\$ 3,348
Accrued employee compensation and benefits	4,967	4,508
Accrued expenses and other current liabilities	1,258	1,293
Operating lease liabilities, current	916	800
Deferred revenue	456	465
Total Current Liabilities	<u>12,123</u>	<u>10,414</u>
Long-Term Liabilities:		
Warrant liabilities	4,842	—
Contingent consideration	1,930	1,256
Noncurrent operating lease liabilities	4,579	4,738
Total Liabilities	<u>23,474</u>	<u>16,408</u>
Commitments and Contingencies		
Stockholders' Equity		
Common stock \$0.001 par value, 750,000,000 shares authorized at September 30, 2023 and December 31, 2022; 264,111,257 and 236,895,440 issued and outstanding at September 30, 2023 and December 31, 2022, respectively	264	237
Preferred stock, \$0.01 par value, 25,000,000 shares authorized, no shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Additional paid-in capital	970,952	962,731
Accumulated deficit	(922,133)	(860,935)
Accumulated other comprehensive loss	(1,830)	(2,388)
Total Stockholders' Equity	<u>47,253</u>	<u>99,645</u>
Total Liabilities and Stockholders' Equity	<u>\$ 70,727</u>	<u>\$ 116,053</u>

Asensus Surgical, Inc.
Condensed Consolidated Statements of Cash Flows

(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2023	2022
Operating Activities:		
Net loss	\$ (61,198)	\$ (57,671)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	2,405	2,481
Amortization of intangible assets	340	7,601
(Accretion) amortization of discounts and premiums on investments, net	(454)	556
Stock-based compensation	5,913	6,361
Deferred tax expense	136	224
Change in inventory reserves	297	386
Bad debt expense	—	9
Property and equipment impairment	—	432
Loss on disposal of property and equipment	—	97
Change in fair value of warrant liabilities	(2,278)	—
Change in fair value of contingent consideration	674	(1,168)
Changes in operating assets and liabilities:		
Accounts receivable	1,587	(1,735)
Inventory	536	(535)
Operating lease right-of-use assets	(142)	237
Prepaid expenses	(590)	(693)
Employee retention tax credit receivable	554	164
Other current and long-term assets	310	(2,123)
Accounts payable	1,236	449
Accrued employee compensation and benefits	566	236
Accrued expenses and other current liabilities	(97)	—
Deferred revenue	(5)	(139)
Operating lease liabilities	(43)	(53)
Net cash and cash equivalents used in operating activities	(50,253)	(44,884)
Investing Activities:		
Purchase of available-for-sale investments	(12,268)	(25,588)
Proceeds from maturities of available-for-sale investments	69,835	67,702
Purchase of property and equipment	(488)	(904)
Net cash and cash equivalents provided by investing activities	57,079	41,210
Financing Activities		
Proceeds from issuance of common stock and warrants, net of issuance costs	9,946	—
Taxes paid related to net share settlement of vesting of restricted stock units	(497)	(350)
Proceeds from exercise of stock options	5	18
Net cash and cash equivalents provided by (used in) financing activities	9,454	(332)
Effect of exchange rate changes on cash and cash equivalents	(466)	(300)
Net increase (decrease) in cash, cash equivalents and restricted cash	15,814	(4,306)
Cash, cash equivalents and restricted cash, beginning of period	7,470	19,283
Cash, cash equivalents and restricted cash, end of period	\$ 23,284	\$ 14,977
Supplemental Disclosure for Cash Flow Information:		
Cash paid for leases	\$ 1,067	\$ 729
Cash paid for taxes	\$ 230	\$ 79
Supplemental Schedule of Non-cash Investing and Financing Activities:		
Transfer of inventories to property and equipment	\$ 2,227	\$ 1,293
Lease liabilities arising from obtaining right-of-use assets	\$ 796	\$ 316

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

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss attributable to common stockholders (GAAP)	\$ (18,318)	\$ (18,924)	\$ (61,198)	\$ (57,671)
Adjustments				
Amortization of intangible assets (a)	114	2,398	340	7,601
Change in fair value of contingent consideration (b)	366	(416)	674	(1,168)
Impairment of property and equipment (c)	—	—	—	432
Change in fair value of warrant liabilities (d)	2,278	—	2,278	—
Adjusted net loss attributable to common stockholders (Non-GAAP)	\$ (15,560)	\$ (16,942)	\$ (57,906)	\$ (50,806)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss per share attributable to common stockholders (GAAP)	\$ (0.07)	\$ (0.08)	\$ (0.25)	\$ (0.24)
Adjustments				
Amortization of intangible assets (a)	—	0.01	—	0.03
Change in fair value of contingent consideration (b)	—	—	—	—
Impairment of property and equipment (c)	—	—	—	—
Change in fair value of warrant liabilities (d)	0.01	—	0.01	—
Adjusted net loss per share attributable to common stockholders (Non-GAAP)	\$ (0.06)	\$ (0.07)	\$ (0.24)	\$ (0.21)

The non-GAAP financial measures for the three and nine months ended September 30, 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 7 to 10 years.

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

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

d) During the three months ended September 30, 2023, the Company recorded warrant liabilities related to common stock warrants issued in the registered direct offering in July 2023.

Warrant liabilities were recorded at their initial estimated fair value. Adjustments associated with changes in fair value of the warrant liabilities are included in the Company's condensed consolidated statements of operations and comprehensive loss.

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Source: Asensus Surgical, Inc.