



Asensus Surgical, Inc. Reports Operating and Financial Results for the Fourth Quarter 2023 and Full Year 2023

March 21, 2024

RESEARCH TRIANGLE PARK, N.C., March 21, 2024 (GLOBE NEWSWIRE) -- [Asensus Surgical](#), Inc. (NYSE American: ASXC), a medical device company that is digitizing the interface between the surgeon and the patient, announced its operating and financial results for the fourth quarter and full year 2023.

Full Year Highlights

- Completed in vivo evaluation of the LUNA™ Surgical System by nine independent surgeons through thirteen procedures across gynecology, urology, and general surgery
- Over 3,550 surgical procedures were performed globally using the Senhance Surgical System, representing growth of over 13% compared to 2022
- In 2023, 8 Senhance Surgical Programs were initiated, which is in line with guidance of 8-10 systems
- Full year 2023 revenue of \$8.6 million
- The Company had cash, cash equivalents and short-term investments, excluding restricted cash, of approximately \$21.1 million at December 31, 2023

Fourth Quarter Highlights

- Over 835 surgical procedures were performed globally using the Senhance® Surgical System
- Five Senhance Surgical Programs were initiated, including one in Germany, one in Romania, two in the CIS region and one in Japan
- Fourth quarter unaudited revenue of \$5.4 million

"Reflecting on our progress in 2023, I'm pleased with the solid groundwork we continue to lay for the future," said Anthony Fernando, Asensus Surgical President and CEO. "As we look at 2024, there's a sense of optimism as we aim to hit significant milestones in the coming quarters. Our main focus right now is on the thorough testing and evaluation phase of the LUNA Surgical System, as we prepare for regulatory submissions. Additionally, I'm particularly excited about the progress we're making in pediatric applications, highlighting our commitment to advancing surgical technology for all patients through the unique features of the Senhance System."

2024 Milestones

For the full year 2024, the Company expects:

- To initiate 8 - 10 new Senhance programs.
- Procedure volume growth of 15% to 20% over 2023.
- Freezing the system's design for the LUNA Surgical System
- Verification and validation testing, and pilot manufacturing for the LUNA Surgical System

Market Development

2023 Senhance Program Initiations

During the fourth quarter of 2023, the Company initiated five new Senhance Surgical System placements, one in Germany, one in Romania, two in the CIS region and one in Japan at Nagoya University Hospital.

In 2023, the Company initiated eight new Senhance Surgical System placements: one in the United States, one in Germany, three in Japan, one in Romania, and two in the CIS region.

Procedure Volumes

In 2023, surgeons performed over 3,550 procedures utilizing the Senhance System, representing a 13% increase over the previous year. These procedures included general surgery, gynecology, urology, colorectal, pediatric, and bariatric surgical cases.

Pediatric Update

In 2023, the Company made notable progress in improving pediatric care. A key milestone was the FDA's clearance for use of the Senhance System in pediatric cases, marking it as the first approved digital laparoscopic surgery solution for pediatric patients in the U.S. This clearance, alongside existing approvals in the EU and Japan, highlights the Senhance System's unique features, including 3mm instrumentation, a 5mm camera scope, haptic feedback, and advanced clinical intelligence from the Intelligent Surgical Unit™ (ISU™). These features work together to contribute to a less invasive approach in pediatric robotic surgery. In addition to regulatory milestones, the Company has introduced four Senhance System programs dedicated to pediatric departments in the U.S. and internationally.

Clinical Registry (TRUST)

The Company continues to leverage its growing body of real-world clinical data through the utilization of its TRUST™ clinical registry. The Company believes TRUST is the largest multi-specialty robotic-assisted laparoscopic registry in the industry, with approximately 3,200 patients enrolled to date, a 45% increase from 2022.

Clinical Validation

During the year, there were nine peer-reviewed clinical papers published providing further support for the clinical utility of the Senhance System across a variety of surgical specialties. These papers, along with a library of similar papers, can be found on the Company's website:

<https://www.asensus.com/resources/clinical-publications>.

LUNA™ Surgical Robotic System

LUNA Development

The LUNA Surgical System's development is in progress and is now in the testing and evaluation phase before regulatory submissions. In December 2023, the Company hosted a Surgeon Lab in Research Triangle Park, North Carolina, to conduct an in vivo evaluation of LUNA's hardware, software, and instruments in porcine models. The lab allowed nine participating surgeons to evaluate the LUNA system's functionality through thirteen procedures across gynecology, urology, and general surgery. For a closer look at the Surgeon Lab and insights from the participating surgeons, a video is available at <https://ir.asensus.com/events-and-presentations>. The video provides an overview of the LUNA system's features, demonstrating its range of motion, instrument strength, and ergonomic benefits.

Future milestones include freezing the system's design in the second half of 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 traditional 510(k) submission 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. LUNA is currently under development and has not been submitted to, or cleared by, the U.S. FDA or other global regulators, and is not available for sale in any market.

Agreement with Flex for LUNA Surgical System Design and Advanced Manufacturing Services

In November, the Company announced an agreement with Flex for design and manufacturing support for the LUNA Surgical System. This collaboration aims to facilitate the efficient market entry of LUNA by leveraging Flex's expertise in electromechanical systems. The agreement underscores a joint commitment to advancing surgical technology for improved patient care.

Fourth Quarter Financial Results (unaudited)

For the three months ended December 31, 2023, the Company reported revenue of \$5.4 million, as compared to revenue of \$2.5 million in the three months ended December 31, 2022. Revenue in the fourth quarter of 2023 included \$3.6 million in system revenue, \$1.0 million in instruments and accessories, \$0.5 million in lease revenue, and \$0.3 million in services.

For the three months ended December 31, 2023, total operating expenses were \$17.2 million, as compared to \$18.3 million, in the three months ended December 31, 2022.

For the three months ended December 31, 2023, net loss was \$17.2 million, or \$0.07 per share, as compared to a net loss of \$17.9 million, or \$0.08 per share, in the three months ended December 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 December 31, 2023, the adjusted net loss was \$17.5 million, or \$0.07 per share, as compared to the adjusted net loss of \$16.7 million, or \$0.07 per share in the three months ended December 31, 2022, after adjusting for the following non-cash charges: amortization of intangible assets, change in fair value of contingent consideration, property and equipment impairment, 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 \$21.1 million as of December 31, 2023.

Based on the recent financing and our current operating plan, the Company anticipates that available cash will now sustain operations until early June 2024.

The Company intends to file its Annual Report on Form 10-K for the fiscal year ended December 31, 2023 on or about March 21, 2024, 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.

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 is revolutionizing surgery with the first intra-operative Augmented Intelligence technology approved for use in operating rooms around the world. Recognized as an award-winning leader in digital technology, Asensus is committed to making surgery more accessible and predictable while delivering consistently superior outcomes. The Company's novel approach to digitizing laparoscopy has led to system placements globally. Led by engineers, medical professionals, and industry luminaries, Asensus is powered by human ingenuity and driven by collaboration. To learn more about the Senhance® Surgical System and the new LUNA™ System in development, visit www.asensus.com.

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Forward-Looking Statements

This press release includes statements relating to Asensus Surgical, our 2024 fourth quarter results, and our plans for the remainder of 2024. 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 early June 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 2024, whether our LUNA System development efforts, including the design freeze, verification and validation testing, and pilot manufacturing, will continue on the anticipated timeline, whether our regulatory submissions for the LUNA System will be successful on the timeline, and in the regulatory pathway, we expect, and whether Senhance System procedure growth will increase 15%-20% over 2023 procedures. 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, | |
| | 2023 | 2022 | 2023 | 2022 |
| Revenue: | | | | |
| Product | \$ 4,627 | \$ 1,762 | \$ 5,519 | \$ 4,327 |
| Service | 273 | 306 | 1,052 | 1,373 |
| Lease | 531 | 396 | 2,006 | 1,387 |
| Total revenue | 5,431 | 2,464 | 8,577 | 7,087 |
| Cost of revenue: | | | | |
| Product | 2,858 | 987 | 6,866 | 5,303 |
| Service | 444 | 668 | 2,293 | 2,174 |
| Lease | 963 | 643 | 3,996 | 3,395 |
| Total cost of revenue | 4,265 | 2,298 | 13,155 | 10,872 |
| Gross profit (loss) | 1,166 | 166 | (4,578) | (3,785) |
| Operating expenses: | | | | |
| Research and development | 8,614 | 8,520 | 37,023 | 28,942 |
| Sales and marketing | 3,781 | 3,820 | 16,921 | 14,756 |
| General and administrative | 3,992 | 4,794 | 19,155 | 20,172 |
| Amortization of intangible assets | 113 | 107 | 453 | 7,708 |
| Change in fair value of contingent consideration | 290 | 53 | 964 | (1,115) |
| Property and equipment impairment | 374 | 999 | 374 | 1,431 |
| Total operating expenses | 17,164 | 18,293 | 74,890 | 71,894 |
| Operating loss | (15,998) | (18,127) | (79,468) | (75,679) |

| | | | | |
|---------------------------------------------------------------------------------------------------|--------------------|--------------------|--------------------|--------------------|
| Other (expense) income, net: | | | | |
| Change in fair value of warrant liabilities | (1,046) | — | 1,232 | — |
| Interest income | 276 | 365 | 1,553 | 1,141 |
| Interest expense | — | — | — | (410) |
| Other expense, net | (289) | (34) | (1,436) | (295) |
| Total other (expense) income, net | <u>(1,059)</u> | <u>331</u> | <u>1,349</u> | <u>436</u> |
| Loss before income taxes | (17,057) | (17,796) | (78,119) | (75,243) |
| Income tax expense | (178) | (94) | (314) | (318) |
| Net loss | <u>(17,235)</u> | <u>(17,890)</u> | <u>(78,433)</u> | <u>(75,561)</u> |
| Net loss per common share attributable to common stockholders – basic and diluted | <u>\$ (0.07)</u> | <u>\$ (0.08)</u> | <u>\$ (0.31)</u> | <u>\$ (0.32)</u> |
| Weighted average number of shares used in computing net loss per common share – basic and diluted | <u>264,348</u> | <u>236,843</u> | <u>249,685</u> | <u>236,492</u> |
| Comprehensive loss: | | | | |
| Net loss | (17,235) | (17,890) | (78,433) | (75,561) |
| Foreign currency translation gain (loss) | 1,196 | 2,151 | 1,280 | (1,867) |
| Unrealized gain (loss) on available-for-sale investments | 23 | 353 | 496 | (257) |
| Comprehensive loss | <u>\$ (16,016)</u> | <u>\$ (15,386)</u> | <u>\$ (76,657)</u> | <u>\$ (77,685)</u> |

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

| | <u>December 31,</u> <u>2023</u> | <u>December 31,</u> <u>2022</u> |
|------------------------------------------------|------------------------------------|------------------------------------|
| Assets | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 17,096 | \$ 6,329 |
| Short-term investments, available-for-sale | 3,971 | 64,195 |
| Accounts receivable, net | 3,508 | 2,256 |
| Inventory, net | 7,172 | 8,284 |
| Prepaid expenses | 3,143 | 3,584 |
| Employee retention tax credit receivable | — | 554 |
| Other current assets | <u>1,496</u> | <u>1,671</u> |
| Total Current Assets | <u>36,386</u> | <u>86,873</u> |
| Restricted cash | 1,642 | 1,141 |
| Long-term investments, available-for-sale | — | 3,865 |
| Inventory, net of current portion | 4,043 | 5,469 |
| Property and equipment, net | 8,959 | 9,542 |
| Intellectual property, net | 1,237 | 1,576 |
| Deferred tax assets, net | 44 | 174 |
| Operating lease right-of-use assets, net | 5,165 | 4,950 |
| Other long-term assets | <u>1,610</u> | <u>2,463</u> |
| Total Assets | <u>\$ 59,086</u> | <u>\$ 116,053</u> |
| Liabilities and Stockholders' Equity | | |
| Current Liabilities: | | |
| Accounts payable | \$ 4,145 | \$ 3,348 |
| Accrued employee compensation and benefits | 5,390 | 4,508 |
| Accrued expenses and other current liabilities | 1,636 | 1,293 |
| Operating lease liabilities, current | 1,036 | 800 |
| Deferred revenue | <u>421</u> | <u>465</u> |
| Total Current Liabilities | 12,628 | 10,414 |

| | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|------------|
| Long-Term Liabilities: | | |
| Deferred revenue – less current portion | 290 | — |
| Contingent consideration | 2,220 | 1,256 |
| Warrant liabilities | 5,888 | — |
| Noncurrent operating lease liabilities | 4,646 | 4,738 |
| Total Liabilities | 25,672 | 16,408 |
| Commitments and Contingencies | | |
| Stockholders' Equity | | |
| Common stock \$0.001 par value, 750,000,000 shares authorized at December 31, 2023 and December 31, 2022; 264,921,526 and 236,895,440 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively | 265 | 237 |
| Preferred stock, \$0.01 par value, 25,000,000 shares authorized, no shares issued and outstanding at December 31, 2023 and December 31, 2022 | — | — |
| Additional paid-in capital | 973,129 | 962,731 |
| Accumulated deficit | (939,368) | (860,935) |
| Accumulated other comprehensive loss | (612) | (2,388) |
| Total Stockholders' Equity | 33,414 | 99,645 |
| Total Liabilities and Stockholders' Equity | \$ 59,086 | \$ 116,053 |

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

| | Years Ended | |
|--------------------------------------------------------------------------------------------------|--------------|-------------|
| | December 31, | |
| | 2023 | 2022 |
| Operating Activities: | | |
| Net loss | \$ (78,433) | \$ (75,561) |
| Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities: | | |
| Depreciation | 3,276 | 3,368 |
| Amortization of intangible assets | 453 | 7,708 |
| (Accretion) amortization of discounts and premiums on investments, net | (482) | 565 |
| Stock-based compensation | 7,918 | 8,416 |
| Deferred tax expense | 132 | 318 |
| Change in inventory reserves | 324 | 620 |
| Bad debt expense | — | 9 |
| Property and equipment impairment | 374 | 1,431 |
| Loss on disposal of property and equipment | — | 122 |
| Change in fair value of warrant liabilities | (1,232) | — |
| Change in fair value of contingent consideration | 964 | (1,115) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (1,178) | (1,528) |
| Inventory | 129 | (2,302) |
| Operating lease right-of-use assets | (206) | 232 |
| Prepaid expenses | 424 | (450) |
| Employee retention tax credit receivable | 554 | 757 |
| Other current and long-term assets | 1,173 | (2,101) |
| Accounts payable | 574 | 35 |
| Accrued employee compensation and benefits | 881 | 4,523 |
| Accrued expenses and other current liabilities | 365 | (3,955) |
| Deferred revenue | 233 | (55) |
| Operating lease liabilities | 130 | 26 |
| Net cash and cash equivalents used in operating activities | (63,627) | (58,937) |
| Investing Activities: | | |
| Purchase of available-for-sale investments | (12,268) | (33,886) |
| Proceeds from maturities of available-for-sale investments | 77,335 | 82,702 |
| Purchase of property and equipment | (561) | (1,279) |

| | | |
|---------------------------------------------------------------------------------|-----------|----------|
| Net cash and cash equivalents provided by investing activities | 64,506 | 47,537 |
| Financing Activities | | |
| Proceeds from issuance of common stock and warrants, net of issuance costs | 10,118 | — |
| 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 | 9,626 | (332) |
| Effect of exchange rate changes on cash and cash equivalents | 763 | (81) |
| Net increase (decrease) in cash, cash equivalents and restricted cash | 11,268 | (11,813) |
| Cash, cash equivalents and restricted cash, beginning of period | 7,470 | 19,283 |
| Cash, cash equivalents and restricted cash, end of period | \$ 18,738 | \$ 7,470 |
| Supplemental Disclosure for Cash Flow Information: | | |
| Cash paid for leases | \$ 1,475 | \$ 984 |
| Cash paid for taxes | \$ 352 | \$ 165 |
| Supplemental Schedule of Non-cash Investing and Financing Activities: | | |
| Transfer of inventories to property and equipment | \$ 2,941 | \$ 2,693 |
| Lease liabilities arising from obtaining right-of-use assets | \$ 1,143 | \$ 577 |

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, | |
|-------------------------------------------------------------------------|------------------------------------|-------------|-----------------------------|-------------|
| | 2023 | 2022 | 2023 | 2022 |
| Net loss attributable to common stockholders (GAAP) | \$ (17,235) | \$ (17,890) | \$ (78,433) | \$ (75,561) |
| Adjustments | | | | |
| Amortization of intangible assets (a) | 113 | 107 | 453 | 7,708 |
| Change in fair value of contingent consideration (b) | 290 | 53 | 964 | (1,115) |
| Impairment of property and equipment (c) | 374 | 999 | 374 | 1,431 |
| Change in fair value of warrant liabilities (d) | (1,046) | — | 1,232 | — |
| Adjusted net loss attributable to common stockholders (Non-GAAP) | \$ (17,504) | \$ (16,731) | \$ (75,410) | \$ (67,537) |

| | Three Months Ended December 31, | | Years Ended December 31, | |
|-----------------------------------------------------------------------------------|------------------------------------|-----------|-----------------------------|-----------|
| | 2023 | 2022 | 2023 | 2022 |
| Net loss per share attributable to common stockholders (GAAP) | \$ (0.07) | \$ (0.08) | \$ (0.31) | \$ (0.32) |
| Adjustments | | | | |
| Amortization of intangible assets (a) | — | — | — | 0.03 |
| Change in fair value of contingent consideration (b) | — | — | — | (0.01) |
| Impairment of property and equipment (c) | — | 0.01 | — | 0.01 |
| Change in fair value of warrant liabilities (d) | — | — | 0.01 | — |
| Adjusted net loss per share attributable to common stockholders (Non-GAAP) | \$ (0.07) | \$ (0.07) | \$ (0.30) | \$ (0.29) |

The non-GAAP financial measures for the three months and years ended December 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 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 Senhance Systems under operating leases that are not expected to generate future cash flows sufficient to recover their net book value.
- d) During 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 consolidated statements of operations and comprehensive loss.

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