

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

November 14, 2023
Date of Report (date of earliest event reported)

Asensus Surgical, Inc.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

0-19437
(Commission
File Number)

11-2962080
(I.R.S. Employer
Identification Number)

1 TW Alexander Drive, Suite 160
Durham, NC 27703
(Address of principal executive offices)
919-765-8400
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock \$0.001 par value per share	ASXC	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On November 14, 2023, Asensus Surgical, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the third quarter ended September 30, 2023. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on November 14, 2023, following the issuance of the press release referred to above, the Company conducted a conference call to discuss the reported operating and financial results for the third quarter ended September 30, 2023. The Company had issued a press release on November 7, 2023 to announce the scheduling of the conference call. A copy of the transcript of the conference call is furnished herewith as Exhibit 99.2.

The information included herein and in Exhibit 99.1 and Exhibit 99.2 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (“Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated November 14, 2023
99.2	November 14, 2023 conference call transcript
104	Cover Page Interactive Data File (formatted in inline XBRL)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ASENSUS SURGICAL, INC.

Date: November 16, 2023

/s/ Shameze Rampertab

Shameze Rampertab

Executive Vice President and Chief Financial Officer

Exhibit 99.1

Asensus Surgical, Inc. Reports Operating and Financial Results for the Third Quarter 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 September 30,		Nine Months Ended 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, 2023</u>	<u>December 31, 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	<u>(50,253)</u>	<u>(44,884)</u>
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	<u>57,079</u>	<u>41,210</u>
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	<u>9,454</u>	<u>(332)</u>
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	<u>\$ 23,284</u>	<u>\$ 14,977</u>
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)	<u>\$ (15,560)</u>	<u>\$ (16,942)</u>	<u>\$ (57,906)</u>	<u>\$ (50,806)</u>

	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)	<u>\$ (0.06)</u>	<u>\$ (0.07)</u>	<u>\$ (0.24)</u>	<u>\$ (0.21)</u>

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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ASXC Third Quarter 2023 Earnings Call Transcript**Forward Looking Statements - Mark Klausner**

Good afternoon, everyone, and thank you for joining us for the Asensus Surgical third quarter 2023 business and financial update conference call. On the call with me today are Anthony Fernando, President and Chief Executive Officer; and Shameze Rampertab, Chief Financial Officer.

Before we begin, I would like to caution listeners that certain information discussed by management during this conference call, including any guidance provided, are forward-looking statements covered under the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. Actual results could differ materially from those stated or implied by our forward-looking statements due to risks and uncertainties associated with the company's business, including any geopolitical factors beyond our control. The company undertakes no obligation to update the information provided on this call. For a discussion of risks and uncertainties associated with the Asensus Surgical business, I encourage you to review the company's filings with the Securities and Exchange Commission, including the 2022 Form 10-K filed in March 2023 and the Form 10-Q expected to be filed later today and any other filings we make with the SEC.

During this call, we will also present certain non-GAAP financial information related to adjusted net loss attributable to common stockholders and the adjusted net loss per common share attributable to common stockholders. Management believes that these non-GAAP financial measures, taken in conjunction with US GAAP financial measures, provide useful information for both management and investors by excluding certain non-cash and other expenses that are not indicative of the company's core operating results.

Management uses non-GAAP financial measures to compare our performance relative to forecast and strategic plans, to benchmark outperformance externally against competitors and for certain compensation decisions. Reconciliations from US GAAP to non-GAAP results are presented in the tables accompanying our earnings release, which can be found in the Investor Relations section of our website.

With that, it's my pleasure to turn the call over to Asensus Surgical's President and Chief Executive Officer, Anthony Fernando.

CEO Introductory Section – Anthony Fernando

Thanks, Mark, and thank everyone for joining us today. To kick off, I'll provide an overview of our recent performance and key achievements, after which Shameze will detail our financial results. Next, I'll update you on our priorities for the remainder of 2023 before we open the line for questions.

Before I dive into the quarterly review, I would like to take a moment to acknowledge the recent events in Israel. The attacks and escalating conflict there have deeply affected us all. I extend our deepest sympathies to those who have suffered losses or injuries, and to all impacted by the violence. Our thoughts and support are with our team in Israel and their families during this time. We're proud of the incredible care and support they've shown one another, with some of our own team members and their spouses having been called to military service. I would like to say thank you to our team in Israel for managing through this trying time.

Turning to an overview of the third quarter. We're pleased to share that we've reached significant milestones recently. One of the key achievements includes finalizing an advance manufacturing partnership for our upcoming LUNA Surgical System, ensuring a reliable manufacturing process for this innovative technology. Additionally, we've partnered with a graphics hardware provider to enhance the capabilities of our ISU, which will contribute to improved performance. Our ongoing focus remains on expanding the adoption of Senhance, increasing utilization, advancing our clinical evidence, refining our portfolio to enhance Senhance's capabilities and deliver the value of Performance-Guided Surgery through the launch of LUNA.

During the quarter, four clinical papers were published, two of which I want to discuss. These studies highlight the promising performance of Senhance in comparison to the current market leading robotic system and traditional laparoscopy in various procedures. The first study from Taiwan reveals cost advantages of Senhance, with shorter operative times and comparable patient outcomes vs the current market leading robotic system. The second study emphasizes Senhance's comparable outcomes to laparoscopic procedures, with the added benefit of shorter hospital stays. Incision-to-suture times also showed a close match between Senhance and laparoscopy. More information on all the papers published can be found on our website.

Procedure volumes continue to be an important input to develop and improve our digital surgery capabilities. Year-to-date, our performance reflects a strong 17% growth in procedures. During the third quarter, we saw 2% year over year growth, and over 760 Senhance procedures performed across a variety of specialties globally. Our machine learning engine improves as we continue to gather surgical data, enabling us to offer useful clinical intelligence to surgeons via the ISU.

Another positive aspect of increased procedure volumes is the expansion of our clinical registry. As of this call, our TRUST registry has grown to include data from over 3,000 patients, with cases across gynecology, general surgery, and urology. This growth signifies a notable step forward in our efforts to accumulate valuable patient data to help inform surgical decision-making and ultimately help to improve patient care.

The Senhance clinical registry is one of a kind collection of data and the only registry focused on digital laparoscopy. The TRUST registry is a multi-specialty clinical registry that is investigator-led and managed by a 3rd party clinical research organization with full ethics committee approval at each institution.

The primary goal of this registry is to create a collection of 60+ intraoperative data points and 12-month postoperative follow-up data. This information will serve as a foundation for a greater number of high-quality clinical publications and play a vital role in advancing our market development strategy.

Moving to new program initiations, we initiated two new Senhance programs in the quarter ended September 30, 2023.

In August, we initiated a program with First Towakai Hospital in Japan. The Senhance System is being used in their urology and gynecology centers and gastroenterology department. We're seeing ongoing expansion in Japan, solidifying agreements with highly regarded institutions. The encouraging progress in Japan is a testament to our efforts, and we're enthusiastic about further driving adoption in the region.

The second was Mayo Clinic Hospital, Saint Marys Campus, the leading United States-based hospital that was announced in July. This marks an important milestone as this is the first system to be exclusively utilized by pediatric surgeons at a United States-based hospital. The Senhance system is well-suited for pediatric procedures, given a mix of unique features like augmented intelligence, machine learning, haptic feedback, eye-tracking camera control, 3D visualization, and most importantly, specialized 3 & 5 mm instruments.

Subsequent to the end of the third quarter, we initiated two additional Senhance programs:

The first was Klinikum Idar-Oberstein Hospital in Germany to be used by their Clinic for General, Visceral and Minimally Invasive Surgery. The second system was sold to the Company's distribution partner, and will be placed in a pediatric hospital in the Commonwealth of Independent States (CIS) region.

In March of this year, we expanded our U.S. Pediatric indication, complementing our existing regulatory approvals in Europe and Japan. This expansion allowed us to engage with leading pediatric surgeons, especially those operating at top childrens' hospitals, who have recognized the distinct advantages of Senhance for younger patients. The system's smaller instruments, a digital fulcrum to minimize tissue trauma, and haptic feedback for precise touch and feel have been particularly appreciated by surgeons, as they enable the preservation of the benefits of minimally invasive surgery for delicate pediatric tissues.

As we discussed on our last call, July marked an important milestone for Pediatric surgeons from around the world to converge at the 1st Joint meeting of the European Society of Pediatric Endoscopic Surgeons and International Pediatric Endosurgery Group societies in Sorrento, Italy. Asensus played a prominent role delivering an impactful Robotics Masterclass highlighting the integration of cognitive science, data science, and robotics, providing attendees with valuable insights on the application of robotics in pediatrics as well as the opportunity to gain hands-on experience. With hundreds of customer interactions at this surgical forum, Asensus went on to host potential customers at our headquarters in Research Triangle Park and in Milan as well as partner with leading childrens' hospitals to execute awareness events that engaged these leaders in considering how to incorporate Senhance into their clinical programs.

With Pediatric surgeons and thought leaders recognizing Asensus's unique system design which not only preserves minimally invasive surgery but goes beyond by advancing laparoscopy and robotics with digital surgery solutions, the interest in Senhance and the ISU for pediatric applications continues to grow, and we're committed to meeting this rising demand in the pediatric market.

I'd also like to highlight our recently launched eBook, titled, "Augmented Intelligence: The Answer to Surgery's Shortcomings", which has generated positive responses from the medical community. The eBook explores how Performance-Guided Surgery can address surgical variability, providing operational advantages for surgeons, cost-efficient advancements for hospitals, and improved patient outcomes. It highlights the potential for technology adoption to attract and nurture talent in the medical field, ultimately enhancing hospital reputations. The eBook can be found on our website or LinkedIn, and I'd encourage everyone to read it.

Now taking a look at the portfolio development front.

Starting with the recently announced agreement with Flex for LUNA System manufacturing. Under this agreement, Flex will provide a range of design and advanced manufacturing services across LUNA's product lifecycle to enable us to deliver the LUNA platform at scale. Flex's proven track record of delivering complex electromechanical systems across diverse industries and deep understanding of the complex requirements for medical devices will enable us to accelerate time-to-market for our LUNA platform. Also, Flex's focused portfolio of advanced manufacturing capabilities and trusted supply chain network will also be instrumental in scaling LUNA globally."

In September, we announced a collaboration with NVIDIA to enhance the capabilities of the ISU. By directly collaborating on NVIDIA's advanced tools, we aim to refine the ISU's augmented intelligence features and further develop advanced features based on surgeon feedback. The ISU, already powered by NVIDIA's hardware, has been providing real-time support to surgeons since 2021. This announced collaboration will expand the relationship to facilitate shared access to product roadmaps. We are exploring innovative models for the development and deployment of digital surgical solutions, leveraging NVIDIA's edge AI computing platform, Holoscan. This collaboration highlights the potential for improved decision-making in surgical procedures through the application of advanced AI tools, aligning the goals of both companies and highlighting the growing importance of data-driven technologies that support surgeons and advance surgery.

With an overarching focus on data, our collaboration with Google also holds immense value, particularly in our joint efforts in data collection and analysis. This partnering integrates Google's cutting-edge machine learning tools and secure cloud data architecture with our Performance-Guided Surgery framework. By harnessing the data gathered through the ISU in tandem with Google Cloud's leading technologies and providing surgeons with real-time intraoperative clinical intelligence, we have the potential to achieve superior outcomes for patients.

Regarding KARL STORZ, our discussions are ongoing. Both organizations are dedicated to expediting the finalization of an agreement and we will provide an update once these conversations conclude.

To wrap up, I'm pleased with the progress we've achieved in the third quarter and continue to build on the groundwork for sustained success. I'll now pass the floor to Shameze for a financial update.

Financials - Shameze Rampertab

Thanks, Anthony. Turning to the third quarter, 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 attributable to common stockholders was \$18.3 million, or \$0.07 per share, as compared to a net loss attributable to common stockholders of \$18.9 million, or \$0.08 per share, in the three months ended September 30, 2022.

For the three months ended September 30, 2023, the adjusted net loss attributable to common stockholders was \$15.6 million, or \$0.06 per share, as compared to an adjusted net loss of \$16.9 million, or \$0.07 per share, in the three months ended September 30, 2022.

Adjusted net loss is GAAP net loss, adjusted for the following items; amortization of intangible assets, change in fair value of contingent consideration, and change in fair value of warrant liabilities, all of which are non-cash charges. Adjusted net loss attributable to common stockholders is a non-GAAP financial measure. Reconciliation from GAAP to non-GAAP measures can be found in our earnings release.

Turning to the balance sheet. In July, we completed a registered direct offering, bringing in gross proceeds of approximately \$10 million. We plan to allocate these funds to reinforce our working capital and contribute to research and development. The company had cash, cash equivalents, and short-term investments, excluding restricted cash of approximately \$33.1 million as of September 30, 2023. Based on the recent financing and our current operating plan, we project our cash runway has been extended through late second quarter of 2024.

I'll turn the call back over to Anthony.

CEO Conclusion - Anthony Fernando

Thanks, Shameze.

As we look ahead, let's delve into what lies on the horizon for Asensus and what you can anticipate in the coming months

With regards to the LUNA program, our timeline remains on track and we expect to complete full system integration and testing and the pre-clinical evaluation by the end of the fourth quarter, this year. We will freeze the system's design in Q1 2024, conduct verification and validation testing, and ramp up pilot manufacturing and prepare for regulatory submissions.

In terms of our LUNA go-to-market strategy, I'd like to reiterate our two key advantages. Firstly, we've established a clear regulatory pathway for LUNA. Based on our communications with the FDA, in-house regulatory expertise, and our track record with successful submissions for Senhance, we anticipate leveraging the time and cost-effective Traditional 510(k) pathway in the U.S., as opposed to a more rigorous de novo pathway. Second, LUNA's innovative economic model, coupled with its clinical performance, is poised to drive commercial adoption. Beyond our current leasing and capital purchase options, we're exploring a subscription-based model for hospitals.

Turning to our ongoing ISU development efforts. We have one milestone for the remainder of the year, the ramp up of manufacturing for the future ISU, which we believe we will have by the end of the fourth quarter.

Regarding Senhance initiations, we are refining our expectations to initiate 8 to 10 new programs in 2023, down from 10 to 12. This adjustment is in response to the evolving capital environment. We're taking into consideration factors like market trends and tightened budget considerations. We believe this refined outlook provides a balanced approach that aligns with the current landscape.

In conclusion, we are poised for significant milestones in the coming quarters. With the LUNA program's timeline remaining steady, our ongoing focus remains on expanding the adoption of Senhance, increasing utilization, advancing our clinical evidence, and advancing our digital capabilities. I want to thank our global team for their hard work and dedication to make these truly novel technologies a reality. Our commitment to advancing surgical technology and delivering exceptional outcomes for patients remains strong.

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

Q&A

Operator

Your first question comes from the line of Swayampakula Ramakanth from H.C. Wainwright. Your line is now open.

First Question – RK Ramakanth

Thank you. This is RK from H.C. Wainwright. Good afternoon, Anthony and Shameze. Hope you guys are doing good. Yes, so to start off, with the installations from where you ended the conversation. You will have currently five installations so far for the year. With less than four or five weeks of business weeks, what gives you confidence that you can get three installations done before ending the year?

Response – Anthony Fernando

Thanks for the question, RK. I mean, we are quite bullish about the forecast that we put out. Again, these are already pipeline accounts, and we've been working through some of these transactions over the months during Q3 and into Q4. I think, therefore, for most of these pipeline accounts, there are a few more steps in the process, and so far, they are all tracking to be completed before the end of the fourth quarter. Time is short, but we feel pretty good about getting to the 8 to 10 number from where we are.

Question – RK Ramakanth

Very good. In terms of procedures, it's nice to see that cadence of growth in terms of the procedures itself. But is there a way for you to amplify that into what sort of procedures you're seeing? Are there certain kinds of procedures which are being performed on a regular basis? So that we understand where the utility is of this Senhance system itself. Also, any commentary at all from the folks at Mayo Clinic in the pediatric hospitals?

Response – Anthony Fernando

Yes. Okay. I think when it comes to procedure mix, we have not seen a big change per se. General surgery kind of leads the charge with gynecology following, and then urology being a third specialty. It's been relatively consistent through the year and even moving from last year.

I think the one piece that's added on to it and kind of increasing or growing this year is pediatric, because we've seen increased pediatric use in Europe, and then also with Mayo Clinic starting their program, that's going extremely well. The case numbers are increasing week over week with them scheduling more cases. So, we are still at an early point. We have more than 1/3 trained there. I think one or two more to be trained but procedure numbers are growing, and they are doing quite well in getting started at the Mayo Clinic.

Question – RK Ramakanth

Very good. In terms of the Japanese installation, in your commentary, you were saying how comfortable you are with the growth and where the adoption is going in terms of in Japan. How much of the market is still left because I think a couple of years ago, Japan kind of jumped in terms of your installations of the device. Then this year, we have not seen as many. So, what are your thoughts on that? Do you think you need to add more resources in Japan to make sure that you can fully utilize that opportunity?

Response – Anthony Fernando

RK, with respect to Japan, year-to-date we've done the two systems, and we have some pipeline to close there between now and year-end as well. I think the thing is trying to find the right institutions who can perform cases, demonstrate really good utility, and then be able to publish and share their experiences. That's really the focus that we really want to drive in Japan to make sure that we have a very robust foundation of procedures and institutions, and build a nice KOL network who can speak about their performance and Senhance performance, so that it will become even simpler for us to expand.

I mean, the team in Japan is doing—for the size of team, they're doing extremely well. Even looking at procedure growth, I think Japan, this year, is really having a record year in terms of procedure volume growth compared to last year. That's the reason why we feel really good about how things are progressing. In Japan, it's growing, and you've seen the two. We are hoping to be able to close the year with some additional sites in Japan this year.

Question – RK Ramakanth

The last question for me. You made some commentary on ongoing discussions with KARL STORZ. What sort of discussions are we talking about? I know you had like two or three different conversations going on with them, and I'm just trying to understand which conversation is this about?

Response – Anthony Fernando

I wouldn't say there's a drastic difference in the conversation. It's just trying to—it becomes very complicated given the field that we are in, and also looking at what we intend to do in the future and our portfolio and road map, and what they are intending to do. We are still talking about visualization and even potentially the digital element of it and try to find the right balance in terms of what the right relationship might look like and be mutually beneficial.

Question – RK Ramakanth

Thank you. Thanks for answering all my questions.

Response – Anthony Fernando

Thank you, RK.

Operator

The final question comes from the line of Ross Osborn from Cantor Fitzgerald. Your line is now open.

Question – Ross Osborn

Hi, guys. Thanks for taking our questions. Following the announcement that Mayo has adopted your system, have you seen an increase in inbound interest, given the reputation, particularly from a pediatric stance?

Response – Anthony Fernando

Hi, Ross. Great question. The simple answer is yes. I think after we announced Mayo, and also some of the pediatric meetings that we attended in Europe, and then subsequent there was a smaller meeting in Texas. All of that has generated really good interest, so we continue to have discussions with multiple hospitals in the U.S., primarily focused on pediatrics. Having a leading hospital here like Mayo Clinic, already using the system kind of validates that thesis. That has opened some good opportunities, and we are pretty active in having conversations with other pediatric institutions.

Question – Ross Osborn

Great. Glad to hear it. Turning to volumes, and I realize volumes are up year-to-date relative to the last year. But could you provide more color on what drove procedure volumes down to a quarterly low for the year in your view?

Response – Anthony Fernando

Yes, Ross, I think, primarily, the slowdown came from Europe, and the European (inaudible) between the holidays and summer breaks, etc. That had a contribution to that which I think was the primary player for the reason why we didn't see a quarter-over-quarter growth. Also, in the U.S., we didn't see as much growth compared to what we saw last year. That was the primary reason for the quarter. But on an annualized basis, I think 17% is where we are, and we are hoping to keep driving that number up in the fourth quarter as well.

Question – Ross Osborn

Okay. Got it. Lastly, could you provide a little bit of background on Flex and what drove you to partner with them for LUNA?

Response – Anthony Fernando

Yes, Ross. I think the LUNA platform is a relatively complex system. For us, we've always tried to focus on what we are good at and really where we can add value. We understand the robotic space and the digital space and have very strong R&D, regulatory capabilities to execute on that.

When it comes to manufacturing, several years ago, probably about two, two and a half years ago, we came to the conclusion that it doesn't make sense for us to deploy capital in a sense when there are specialists in the field like Flex who understand medical device, who have really extensive supply chain networks that can provide us really good cost in terms of procurement.

With that, we started this dialogue almost two years ago, and we've been working on multiple small projects with them, and that led to us trying to take a much bigger holistic view and say, "Okay, why don't we work with you guys on the entire platform, instead of the subassemblies or subcomponents that we've been talking about over the last two years, which led to this agreement where they will help us, and they will share their expertise, and we'll collaborate on them ultimately taking over the full manufacturing where they are very well suited to take this on.

Question – Ross Osborn

Got it. Thanks for taking our questions.

Response – Anthony Fernando

Thank you, Ross.

Operator

There are no further questions at this time. I will now hand the call back to Anthony Fernando for closing remarks.

Anthony Fernando

Thanks again for joining us today and for your support of Asensus. We look forward to updating you on our next quarterly call. Thank you.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for your participation. You may now disconnect.