

**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**

March 21, 2024
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 March 21, 2024, Asensus Surgical, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2023. A copy of the press release is furnished herewith as Exhibit 99.1.

The press release includes a link to a specific item on the Company’s website. The Company’s website is not incorporated by reference into this Form 8-K.

Also on March 21, 2024, 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 fourth quarter and full year ended December 31, 2023. The Company had issued a press release on March 15, 2024 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 Exhibits 99.1 and 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 March 21, 2024
99.2	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.

Date: March 25, 2024

ASENSUS SURGICAL, INC.

/s/ Shameze Rampertab

Shameze Rampertab

Executive Vice President and Chief Financial Officer

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

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 December 31,		Years Ended 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	(1,059)	331	1,349	436
Loss before income taxes	(17,057)	(17,796)	(78,119)	(75,243)
Income tax expense	(178)	(94)	(314)	(318)
Net loss	(17,235)	(17,890)	(78,433)	(75,561)
Net loss per common share attributable to common stockholders – basic and diluted	\$ (0.07)	\$ (0.08)	\$ (0.31)	\$ (0.32)
Weighted average number of shares used in computing net loss per common share – basic and diluted	264,348	236,843	249,685	236,492
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	\$ (16,016)	\$ (15,386)	\$ (76,657)	\$ (77,685)

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	1,496	1,671
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	1,610	2,463
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	421	465
Total Current Liabilities	<u>12,628</u>	<u>10,414</u>
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	<u>25,672</u>	<u>16,408</u>
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	<u>33,414</u>	<u>99,645</u>
Total Liabilities and Stockholders' Equity	<u>\$ 59,086</u>	<u>\$ 116,053</u>

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	<u>(63,627)</u>	<u>(58,937)</u>
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	<u>64,506</u>	<u>47,537</u>
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	<u>9,626</u>	<u>(332)</u>
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	<u>\$ 18,738</u>	<u>\$ 7,470</u>
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)	<u>\$ (17,504)</u>	<u>\$ (16,731)</u>	<u>\$ (75,410)</u>	<u>\$ (67,537)</u>

	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)	<u>\$ (0.07)</u>	<u>\$ (0.07)</u>	<u>\$ (0.30)</u>	<u>\$ (0.29)</u>

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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617-874-5488

ASXC Fourth Quarter 2023 Earnings Call Transcript

Forward Looking Statements - Mark Klausner

Good afternoon, everyone, and thank you for joining us for the Asensus Surgical fourth quarter and full year 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 2023 Form 10-K expected to be filed 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 you all for being with us today. To start, I'll give a summary of our recent performance and notable accomplishments in 2023. Then, Shameze will dive into our financial results. Following that, I'll discuss our focus areas for 2024, and finally, we'll open the floor for any questions you may have.

I am pleased with the progress we've made throughout 2023 and the solid foundation we've built for the future. We continued to drive greater adoption and utilization of both Senhance and the ISU, while at the same time making significant progress towards the development of our next generation LUNA surgical system.

Growing procedure volumes remains a critical factor as we seek to refine and enhance our digital surgery capabilities. Globally, over 3,550 procedures were performed using the Senhance System in 2023, marking a 13% increase from 2022. During the fourth quarter, we saw over 835 Senhance procedures performed across a variety of specialties globally. As we continue to gather surgical data, our machine learning engine improves, enabling us to provide valuable clinical insights to surgeons through the ISU.

A testament to this, last month, we announced the completion of more than 1,000 successful cases each, at three hospitals: Evangelisches Krankenhaus Wesel in Germany, Klaipeda University Hospital in Lithuania and Presidential Clinic Astana in the CIS region. Another encouraging trend we've observed is at Idar-Oberstein Hospital, where, in just four months since the program's initiation in November 2023, they have completed over 110 cases. These achievements underscore the growing acceptance and confidence in Senhance, and how our customers are realizing the value Senhance brings to the OR.

Due to the increased procedure volumes, our TRUST registry now includes data from over 3,200 patients, with a growing number of cases which has been aided by the continued expansion of sites participating in the registry.

Additionally, during the year, nine peer-reviewed clinical papers were published, including a paper exploring surgeon stress levels using Senhance. Led by TRUST investigators, this study compared stress levels between surgeons using Senhance and traditional laparoscopic surgery. After analyzing 350 procedures, the research found that Senhance users experienced lower overall stress levels compared to laparoscopic surgeons due to reduced physical demands and distractions during procedures.

Moving to new program initiations, we initiated five new Senhance programs in the fourth quarter, including one in Germany, one in Romania, two in the CIS region and one in Japan at Nagoya University Hospital, bringing the total for the year to eight. One of these program initiations was to a pediatric hospital in Romania, representing the 6th hospital to be leveraging the Senhance for pediatric procedures. With specialized 3mm and 5mm instruments, the Senhance Surgical System is uniquely designed for the delicate nature of pediatric procedures. As more pediatric surgeons recognize Asensus's unique system design, which not only preserves minimally invasive surgery but also advances laparoscopy and robotics with digital surgery solutions, we expect interest in Senhance and the ISU for pediatric applications to continue to grow. We're committed to meeting this rising demand in the pediatric market.

To wrap up, I'm pleased with the progress we've achieved in the fourth 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 fourth quarter, 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 attributable to common stockholders was \$17.2 million, or \$0.07 per share, as compared to a net loss attributable to common stockholders of \$17.9 million, or \$0.08 per share, in the three months ended December 31, 2022.

For the three months ended December 31, 2023, the adjusted net loss attributable to common stockholders was \$17.5 million, or \$0.07 per share, as compared to an adjusted net loss of \$16.7 million, or \$0.07 per share, in the three months ended December 31, 2022.

Adjusted net loss is GAAP net loss, adjusted for the following items; amortization of intangible assets, change in fair value of contingent consideration, property and equipment impairment, 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. The company had cash, cash equivalents, and short-term investments, excluding restricted cash of approximately \$21.1 million as of December 31, 2023. In the third quarter of 2023, we initiated a cash burn reduction plan to streamline expenses. As a result of the plan, we saw a cash burn decrease in the fourth quarter and into the first quarter. Based on the recent financing and our current operating plan, we project that available cash will now sustain operations until early June 2024.

I'll turn the call back over to Anthony.

CEO Conclusion - Anthony Fernando

Thanks, Shameze.

We wanted to provide an update on what lies ahead at Asensus in 2024.

Starting with LUNA - in December, we 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 system's functionality in thirteen different procedures across gynecology, urology, and general surgery. The Surgeon Lab highlighted LUNA's notable range of motion and instrument dexterity, essential for precise surgical maneuvers. Surgeons also appreciated the strength and reliability of the 5mm TrueWrist instrument line, offering versatility with different instrument types. Additionally, they found the ergonomic design of the LUNA surgeon console and easy patient access to be noteworthy features. The positive feedback from participating surgeons underscores our dedication to developing and delivering a surgical robotic platform that exceeds expectations. Insights gathered during this evaluation will aid in refining the system design, bringing us closer to a finalized product.

For a closer look at the Surgeon Lab and insights from the participating surgeons, a video is available on our investor relations website. The video provides an overview of the LUNA system's features, demonstrating its range of motion, instrument strength, and ergonomic benefits.

In order to conserve capital, we are adjusting our development timeline. This decision allows us to maintain fiscal stability while still advancing towards key milestones for LUNA. We now intend to freeze the system's design in Q3 2024, and conduct verification and validation testing in Q4 2024. Subsequently, we will initiate pilot manufacturing and prepare for regulatory submissions. The submission is now expected in the second half of 2025, with clearance anticipated in the first half of 2026, followed by a launch thereafter. As we have shared before, we are following a clear and defined regulatory pathway for LUNA. Drawing from our interactions with the FDA, and our proven success in submissions for Senhance, we anticipate following a Traditional 510(k) pathway in the U.S., rather than the more rigorous de novo pathway, which we believe will save both time and costs.

Additionally, we have some important LUNA digital solutions milestones to highlight in the near term. By Q2 2024, we aim to integrate several new features into our digital platform, including advanced analytical tools with multi-point and plane measurement functions, innovative training and communication tools with Telestration capabilities, and enhanced safety features.

Furthermore, we're striving to conduct prototype testing for our digital features within the same timeframe. Surgeon advisors will give us valuable feedback on functionality and user experience, helping us ensure that our digital solutions are user-friendly and effective.

In parallel, we're planning to launch our Customer Portal Website globally during Q2 2024. This platform will be accessible to all Senhance users with Asensus Cloud connectivity, providing useful resources like procedure-specific data, statistics, and downloadable or shareable videos. It's a significant step forward in improving collaboration and accessibility within our user community.

Turning to our ongoing ISU development efforts, our primary goal for the year is to ramp up manufacturing for the future ISU hardware with our partners. Additionally, we're working on completing the design for two ISU configurations and expect that we will be finalizing the hardware by the second quarter of 2024. These configurations include the LUNA ISU, which supports a robotic platform configuration, and the Standalone ISU, aimed at enhancing laparoscopic procedures. These configurations will offer flexibility and efficiency to meet various surgical needs and preferences.

Regarding Senhance initiations, we intend to initiate 8 to 10 new programs in 2024. Additionally, we expect procedure volume growth for 2024 to track close to 15 to 20% growth over 2023. The data gathered from the TRUST registry during these procedures has been immensely valuable, and with the adoption of ISU by more sites in the coming months, our data pool will expand further. This data collection from the TRUST registry and independent studies plays a vital role in bridging Senhance and LUNA. Additionally, we aim to enhance our cloud data architecture, leveraging Google Cloud's advanced technologies to provide surgeons with real-time intraoperative clinical intelligence. This initiative has the potential to achieve superior outcomes for patients.

Looking ahead to 2024, we're optimistic about reaching important milestones in the coming quarters. Our LUNA Surgical System remains our primary focus in the year. Additionally, we're dedicated to expanding Senhance adoption, increasing utilization, advancing clinical evidence, and enhancing our digital capabilities. We sincerely appreciate the hard work and dedication of our global team in bringing these innovations to life, underscoring our commitment to advancing surgical technology and improving patient outcomes.

With that, we would now like to open the line for questions.

Q&A

Operator

Your first question comes from Ross Osborn from Cantor Fitzgerald. Your line is now open.

First Question – Ross Osborn

Hey, guys. Thanks for taking the questions. I'm going to apologize for the background noise; traveling today. But starting off, would you walk through your thoughts around financing in terms of size and structure to keep the Company going past June? Then as a follow-up, where were you able to cut costs during the fourth quarter and has burn improved during the first quarter?

Response – Anthony Fernando

Hey, Ross. Thanks for the question. I think as we noted on the cash, we ended the fourth quarter with \$21 million in cash. Obviously, for capital raise and cash, we are exploring several options, including equity, non-dilutive transactions, licensing agreements. We will look to execute something, obviously, that's in the best interest of the Company and the shareholders. That's the plan.

Then on the cost, it came out from several areas. Some on the R&D front, which is why we had to shift the time lines for LUNA development and also from all the other functions. It was across the company, streamlining of expenses and our planned budgets.

Question – Ross Osborn

Okay. Understood. Then just one more question, if I may. Assuming financing comes through as needed, the story is obviously going to be about LUNA, at that point. How much capital do you think you'll need to raise to successfully develop and then commercialize LUNA, especially given the cuts over the past couple of quarters?

Response – Anthony Fernando

Ross, I think you can work through the burn based on what we've done before the previous quarters, and that's the trajectory that we need to continue to intersect with the time lines that we have outlined. We have the right—we have the team in place, and then we've been doing all the right things to get to where we need to. Now it's just a matter of time purely for execution. I'm sure you can work up the numbers based on historical burn and that will continue on through to regulatory approval.

Question – Ross Osborn

Understood. Thanks for taking my questions.

Response – Anthony Fernando

Thank you, Ross.

Operator

Your next question comes from RK Ramakanth from H.C. Wainwright. Your line is now open.

Question – RK Ramakanth

Thank you. Good afternoon, Anthony and Shameze. Looking at your past history and how you've been able to add new initiations year-after-year. Have you understood how the market is working for you in the sense because you certainly managed to get your eight to 10 initiations, but in terms of trying to get better than that, what needs to be done? Also, how are you thinking of managing the growth of the procedure volumes as well?

Response – Anthony Fernando

Okay. Thank you for the question. I'll take the two parts; I'll take the latter part first. With respect to procedures, some of the sites are mature sites that have seen the benefit of Senhance in terms of efficiency and cost and familiarity with laparoscopy and their training. That is driving increased usage at some of the mature sites. Then some of the newer sites have seen this, and they are trying to mimic that kind of performance and obviously, over the years we've also gained a significant amount of experience about how best to stand up a site and drive volume at a specific site efficiently. All of that's playing through quite nicely for us to continue to grow utilization. Like I've said before, if we look at the trend of utilization on a per system basis, globally, that has been increasing year after year after year. It's not just the new systems doing more cases. That's one part.

The second part, driving Senhance adoption in terms of systems, pediatrics has been helping us quite a bit because we are seeing really good interest in pediatrics in Japan, in Europe and even in the U.S. Like last year, this time we had maybe one or two pediatric sites, now we are up to six and we anticipate that to continue to grow. Also the other sites that are working with us, they want economics to be responsible in terms of procedure costs and where there is a priority for cost. Obviously, we have a proven track record there. We are able to work together. Those are the two things I would say that we continue to be able to do that. Obviously, it will continue to grow beyond that once we get further ahead.

Question – RK Ramakanth

Okay. Thank you for that. Then in terms of the ISU, and trying to come up with these two novel configurations, I'm just trying to understand what the development time line on this and how do you plan to commercialize this at the end of the day?

Response – Anthony Fernando

Yes, okay. The two configurations, obviously, we have the first generation ISU on the market today. We are in the process of developing the second generation ISU and one version of that will be part of LUNA, that is the robotic version of the ISU. It will have some of the features that we currently have and continue to evolve in terms of performance, features, applications and so on that are related to robotic platform, robotic manipulation.

The second version of the new ISU primarily for stand-alone use on laparoscopy without a robot. We have seen interest in that area, and we are going to continue to build some of the applications that are relative and relevant to non-robotic surgery. As for commercialization, I think there are multiple ways that and again, several options are being explored. Do we do it ourselves and other partnership opportunities for us to leverage other commercial infrastructure to be able to gain adoption.

That's the commercial part is exploratory, but we know there is a need for this, and we have the clear regulatory pathway and also the features relatively well developed. That's the reason why we decided that we're going to go down two pathways and be able to offer these not only for robotic but also stand-alone use.

Question – RK Ramakanth

Okay. Thanks. Thank you for taking my questions.

Response – Anthony Fernando

Thank you, RK

Operator

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

Anthony Fernando

Thank you operator. Thank you everyone for joining today's call, and we look forward to updating you on our progress throughout the year.

Operator

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