

**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**

**August 10, 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 August 10, 2023, Asensus Surgical, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the second quarter ended June 30, 2023. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on August 10, 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 second quarter ended June 30, 2023. The Company had issued a press release on August 1, 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 August 10, 2023
99.2	August 10, 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.

Date: August 11, 2023

ASENSUS SURGICAL, INC.

By: /s/ Shameze Rampertab

Shameze Rampertab

Executive Vice President and Chief Financial Officer

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

RESEARCH TRIANGLE PARK, N.C.--(GLOBE NEWSWIRE)—August 10, 2023-- Asensus Surgical, Inc. (“the Company”) (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 second quarter 2023.

Recent Highlights

- 27% year-over-year growth in surgical procedures, with over 1,000 procedures performed globally during the quarter
- Two Senhance Surgical Programs initiated year-to-date
- Second quarter revenue of \$1.1 million
- The Company had cash and cash equivalents and short-term investments, excluding restricted cash, of approximately \$40.0 million at June 30, 2023
- Completed a \$10 million registered direct offering in July 2023

"During the second quarter, we continued to make progress on all fronts, highlighted by strong 27% year-over-year growth in procedure volumes. This continued growth plays a vital role in our ability to expand and optimize our digital surgery capabilities, enabling our machine learning engine to better provide valuable clinical intelligence to surgeons through the ISU," said Anthony Fernando, Asensus Surgical President and CEO. "Our focus for the remainder of the year will be on expanding the utilization of Senhance and advancing our clinical body of evidence. Additionally, we have some exciting milestones on the horizon, including the initiation of a preclinical evaluation of the LUNA™ Surgical System."

Upcoming 2023 Milestones

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

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

- Complete integrated system testing for LUNA Surgical System
 - Finalize manufacturing strategy for LUNA Surgical System
 - Initiate preclinical evaluation for LUNA Surgical System
 - Finalize strategic relationship with a graphics hardware provider
 - Establish pilot manufacturing for the updated Intelligent Surgical Unit™ (ISU™) platform
-

LUNA

LUNA System development has made notable progress in R&D, now transitioning to testing and evaluation before regulatory filings. Integrated system testing is set to begin in the upcoming quarter, alongside finalization of the manufacturing strategy. The pre-clinical evaluation is on track to conclude by the fourth quarter. Future milestones include freezing the system's design in Q1 2024, followed by verification, validation testing, and pilot manufacturing. By the close of 2024, submissions to the FDA and other regulatory bodies are targeted, with the anticipation of FDA clearance in mid-2025, followed by a commercial pilot launch in the second half of 2025.

The Company believes that there is a clear regulatory pathway for the LUNA System. Based on ongoing communications with the FDA, significant in-house regulatory expertise and the successful regulatory submissions for Senhance, the Company expects to utilize a traditional 510(k) pathway in the U.S., rather than the more extensive de novo pathway. The Company believes this streamlined regulatory strategy will apply not only to the United States but also to the European Union, Japan, and other parts of the world. This de-risked regulatory process should allow for a quicker time-to-market compared to new entrants in this space.

Market Development

Procedure Volumes

During the second quarter of 2023, there was a 27% increase in total surgical 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, an increase of new surgeon users at existing installations, and a broader market recovery.

2023 Senhance Program Initiations

Year to date, the Company initiated two new Senhance Surgical System placements, which consisted of one in Japan and one in the United States.

Second Quarter Financial Results

For the three months ended June 30, 2023, the Company reported revenue of \$1.1 million, as compared to revenue of \$1.0 million in the three months ended June 30, 2022. Revenue in the second 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 June 30, 2023, total operating expenses were \$18.9 million, as compared to \$18.2 million, in the three months ended June 30, 2022.

For the three months ended June 30, 2023, net loss was \$20.7 million, or \$0.09 per share, as compared to a net loss of \$19.6 million, or \$0.08 per share, in the three months ended June 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 June 30, 2023, the adjusted net loss was \$20.3 million, or \$0.09 per share, as compared to the adjusted net loss of \$17.3 million, or \$0.07 per share in the three months ended June 30, 2022, after adjusting for the following non-cash charges: amortization of intangible assets, change in fair value of contingent consideration, and impairment of property and equipment.

Balance Sheet Updates

The Company had cash and cash equivalents and short-term investments, excluding restricted cash, of approximately \$40.0 million as of June 30, 2023.

In July, subsequent to the conclusion of the second quarter, 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 late second quarter of 2024.

Conference Call

To listen to the conference call on your telephone, please dial 1-844-826-3033 for domestic callers and 1-412-317-5185 for international callers, approximately ten minutes prior to the start time. To access the live audio webcast or archived recording, use the following link <https://ir.asensus.com/events-and-presentations>. The replay will be available on the Company's website.

About Asensus Surgical, Inc.

Asensus Surgical, Inc. is digitizing the interface between the surgeon and patient to pioneer a new era of Performance-Guided Surgery by unlocking clinical intelligence for surgeons to enable consistently superior outcomes and a new standard of surgery. Based upon the foundations of digital laparoscopy and the Senhance Surgical System, the Company is developing the LUNA Surgical System, a next generation robotic and instrument system as a foundation of its digital surgery solution. These systems will be powered by the Intelligent Surgical Unit to increase surgeon control and reduce surgical variability. With the addition of machine vision, augmented intelligence, and deep learning capabilities throughout the surgical experience, we intend to holistically address the current clinical, cognitive and economic shortcomings that drive surgical outcomes and value-based healthcare. The Senhance Surgical System is now available for sale in the US, EU, Japan, Russia, and select other countries. For a complete list of indications for use, visit: www.senhance.com/indications. To learn more about Performance-Guided Surgery, and digital laparoscopy with the Senhance Surgical System visit www.asensus.com.

Follow Asensus

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

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

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

YouTube: <https://www.youtube.com/@AsensusSurgical>

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

Forward-Looking Statements

This press release includes statements relating to Asensus Surgical, our 2023 second quarter results, and our plans for the rest of 2023. 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 our continued procedure growth will play a vital role in our ability to expand and optimize our digital surgical capabilities, whether we will initiate 10-12 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, whether in the second half of 2023, we will finalize a strategic relationship with a graphics hardware provider and establish pilot manufacturing for the updated ISU platform and whether based on our current cash and current operating plan, we will have sufficient available cash to sustain operations until late second quarter of 2024. 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Product	\$ 298	\$ 254	\$ 591	\$ 601
Service	289	424	484	732
Lease	494	316	982	727
Total revenue	1,081	994	2,057	2,060
Cost of revenue:				
Product	1,612	883	2,837	1,259
Service	519	646	1,268	1,141
Lease	943	818	1,916	1,770
Total cost of revenue	3,074	2,347	6,021	4,170
Gross loss	(1,993)	(1,353)	(3,964)	(2,110)
Operating expenses:				
Research and development	8,980	7,253	19,119	13,681
Sales and marketing	4,449	3,602	9,002	7,321
General and administrative	5,124	4,992	10,592	10,525
Amortization of intangible assets	114	2,533	226	5,203
Change in fair value of contingent consideration	203	(598)	308	(752)
Impairment of property and equipment	—	432	—	432
Total operating expenses	18,870	18,214	39,247	36,410
Operating loss	(20,863)	(19,567)	(43,211)	(38,520)
Interest income	431	260	870	515
Interest expense	—	(141)	—	(341)
Other expense, net	(242)	(86)	(460)	(232)
Total other income (expense), net	189	33	410	(58)
Loss before income taxes	(20,674)	(19,534)	(42,801)	(38,578)
Income tax benefit (expense)	12	(85)	(79)	(169)
Net loss	(20,662)	(19,619)	(42,880)	(38,747)
Net loss per common share attributable to common stockholders – basic and diluted	\$ (0.09)	\$ (0.08)	\$ (0.18)	\$ (0.16)
Weighted average number of shares used in computing net loss per common share – basic and diluted	239,570	236,505	238,929	236,201
Comprehensive loss:				
Net loss	(20,662)	(19,619)	(42,880)	(38,747)
Foreign currency translation gain (loss)	175	(1,713)	725	(2,363)
Unrealized gain (loss) on available-for-sale investments	99	(144)	406	(696)
Comprehensive loss	\$ (20,388)	\$ (21,476)	\$ (41,749)	\$ (41,806)

Asensus Surgical, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except for share data)
(unaudited)

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 7,675	\$ 6,329
Short-term investments, available-for-sale	32,297	64,195
Accounts receivable, net	660	2,256
Inventory	9,083	8,284
Prepaid expenses	3,149	3,584
Employee retention tax credit receivable	554	554
Other current assets	1,492	1,671
Total Current Assets	<u>54,910</u>	<u>86,873</u>
Restricted cash	1,354	1,141
Long-term investments, available-for-sale	—	3,865
Inventory, net of current portion	4,939	5,469
Property and equipment, net	8,815	9,542
Intellectual property, net	1,411	1,576
Net deferred tax assets	155	174
Operating lease right-of-use assets, net	4,888	4,950
Other long-term assets	1,899	2,463
Total Assets	<u>\$ 78,371</u>	<u>\$ 116,053</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 4,281	\$ 3,348
Accrued employee compensation and benefits	3,887	4,508
Accrued expenses and other current liabilities	1,284	1,293
Operating lease liabilities – current portion	819	800
Deferred revenue	376	465
Total Current Liabilities	<u>10,647</u>	<u>10,414</u>
Long Term Liabilities:		
Contingent consideration	1,564	1,256
Noncurrent operating lease liabilities	4,657	4,738
Total Liabilities	<u>16,868</u>	<u>16,408</u>
Commitments and Contingencies		
Stockholders' Equity		
Common stock \$0.001 par value, 750,000,000 shares authorized at June 30, 2023 and December 31, 2022; 239,970,041 and 236,895,440 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	240	237
Preferred stock, \$0.01 par value, 25,000,000 shares authorized, no shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	966,335	962,731
Accumulated deficit	(903,815)	(860,935)
Accumulated other comprehensive loss	(1,257)	(2,388)
Total Stockholders' Equity	<u>61,503</u>	<u>99,645</u>
Total Liabilities and Stockholders' Equity	<u>\$ 78,371</u>	<u>\$ 116,053</u>

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

	Six Months Ended June 30,	
	2023	2022
Operating Activities:		
Net loss	\$ (42,880)	\$ (38,747)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	1,652	1,720
Amortization of intangible assets	226	5,203
Amortization of discounts and premiums on investments, net	(298)	444
Stock-based compensation	3,894	4,328
Deferred tax expense	79	169
Change in inventory reserves	459	(567)
Bad debt expense	—	9
Property and equipment impairment	—	432
Loss on disposal of property and equipment	—	97
Change in fair value of contingent consideration	308	(752)
Changes in operating assets and liabilities:		
Accounts receivable	1,614	(8)
Inventory	(1,240)	(1,933)
Operating lease right-of-use assets	40	409
Prepaid expenses	409	189
Other current and long-term assets	340	(1,169)
Accounts payable	961	524
Accrued employee compensation and benefits	(577)	(284)
Accrued expenses and other current liabilities	(55)	—
Deferred revenue	(94)	(4)
Operating lease liabilities	(42)	(290)
Net cash and cash equivalents used in operating activities	(35,204)	(30,230)
Investing Activities:		
Purchase of available-for-sale investments	(12,268)	(17,792)
Proceeds from maturities of available-for-sale investments	48,735	41,408
Purchase of property and equipment	(166)	(443)
Net cash and cash equivalents provided by investing activities	36,301	23,173
Financing Activities:		
Proceeds from issuance of common stock, net of issuance costs	196	—
Taxes paid related to net share settlement of vesting of restricted stock units	(490)	(349)
Proceeds from exercise of stock options	5	18
Net cash and cash equivalents used in financing activities	(289)	(331)
Effect of exchange rate changes on cash and cash equivalents	751	239
Net increase (decrease) in cash, cash equivalents and restricted cash	1,559	(7,149)
Cash, cash equivalents and restricted cash, beginning of period	7,470	19,283
Cash, cash equivalents and restricted cash, end of period	<u>\$ 9,029</u>	<u>\$ 12,134</u>
Supplemental Disclosure for Cash Flow Information:		
Cash paid for leases	\$ 655	\$ 549
Cash paid for taxes	\$ 262	\$ 65
Supplemental Schedule of Non-cash Investing and Financing Activities:		
Transfer of inventories to property and equipment	\$ 802	\$ 724
Lease liabilities arising from obtaining right-of-use assets	\$ 417	\$ —

Asensus Surgical, Inc.
Reconciliation of GAAP to Non-GAAP Financial Measures
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss attributable to common stockholders (GAAP)	\$ (20,662)	\$ (19,619)	\$ (42,880)	\$ (38,747)
Adjustments				
Amortization of intangible assets(a)	114	2,533	226	5,203
Change in fair value of contingent consideration(b)	203	(598)	308	(752)
Impairment of property and equipment(c)	—	432	—	432
Adjusted net loss attributable to common stockholders (Non-GAAP)	<u>\$ (20,345)</u>	<u>\$ (17,252)</u>	<u>\$ (42,346)</u>	<u>\$ (33,864)</u>
	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss per share attributable to common stockholders - basic and diluted (GAAP)	\$ (0.09)	\$ (0.08)	\$ (0.18)	\$ (0.16)
Adjustments				
Amortization of intangible assets(a)	—	0.01	—	0.02
Change in fair value of contingent consideration(b)	—	—	—	—
Impairment of property and equipment(c)	—	—	—	—
Adjusted net loss per share attributable to common stockholders – basic and diluted (Non-GAAP)	<u>\$ (0.09)</u>	<u>\$ (0.07)</u>	<u>\$ (0.18)</u>	<u>\$ (0.14)</u>

The non-GAAP financial measures for the three and six months ended June 30, 2023 and 2022, which provide management with additional insight into the Company's results of operations from period to period without certain non-cash charges, are calculated using the following adjustments:

- a) Intangible assets that are amortized consist of developed technology and purchased patent rights recorded at cost and amortized over 5 to 10 years.
- b) Contingent consideration in connection with the acquisition of the Senhance System in 2015 is recorded as a liability and is the estimate of the fair value of potential milestone payments related to business acquisitions. Contingent consideration is measured at fair value using a Monte-Carlo simulation utilizing significant unobservable inputs including the probability of achieving each of the potential milestones, revenue volatility, EURO to USD exchange rate, and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.
- c) Impairment of property and equipment associated with returned Senhance Systems under operating leases that are not expected to generate future cash flows sufficient to recover their net book value.

INVESTOR CONTACT:

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

MEDIA CONTACT:

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

ASXC Second Quarter 2023 Earnings Call Transcript

Mark Klausner

Good afternoon, everyone, and thank you for joining us for the Asensus Surgical second 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 rest of 2023 before we open the line for questions.

During the second quarter, we made good progress across all our key areas. Our focus remains on expanding the adoption of Senhance, driving broader utilization of our Intelligent Surgical Unit or ISU, advancing our clinical body of evidence, and refining our portfolio to further enhance the capabilities of Senhance. Looking ahead, we are excited about the future, with plans in place for the development of our new LUNA Surgical System.

Procedure volumes remain a key factor in our ability to expand and optimize our digital surgery capabilities. As we continue to collect surgical data, our machine learning engine becomes more effective, allowing us to provide valuable clinical intelligence to surgeons through the ISU. During the second quarter, we continued to see robust positive trends, delivering 27% year over year growth, and over 11% sequential growth, with over 1,000 Senhance procedures performed across a variety of specialties globally. Over the past quarters, we have maintained a consistent 10% sequential growth rate, reflecting our commitment to progress and stability.

Another positive aspect of increased procedure volumes is the expansion of our clinical registry. Our TRUST registry now includes data from over 2,500 patients, with a growing number of cases across gynecology, general surgery, and urology - which has been aided by the continued expansion of sites participating in the registry.

The primary goal of this registry is to create a collection of intraoperative and 12-month postoperative follow-up data. This data will be used to support an increased number of quality clinical publications and contribute to our market development strategy.

Moving to new program initiations, we initiated two new Senhance programs year to date. The first was Fukuoka Tokushukai Hospital in Kasuga City which we highlighted in our previous earnings call. In Japan, our growth continues, as we enter into agreements with prominent institutions. We are pleased with the positive momentum in the country and are looking forward to supporting further adoption in the region. The second is a leading U.S. hospital that has initiated a Senhance program exclusively within their pediatric surgery department, highlighting Senhance's unique suitability for pediatric applications. This marks an important milestone as this is the first system to be exclusively utilized by pediatric surgeons at a United States-based hospital.

We continued to be active at key industry meetings to generate excitement about Senhance, the ISU, and ultimately LUNA.

In July, we participated in The Society of Robotic Surgery or SRS Annual Meeting held in Melbourne, Australia. SRS is a unique event where all robotics surgical technologies from various specialties come together. During the event we had several podium presentations and symposiums, featuring both company representatives and surgeons, providing an excellent opportunity to showcase the unique capabilities of Senhance, LUNA, and the ISU. The substantial interest and engagement we received regarding ISU and LUNA were particularly encouraging and our presence at this event signifies our commitment to driving innovation in Robotic and Digital Surgery.

Additionally we attended the 1st Joint Meeting of the International Pediatric Endosurgery Group, or IPEG, and the European Society of Paediatric Endoscopic Surgeons, or ESPES meetings. We hosted a number of key events, including our sponsored ESPES Robotic Masterclass, which allowed surgeons from around the globe to explore robotics in pediatric surgery. The Masterclass received positive feedback, and our hands-on training sessions showcased the precision and efficiency of the Senhance System in pediatric procedures.

After attending several of these conferences over the past few quarters, we've seen strong validation of Senhance's potential amidst the influx of new systems planning to be on the market. Our understanding of market needs, backed by real-world data, experience and valuable user input, sets us apart. The unique offering of real-time Augmented Intelligence has generated excitement from surgeons and hospital administrators alike and we are confident we hold an edge over future market entrants.

Turning to other recent developments.

As we stated earlier, during the quarter, we made progress in expanding our presence in the pediatrics space. Since having received FDA clearance in March 2023, we have seen strong interest from pediatric surgeons. Our efforts to develop pediatric-specific real-world data have shown promising results, demonstrating the safety and feasibility of using Senhance in pediatric cases. The combination of Senhance's features, such as 3mm instrumentation and haptic feedback, along with the ISU's clinical intelligence, makes it highly effective for pediatric procedures. We have obtained the necessary clearances and approvals, including a CE Mark and FDA 510(k) clearance, allowing us to support surgeons globally and improve outcomes. We continue to see increased interest in Senhance and the ISU for pediatrics and are committed to meeting the growing demand in the pediatric market.

In conclusion, I am happy with the progress we've made in the second quarter and our strategic positioning for long-term success. Now, I will hand over the call to Shameze, who will provide a financial update.

Financials - Shameze Rampertab

Thanks, Anthony.

Turning to the second quarter, for the three months ended June 30, 2023, the company reported revenue of \$1.1 million as compared to revenue of \$1.0 million in the three months ended June 30, 2022. Revenue in the second 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 June 30, 2023, total operating expenses were \$18.9 million, as compared to \$18.2 million in the three months ended June 30, 2022.

For the three months ended June 30, 2023, net loss attributable to common stockholders was \$20.7 million, or \$0.09 per share, as compared to a net loss attributable to common stockholders of \$19.6 million, or \$0.08 per share, in the three months ended June 30, 2022.

For the three months ended June 30, 2023, the adjusted net loss attributable to common stockholders was \$20.3 million, or \$0.09 per share, as compared to an adjusted net loss of \$17.3 million, or \$0.07 per share, in the three months ended June 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 impairment of property and equipment, 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 \$40 million as of June 30, 2023.

In July, subsequent to the end of the second quarter, 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.

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.

Turning to the balance of 2023, and what we expect to achieve during the back half of the year.

With regards to the LUNA program, we have made significant progress in R&D and are now focused on testing and evaluation ahead of preparing for regulatory filings in 2024. By the end of the third quarter 2023, we intend to complete full system integration and system testing and finalize our manufacturing strategy. Pre-Clinical evaluation, which includes surgeons performing several procedures with the LUNA system on a porcine model, is scheduled for completion by the end of the fourth quarter of this year. Looking ahead beyond 2023, our plan is to freeze the system's design in Q1 2024, conduct verification and validation testing, and ramp up pilot manufacturing. By the end of 2024, we aim to submit to the FDA and other regulatory bodies in Europe and Japan, with the expectation of receiving FDA clearance in mid-2025. Following this milestone, we will proceed with a commercial pilot launch during H2 2025.

As it relates to our LUNA go-to-market efforts, two key advantages I would like to highlight.

First, we believe that we have a clear regulatory pathway outlined for LUNA. In the U.S. based on our continued communications with the FDA, significant in-house regulatory expertise and our series of successful regulatory submissions for Senhance, we expect to be able to leverage a time and cost effective Traditional 510(k) pathway in the U.S., rather than a more intensive de novo pathway. We believe this streamlined regulatory strategy applies not only to the United States but also to the European Union, Japan, and other parts of the world. This de-risked regulatory process will significantly contribute to time-to-market advantages compared to other new entrants to the space. This approach positions us favorably for expanding LUNA's market presence globally.

Second, we believe LUNA's disruptive economic model, which, when combined with the platform's innovative clinical performance, will allow us to drive strong commercial adoption. In addition to our current leasing model and capital purchase model, there is the potential for LUNA to be available to hospitals through a subscription-based model. This innovative approach aims to provide a greater level of economic flexibility for our customers, offering increased accessibility, thereby paving the way for broader adoption of the LUNA system without a significant increase in procedure cost compared to Laparoscopy.

Turning to our ongoing ISU development efforts. We anticipate reaching two milestones during 2023. The first being entering into an agreement with a strategic graphics hardware provider in the second half, and second, to finalize and ramp up pilot manufacturing for the future ISU by the end of the fourth quarter. These developments are crucial steps in advancing our LUNA program and expanding our digital capabilities with the ISU.

As it relates to Senhance, we continue to expect to initiate 10 - 12 new programs throughout 2023. Additionally, we are optimistic that procedure volume growth will follow a similar trajectory as seen in the first and second quarter for the remainder of this year. The data collected from these procedures has been crucial, and we anticipate even more valuable insights as additional sites adopt the ISU in the coming months. Lastly, we are excited to make progress with Luna, particularly in the Pre-Clinical evaluation, which we aim to complete by year-end.

These are exciting times at Asensus. We have continued to push the boundaries of what is possible in robotic and digital surgery, and we will keep pushing to deliver the tools and capabilities that surgeons need to deliver better, more consistent outcomes for their patients.

With that, I would like to open the lines for Q&A.

Q&A

Operator

First question comes from RK at H.C. Wainwright. Please go ahead. Mr. Ramakanth.

First Question – RK Ramakanth

Thank you. This is RK from H.C. Wainwright. Good afternoon, Anthony and Shameze. Couple of questions from me. Certainly, it's really encouraging to see the 11% sequential growth in the procedure volume and also seeing that you are growing at least 10% quarter-over-quarter for three quarters now. What is driving that growth and what have either you—when I say you, what has Asensus done to assure yourselves that sustained growth of 10% and above?

Response – Anthony Fernando

Hi, RK. Thanks for the question. I think how we see this is the more familiarity that the hospitals gain, and also, when they gain familiarity, as you know, when we start, we start with a few number of surgeons, and once time passes, there are more surgeons at the same hospital, that try to use the system. The procedures have been growing. That's one area that we've seen growth coming from existing hospitals, doing more cases with the additional surgeons.

The second is, as you remember at the back half of last year, we placed a significant amount of systems, majority were placed in the second-half. That also is playing in now because they've done the installations and getting up to speed and coming up their learning curve. They have begun to produce. I think those are the two factors that are continuing to contribute. When you look at it on a year-to-date basis we have grown procedure volume 27%, compared to last year and I think that's kind of what we think we can continue given these two factors coming together.

Question – RK Ramakanth

Thanks for that. In terms of the installations itself, you know, as you said, you have, for the last couple of years I believe we have been watching more installations happen in the second-half rather than in the first-half. It probably is going to be the same situation this year. What drives it to be a second half event? Is it because these things take a longer sales cycle? I know, doesn't have to be an outright sale anymore. You folks have a subscription, the lease model, which helps, but still, it seems like, it is taking a bit long. I'm not saying a bit longer, but longer. I'm just trying to understand the dynamics of the sales cycle?

Response – Anthony Fernando

Yes. Sure, RK. Again, I think the interest and the pipeline exists. It is trying to convert the pipeline into a placement of a system, whether it's a sale or operating lease. That decision, economics is one part of that decision, but also the hospital and the staff, they also have to be ready and trying to—be willing to do their training, get up to speed and start using the system. I know just looking at the last year and this year it's beginning to feel like somewhat of a pattern, but it takes time and it is continuing to take time for the hospitals to come to that decision to say, okay, now let's start this program.

But, from a pipeline point of view, I can say that we feel very bullish about the pipeline and know that we can deliver on that—this commitment of 10 to 12 systems, but the decision cycle is a long one, because hospitals are doing the diligence and, trying to get as much consensus internally as they can with surgeons so that they can make the program successful.

Question – RK Ramakanth

Yes, thanks for that. Then on the pediatric install that you had, which is obviously—it's trying to kind of expand beyond the other indications. How attractive is it to some of these hospitals? Also are there any conversations in the hospitals that already have some of your initial adopters. How are they thinking about, you know, extending it into the pediatric surgical suites as well?

Response – Anthony Fernando

Yes. RK, I think, you know, great points. I'll talk about two things. One, I'll talk about the existing sites. There are, I would say, a few existing sites, that happened to have a pediatric specialty within the hospital. In cases like that, obviously, we can consider it. But many sites didn't consider Senhance before for pediatrics, because pediatrics, it was somewhat separated and they looked at Senhance for other procedures.

But now with pediatric, I think it is somewhat of an underserved space, and then given the unique nature of Senhance, the pediatric surgical units and the surgeons are looking to it saying, okay, here's a device that have significantly smaller instruments and have certain features like haptic feedback and the digital capabilities and they're seeing the value of what it could do in pediatric, especially in the U.S., because we've been doing pediatric cases in Europe for some time now.

The more we share the data from some of these Congresses and surgeons presenting about their case performance, those get kind of that—that's also influencing especially the U.S. surgeons to start a pediatric program. We just announced one and we are continuing to build on that, but we've had pretty good inbound interest from pediatric surgeons from different hospitals saying that they are seeing interest in the smaller instruments and they feel that this is something that they can adopt. We are having those conversations now.

But pediatrics in general tend to be—the space between pediatrics and other surgical decisions and choices and even surgical centers. That's the reason why it's not all in one.

Question – RK Ramakanth

This is my last question, talking about feedback. You said that LUNA was demonstrated in Melbourne at a conference. What's the feedback you received when this was done? How much of the learnings from that presentation are you incorporating into your treatment studies and also future studies that you need to do as you get the approval for marketing LUNA?

Response – Anthony Fernando

Yes, RK. What we meant by sharing LUNA, it was a video presentation of the LUNA system, not a physical system presentation. I just want to clarify that, in Melbourne, but the team is making extremely good progress on the R&D front. Our goal is to perform with animal lab or preclinical lab at the end of this year where surgeons could do a complete procedure. That will kind of be the key gating milestone, where we can get a surgeon to do a complete procedure. Once that milestone is met, then we would start to proceed to doing all the final validation verification, kind of, tests to prepare the regulatory submission.

But overall, the feedback from the surgeon—we've been engaging with surgeons for the past, I would say couple of years, specifically on the LUNA program and continuing to evolve the system, but I think when surgeons look at the system at what it can deliver and how it's going to help them perform surgery with five millimeter instruments and having the ability to use five millimeter fully wristed instruments and straight instruments, low as three millimeter.

That kind of options and also some other things they like, on Senhance very much, eye tracking and haptic feedback and independent arms, etc. When they see that's already been done and they can also see the improvements, that's kind of what's driving a high level of interest there.

Question – RK Ramakanth

Thanks, Anthony. Thanks for taking all my questions.

Response – Anthony Fernando

Thank you, RK.

Operator

This concludes our question-and-answer session. I would like to turn the conference back over to Anthony Fernando for any closing remarks.

Anthony Fernando

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

Operator

The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.