

**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**

**May 11, 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:

<u>Title of each class</u>	<u>Trading symbol</u>	<u>Name of each exchange on which registered</u>
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 May 11, 2023, Asensus Surgical, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the first quarter ended March 31, 2023. A copy of the press release is furnished herewith as Exhibit 99.1.

Also on May 11, 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 first quarter ended March 31, 2023. The Company had issued a press release on April 27, 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	<a href="#">Press release dated May 11, 2023</a>
99.2	<a href="#">May 11, 2023 conference call transcript</a>
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: May 15, 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 First Quarter 2023**

RESEARCH TRIANGLE PARK, N.C.--(GLOBE NEWSWIRE)—May 11, 2023-- 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 first quarter 2023.

**Recent Highlights**

- 20% year-over-year growth in surgical procedures, with over 900 procedures performed globally during the quarter
- Surpassed 10,000 procedures on Senhance® Surgical System
- One Senhance Surgical Program was initiated during the quarter
- In March 2023, received FDA 510(k) clearance for an expanded indication to treat pediatric patients
- In January 2023, received CE Mark for an expansion of machine vision capabilities on the previously cleared Intelligent Surgical Unit™(ISU™) including 3D measurement, digital tagging, image enhancement, and enhanced camera control
- First quarter revenue of \$1.0 million
- The Company had cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of approximately \$57.4 million at March 31, 2023

"We are thrilled to report another quarter of strong procedure growth and progress in advancing our mission of Performance-Guided Surgery. The expansion of our pediatric indication into the U.S. is a significant milestone for our company, and we are excited to bring the benefits of our technology to a new patient population. Our continued increase in surgical procedures performed globally is a testament to the value our platform brings to surgeons and patients alike," said Anthony Fernando, Asensus Surgical President and CEO. "We remain on track to meet our milestones for the year, including the initiation of new Senhance programs, and the achievement of milestones for our LUNA™ Surgical System which is under development. As we look to the future, we remain focused on revolutionizing patient care through innovative surgical technology."

**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:

- Integrated system testing for LUNA Surgical System
  - Preclinical evaluation for LUNA Surgical System
  - Standalone ISU final testing
-

## **LUNA, the Company's Next Generation Digital Surgery Platform**

Designed based on the feedback received from over 10,000 digital laparoscopic procedures performed with the Senhance System, the LUNA Surgical System is the Company's next generation digital surgery platform. Through a combination of advanced minimally invasive instrumentation, the first ever digital interface between the surgeon and the console, and industry-leading clinical intelligence tools, we believe the LUNA System is poised to revolutionize the way surgery is performed.

The LUNA System is under development, and not currently available for use.

## **KARL STORZ Collaboration Agreement**

The Company previously announced that it had entered into a Memorandum of Understanding with KARL STORZ VentureONE Pte. Ltd. (KARL STORZ), a new wholly owned subsidiary of KARL STORZ SE & Co. KG. As part of the definitive agreements, KARL STORZ intends to market and sell Asensus' ISU as a standalone device, and the companies intend to jointly collaborate on the development and integration of next-generation instrumentation. The agreement is progressing towards signing and will represent an important step expanding our commercial reach and development capabilities.

## **U.S. Pediatric Regulatory Clearance**

The Company received U.S. FDA 510(k) clearance for pediatric surgeries in the U.S. during the first quarter of 2023. The Senhance System's unique combination of 3mm instrumentation with a 5mm camera scope combined with haptic feedback make it a unique robotic assisted laparoscopic solution for pediatric surgeries.

## **Market Development**

### *Procedure Volumes*

During the first quarter of 2023, there was a 20% increase in total surgical procedures completed utilizing the Senhance System over the same period in 2022. Strong utilization patterns brought on by an increased installed base, an increase of new surgeon users at existing installations, and a broader market recovery were the main drivers of this expansion.

### *2023 Senhance Program Initiations*

During the first quarter of 2023, the Company initiated one new Senhance Surgical System placement in Japan.

### *Clinical Validation*

During the quarter, **a peer reviewed paper** was published highlighting early experience of using the Senhance System in pediatric procedures in the United States. Conducted with IRB approval prior to 510(k) clearance, this study highlights the safety and feasibility of using Senhance System in pediatric cases. The surgical team successfully performed surgeries on eight patients ranging from four months to 16 years old, including procedures such as cholecystectomy, inguinal herniorrhaphy, orchidopexy, and exploration for suspected enteric duplication cyst. The successful use of the Senhance System in pediatric surgeries marks an important milestone for the Company in its ongoing mission to advance the field of surgical robotics.

---

## *Intelligent Surgical Unit (ISU) Collects Two Industry Awards on the Heels of Passing 10,000 Procedures on Senhance Surgical System*

The Senhance System has passed the 10,000 worldwide procedures milestone and the Company recently received two prestigious industry awards. The first award comes from MedTech Breakthrough, where the ISU was named the "Best New Technology Solution" in the surgical category. This achievement is remarkable as the ISU competed against nearly 4,000 nominations from across the globe. This marks the third time Asensus has earned a MedTech Breakthrough win. The MedTech Breakthrough Awards program is an independent program devoted to honoring excellence in medical and health-related technology companies, products, services and people. The second award comes from Juniper Research's Future Digital Awards for Excellence in Digital Health Innovation, where the ISU has been honored as the "Best Medical Robotics Solution" and awarded the Platinum Winner title. The awards program recognizes organizations that have made outstanding contributions to their industry and are positioned to make a significant impact in the future.

### **First Quarter Financial Results**

For the three months ended March 31, 2023, the Company reported revenue of \$1.0 million as compared to revenue of \$1.1 million in the three months ended March 31, 2022. Revenue in the first quarter of 2023 included \$0.5 million in lease revenue, \$0.3 million in instruments and accessories, and \$0.2 million in services.

For the three months ended March 31, 2023, total operating expenses were \$20.4 million, as compared to \$18.2 million, in the three months ended March 31, 2022.

For the three months ended March 31, 2023, net loss was \$22.2 million, or \$0.09 per share, as compared to a net loss of \$19.1 million, or \$0.08 per share, in the three months ended March 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 March 31, 2023, the adjusted net loss was \$22.0 million, or \$0.09 per share, as compared to an adjusted net loss of \$16.6 million, or \$0.07 per share in the three months ended March 31, 2022, after adjusting for the following charges: amortization of intangible assets, and change in fair value of contingent consideration, both of which are non-cash charges.

### **Balance Sheet Updates**

The Company had cash, cash equivalents, short-term and long-term investments, excluding restricted cash of approximately \$57.4 million as of March 31, 2023.

### **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](http://www.senhance.com/indications). To learn more about Performance-Guided Surgery, and digital laparoscopy with the Senhance Surgical System visit [www.asensus.com](http://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/c/transenterix>

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

## **Forward-Looking Statements**

This press release includes statements relating to Asensus Surgical, and our 2023 first quarter results. 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 we will be able to meet our milestones for the year, including the initiation of 10-12 new Senhance programs and the development of the LUNA Surgical System; whether we will meet our 2023 second half milestones of integrated system testing for the LUNA Surgical System, preclinical evaluation for the LUNA Surgical System and Standalone ISU final testing; whether, once fully developed and cleared, the LUNA Surgical System will revolutionize the way surgery is performed; whether the Senhance System's unique combination of 3mm instrumentation with a 5mm camera scope with haptic feedback make it a unique robotic assisted laparoscopic solution for pediatric surgeries and whether definitive agreements will be successfully negotiated and lead to a successful collaboration between Asensus Surgical and KARL STORZ. 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)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2023</b>	<b>2022</b>
Revenue:		
Product	\$ 293	\$ 347
Service	195	308
Lease	488	411
Total revenue	<u>976</u>	<u>1,066</u>
Cost of revenue:		
Product	1,225	375
Service	749	496
Lease	973	952
Total cost of revenue	<u>2,947</u>	<u>1,823</u>
Gross loss	<u>(1,971)</u>	<u>(757)</u>
Operating Expenses:		
Research and development	10,139	6,428
Sales and marketing	4,553	3,719
General and administrative	5,468	5,533
Amortization of intangible assets	112	2,670
Change in fair value of contingent consideration	105	(154)
Total Operating Expenses	<u>20,377</u>	<u>18,196</u>
Operating Loss	<u>(22,348)</u>	<u>(18,953)</u>
Other Expense, net:		
Interest income	439	255
Interest expense	—	(200)
Other expense, net	(218)	(146)
Total Other Income (Expense), net	<u>221</u>	<u>(91)</u>
Loss before income taxes	<u>(22,127)</u>	<u>(19,044)</u>
Income tax expense	(91)	(84)
Net loss	<u>(22,218)</u>	<u>(19,128)</u>
Comprehensive loss:		
Net loss	(22,218)	(19,128)
Foreign currency translation gain (loss)	550	(650)
Unrealized gain (loss) on available-for-sale investments	307	(552)
Comprehensive loss	<u>\$ (21,361)</u>	<u>\$ (20,330)</u>
Net loss per common share attributable to common stockholders – basic and diluted	<u>\$ (0.09)</u>	<u>\$ (0.08)</u>
Weighted average number of shares used in computing net loss per common share – basic and diluted	238,280	235,892

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

	<u>March 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
<b>Assets</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 18,737	\$ 6,329
Short-term investments, available-for-sale	37,697	64,195
Accounts receivable, net	658	2,256
Inventories	8,844	8,284
Prepaid expenses	3,326	3,584
Employee retention tax credit receivable	554	554
Other current assets	1,740	1,671
<b>Total Current Assets</b>	<u>71,556</u>	<u>86,873</u>
Restricted cash	1,142	1,141
Long-term investments, available-for-sale	958	3,865
Inventories, net of current portion	5,198	5,469
Property and equipment, net	8,972	9,542
Intellectual property, net	1,506	1,576
Net deferred tax assets	171	174
Operating lease right-of-use assets, net	4,769	4,950
Other long-term assets	2,251	2,463
<b>Total Assets</b>	<u>\$ 96,523</u>	<u>\$ 116,053</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 4,972	\$ 3,348
Accrued employee compensation and benefits	3,391	4,508
Accrued expenses and other current liabilities	1,283	1,293
Operating lease liabilities – current portion	775	800
Deferred revenue	456	465
<b>Total Current Liabilities</b>	<u>10,877</u>	<u>10,414</u>
<b>Long Term Liabilities:</b>		
Contingent consideration	1,361	1,256
Noncurrent operating lease liabilities	4,568	4,738
<b>Total Liabilities</b>	<u>16,806</u>	<u>16,408</u>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity</b>		
Common stock \$0.001 par value, 750,000,000 shares authorized at March 31, 2023 and December 31, 2022; 239,341,570 and 236,895,440 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	239	237
Preferred stock, \$0.01 par value, 25,000,000 shares authorized, no shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	964,162	962,731
Accumulated deficit	(883,153)	(860,935)
Accumulated other comprehensive income	(1,531)	(2,388)
<b>Total Stockholders' Equity</b>	<u>79,717</u>	<u>99,645</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 96,523</u>	<u>\$ 116,053</u>

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Operating Activities:</b>		
Net loss	\$ (22,218)	\$ (19,128)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation	813	869
Amortization of intangible assets	112	2,670
Amortization of discounts and premiums on investments, net	(89)	215
Stock-based compensation	1,916	2,245
Deferred tax expense	91	84
Bad debt expense	—	177
Change in inventory reserves	(374)	(180)
Change in fair value of contingent consideration	105	(154)
Changes in operating assets and liabilities:		
Accounts receivable	1,607	25
Inventories	203	(1,440)
Operating lease right-of-use assets	187	197
Prepaid expenses	250	201
Other current and long-term assets	(27)	(487)
Accounts payable	1,608	74
Accrued employee compensation and benefits	(1,120)	(1,043)
Accrued expenses and other current liabilities	(93)	(107)
Deferred revenue	(13)	(1)
Operating lease liabilities	(206)	(160)
Net cash and cash equivalents used in operating activities	<u>(17,248)</u>	<u>(15,943)</u>
<b>Investing Activities:</b>		
Purchase of available-for-sale investments	(2,949)	(5,967)
Proceeds from maturities of available-for-sale investments	32,750	29,258
Purchase of property and equipment	(64)	(246)
Net cash and cash equivalents provided by investing activities	<u>29,737</u>	<u>23,045</u>
<b>Financing Activities:</b>		
Taxes paid related to net share settlement of vesting of restricted stock units	(488)	(348)
Proceeds from exercise of stock options and warrants	5	12
Net cash and cash equivalents used in financing activities	<u>(483)</u>	<u>(336)</u>
Effect of exchange rate changes on cash and cash equivalents	403	(45)
Net increase in cash, cash equivalents and restricted cash	12,409	6,721
Cash, cash equivalents and restricted cash, beginning of period	7,470	19,283
Cash, cash equivalents and restricted cash, end of period	<u>\$ 19,879</u>	<u>\$ 26,004</u>
<b>Supplemental Disclosure for Cash Flow Information:</b>		
Cash paid for leases	\$ 330	\$ 300
Cash paid for taxes	\$ 190	\$ 29
<b>Supplemental Schedule of Non-cash Investing and Financing Activities:</b>		
Transfer of inventories to property and equipment	\$ 112	\$ 160
Lease liabilities arising from obtaining right-of-use assets	\$ 45	\$ —

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<u>2023</u>	<u>2022</u>
<b>Net loss attributable to common stockholders (GAAP)</b>	\$ (22,218)	\$ (19,128)
<b>Adjustments</b>		
Amortization of intangible assets	112	2,670
Change in fair value of contingent consideration	105	(154)
<b>Adjusted net loss attributable to common stockholders (Non-GAAP)</b>	<u>\$ (22,001)</u>	<u>\$ (16,612)</u>

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<u>2023</u>	<u>2022</u>
<b>Net loss per share attributable to common stockholders (GAAP)</b>	\$ (0.09)	\$ (0.08)
<b>Adjustments</b>		
Amortization of intangible assets	—	0.01
Change in fair value of contingent consideration	—	—
<b>Adjusted net loss per share attributable to common stockholders (Non-GAAP)</b>	<u>\$ (0.09)</u>	<u>\$ (0.07)</u>

---

The non-GAAP financial measures for the three months ended March 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 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.

**INVESTOR CONTACT:**

Mark Klausner or Mike Vallie  
ICR Westwicke  
[invest@asensus.com](mailto:invest@asensus.com)  
443-213-0499

**MEDIA CONTACT:**

Dan Ventresca  
Matter Communications  
[AsensusPR@matternow.com](mailto:AsensusPR@matternow.com)  
617-874-5488

## ASXC First Quarter 2023 Earnings Call Transcript

### Forward Looking Statements - Mark Klausner

Good afternoon, everyone, and thank you for joining us for the Asensus Surgical first 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 share attributable to common stockholders. Management believes that these non-GAAP financial measures taken in conjunction with U.S. GAAP financial measures provide useful information for both Management and investors by excluding certain noncash 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 in strategic plans, to benchmark our performance externally against competitors and for certain compensation decisions. Reconciliations from U.S. 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 joining us today.

I will begin by discussing our recent performance and highlights then Shameze will review our financial results. Following that, I will go over our priorities for the balance of 2023 before turning to Q&A.

The first quarter was highly productive at Asensus. We made significant progress across a number of our key areas of focus, including the expanded utilization of Senhance, the continued development of our clinical body of evidence and the ongoing development of our portfolio. In addition, we had a number of very exciting announcements, in particular, the unveiling of our LUNA Surgical System that is in development.

During the first quarter, we continued to see very positive procedure volume trends with over 900 procedures across multiple specialties and geographies delivering 20% year-over-year growth. Procedure volume is critical as we look to expand and optimize our digital surgery capability. The larger our collection of surgical data, the more effective our machine learning engine becomes, which will enable us to continue to deliver more clinical intelligence to surgeons through the ISU.

---

Another benefit of increased procedure volumes is the expansion of our clinical registry, which now includes over 2,400 patients. The primary purpose of this registry is to build a unique collection of interoperative and 12-month postoperative follow-up data, which will support an increased number of high-quality clinical publications and further bolster our market development strategy.

Moving to new program initiations. Year-to-date, we have initiated one new Senhance program, which was in Japan. Japan continues to be one of our fastest growing regions, and we are excited to be expanding our partnerships with some of the region's leading institutions. Most recently, we initiated a program at Fukuoka Tokushukai Hospital in Kasuga City. We are delighted to see positive feedback from customers and look forward to supporting the continued adoption throughout the region moving forward.

On the portfolio development front, we had multiple achievements. Early in Q1, we obtained CE Mark approval for the expanded machine vision capabilities with the ISU, which continues to receive high praise across the industry.

The ISU was recently honored with two prestigious awards, the first from MedTech Breakthrough, where the ISU was named the Best New Technology Solution in the surgical category. This is a remarkable achievement as we competed against nearly 4,000 nominations from across the globe, and it reflects our commitment to pushing the boundaries of innovation in the medical technology industry.

The second comes from Juniper Research Future Digital Awards for Excellence in Digital Health Innovation, where our ISU has been honored as the Best Medical Robotics Solution and awarded the Platinum Winner title. These recognitions are a testament to the outstanding capabilities and potential of our ISU in revolutionizing the field of surgical robotics and digital surgery.

The ISU integrated with the Senhance System is the only real-time solution on the market today that provides surgeons with a suite of tools to use during their surgical procedures, which includes eye tracking camera control, haptic feedback, digital measurement and digital tags.

Eye tracking allows surgeons to seamlessly control the camera position without pausing the procedure. There are also digital tags that enhance communication between the surgeon at the console and the OR team bed-side to further engage and support the seamless operating room experience.

Digital measurement tools enabled by the ISU allows surgeons to digitally quantify distances and measure over the contour of the anatomy to support interoperative surgical planning and decision-making.

In late March, we attended this year's Society of American Gastrointestinal and Endoscopic Surgeons or SAGES conference. We had an outstanding conference with tremendous interest in Senhance and the ISU. To kick off SAGES, we hosted a moderated broadcast of a live Senhance surgery performed in Germany by Dr. Vivianda Menke to a packed breakfast symposium from the conference in Montreal. This event demonstrated the capabilities of both our Senhance System and ISU as well as our telepresence capabilities with Senhance Connect. Interest from this full room led to strong attendance at our booth, where we also hosted multiple sessions focused on Asensus' ability to deliver augmented intelligence in surgery through our ISU platform.

Finally, with the importance of the underserved pediatric market, we had a special focus on engaging key pediatric surgeons. We hosted an event with several U.S. pediatric surgeons to better understand their needs for this unique specialty.

We also attended the German Surgeons Congress 2023 or DCK hosted in Munich, Germany. During this event, similar to SAGES, we hosted a live surgery in which Senhance and the ISU drew a great deal of attention from more than 100 attendees. This led to a fully booked agenda of hands-on demonstration for surgeons to have individual dedicated time to learn more and experience the Senhance System and the digital ISU tools.

To continue the focus on the pediatric market and expand on our learnings from SAGES, we hosted a group of key European pediatric surgeons to better understand their needs and how we can support further research for the specialty. We will continue this focus into next quarter at the IPEG and ESPES, International Pediatric Endoscopy Group and European Society of Pediatric Endoscopic Surgeons joint global meeting in Italy this summer.

Turning to other recent developments. As we unveiled during our Investor Day in February, we are incredibly excited about our next-generation LUNA System, which is currently in development. LUNA was developed over the course of nearly four years with input from surgeons, OR teams, strategic partners and hospital administration. We encourage you to watch the entire Investor Day webcast to learn about the unique combination of hardware and software that we believe enhances safety, reliability, performance and scalability.

In February, we disclosed we had signed a memorandum of understanding with KARL STORZ, a major player in the surgical device industry. The definitive agreements are progressing towards signing and will represent an important step, expanding our commercial reach and development capabilities. Upon completion, it will enable Asensus to bring the benefits of the ISU to KARL STORZ's extensive global customer base. Both organizations are working diligently to finalize their agreements as quickly as possible.

Before turning the call over to Shameze, I wanted to highlight our continued efforts to expand our presence in the pediatric space. As we have discussed at length on previous calls, the combination of Senhance's 3-millimeter instrumentation, haptic feedback and the ISU's clinical intelligence make the platform uniquely effective at performing pediatric procedure.

After having received a pediatric CE Mark in 2020, we received FDA 510(k) clearance for a U.S. pediatric indication in March of this year. With this FDA clearance, we now have the ability to help surgeons deliver better outcomes globally.

We have also been hard at work to develop pediatric-specific real-world data. During the first quarter, a paper was published that detailed early experience utilizing our Senhance platform in pediatric procedures in the U.S. This study conducted with IRB approval prior to 510(k) clearance showcases the safety and feasibility of using Senhance in pediatric cases.

The surgical team successfully performed surgeries on patients ranging from four months to 16 years of age. These procedures included gall bladder removal, hernia repair and other types of urological and GI procedures. These early results highlight the potential of our platform in the pediatric population and further validate its safety and effectiveness. We have continued to see increased interest in using Senhance and the ISU specifically for pediatrics. As we announced during the fourth quarter, we installed a system in Germany to be used exclusively with their pediatric surgery department.

We believe that there is a significant opportunity to bring all of the benefits of Performance-Guided Surgery to a largely underserved pediatric market, which will continue to be a focus of our expansion efforts to meet the increasing demand.

In summary, I'm thrilled with the breadth of our accomplishments during the first quarter and how we have positioned ourselves for long-term success.

With that, I will turn the call over to Shameze for a financial update.

## Financials - Shameze Rampertab

Thanks, Anthony.

Turning to the first quarter. For the three months ended March 31, 2023, the Company reported revenue of \$1 million as compared to revenue of \$1.1 million in the three months ended March 31, 2022. Revenue in the first quarter of 2023 included \$0.5 million in lease revenue, \$0.3 million in instruments and accessories and \$0.2 million in services.

For the three months ended March 31, 2023, total operating expenses were \$20.4 million as compared to \$18.2 million in the three months ended March 31, 2022.

For the three months ended March 31, 2023, net loss attributable to common stockholders was \$22.2 million or \$0.09 per share as compared to a net loss attributable to common stockholders of \$19.1 million or \$0.08 per share in the three months ended March 31, 2022.

For the three months ended March 31, 2023, the adjusted net loss attributable to common stockholders was \$22 million or \$0.09 per share as compared to an adjusted net loss of \$16.6 million or \$0.07 per share in the three months ended March 31, 2022. Adjusted net loss is GAAP net loss adjusted for the following items: amortization of intangible assets and change in fair value of contingent considerations, both of which are noncash charges. Adjusted net loss attributable to common stockholders is a non-GAAP financial measure. Reconciliations from GAAP to non-GAAP measures can be found in our earnings release.

Turning to the balance sheet. The Company had cash, cash equivalents, short-term and long-term investments excluding restricted cash of approximately \$57.4 million as of March 31, 2023.

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. Starting with the LUNA program, we have completed much of the R&D over the last few years and are moving quickly into testing and evaluation ahead of regulatory filings.

In the second half of 2023, we will have surgeons perform system tests to provide feedback before completing preclinical evaluations of the fully built system by the end of the year. Then during the first half of 2024, we'll freeze the systems design, complete verification and validation testing and ramp up our manufacturing capability.

By the end of 2024, we intend to submit to the FDA and other regulatory bodies in Europe and Japan with the expectation of receiving FDA clearance in mid-2025. We will then move into a commercial pilot launch during the second half of 2025. We are confident in our progress towards the commercial launch of these systems, and we'll continue to provide updates as we move forward.

As it relates to Senhance, we continue to expect to initiate 10 to 12 new Senhance programs during 2023. Additionally, we expect procedure volume growth for the rest of 2023 to track similarly to what we saw in the first quarter.

The data collected through these procedures has been instrumental, and as additional sites utilize the ISU in the coming months, it will increase the data we can leverage. The data collection nearly tripled sequentially, and we hope to have more than half of our sites using the ISU by the fourth quarter. With this level of data collection, we will be able to continue to drive innovation and make significant advancements in Performance-Guided Surgery.

These are exciting times at Asensus. We have continued to push the boundaries of what's possible in robotic surgery. We will keep pushing to deliver the tools and capabilities that surgeons need to deliver better, more consistent outcomes for their patients. I want to thank our global team for their hard work and dedication to make this truly novel technology a reality.

Before turning to Q&A, I wanted to remind investors about details of our upcoming Annual Stockholders Meeting, which will be held virtually on June 6, 2023. For more information on how to access the meeting and what matters will be discussed, please see our annual proxy statement, which was filed at the end of April.

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

## **Q&A**

### **Operator**

Today's first question comes from Ross Osborn with Cantor Fitzgerald. Please go ahead.

#### **First Question – Ross Osborn**

Hi, guys. Congrats on your industry recognitions and progress. Thanks for taking my question. Starting off, is there any more feedback on the pediatric launch you could provide? Do you think that's going to drive an inflection in your system placements?

#### **Response – Anthony Fernando**

Hey, Ross. Just to talk about pediatrics, we have been speaking with U.S. accounts for some time now, and we couldn't—we were not very active until we got the approval. But since then, there's definitely interest which we saw at SAGES and we've been following up on those to see how we might be able to start additional programs. Also in Europe, that's growing. We started, as you know, with one site. Now we are up to two sites and soon be three. Then also in Japan, there's been interest. Definitely, there is no shortage of interest. It's about trying to get the sites organized and some of the early adopters of this technology connected so that they can speak to each other before they start their program.

Overall, I think there is an opportunity. It is a unique solution because there is—given the instrumentation and the haptic feedback that we offer, I think it will truly be differentiated within robotics and to have some meaningful share for the Senhance System in pediatrics.

#### **Question – Ross Osborn**

Great. Thank you. Then maybe one for Shameze. There's a large step in R&D sequentially and year-over-year. Could you just walk through some of the drivers there? I imagine part of it is LUNA, but I had thought that had already come into the model during the fourth quarter.

#### **Response – Shameze Rampertab**

Yes. Thanks for your question, Ross. With regards to Q1, Q1 tends to be a heavier quarter for us in terms of burn in general when you look at the seasonality year-over-year. In Q1 of this year, we did spend a lot of effort in terms of getting ready with our investor event and making sure LUNA was ready for the unveil, which we had at our investor event. We continue to work towards the milestones that Anthony laid out on LUNA.

Also, we disclosed that we are working towards a standalone ISU. We currently have the Intelligent Surgical Unit that's approved in the U.S., Europe and Japan, but that is integrated into Senhance. This will be a standalone ISU. A lot of great projects that we're working towards. But Q1 should not be indicative of the rest of the quarter in terms of that run rate.

**Question – Ross Osborn**

Got it. Thanks for taking my questions.

**Operator**

Thank you. Our next question today comes from Li Chen with H.C. Wainwright. Please go ahead.

**Question – Li Chen**

Hello, Anthony and Shameze, can you hear me?

**Response – Anthony Fernando**

Yes. Go ahead, Li.

**Question – Li Chen**

Yes. Thanks for taking my question. I just want to get a feel of the potential market size in the pediatric patients. Is it like one-tenth of the adult surgery volume or what's the percentage there? Another question is do you anticipate to use the same sales force? Or are you expecting to add additional pediatric specialty sales force there? Thank you.

**Response – Anthony Fernando**

Thanks for the questions, Li. I think so trying to answer the market size, I can tell you approximately it's somewhere between 3 million and 4 million procedures if we just look at the U.S. It's kind of hard to give you a definite number because it's not a whole lot of data available. But in terms of scale, I would say, 3 million to 4 million is a reasonable assumption with respect to market size.

Then with respect to the sales force, I think before we really push hard on the commercial front, I think the goal for us is to really get a few pilot sites up and running and get some early data published. I think we will use our existing clinical sales team and our existing commercial teams to help us move this forward.

But that said, I do want to clarify that we do have in Europe and also, we'll be developing this in Japan, but there are some clinical support staff that have performed a lot more on the pediatric side who tend to focus more on pediatric support of hospitals. There's a little bit of specialization. But for the most part, it will be the existing team that will support the expansion into pediatric.

**Question – Li Chen**

Okay. Thanks for the info. That's very helpful.

**Operator**

Thank you. Our next question comes from RK Ramakanth with H.C. Wainwright. Please go ahead.

**Question – RK Ramakanth**

Thank you. Good afternoon, Shameze and Anthony. I apologize if some of these questions have been already asked. Just trying to get a sense of where you are with the LUNA Surgical System, especially in terms of preclinical evaluation and also some of the testing that you plan to do during this year.

**Response – Anthony Fernando**

Sure, RK. I think the goal for this year like we've stated, we have two milestones. The year-end milestone is to really try to do a full system test in a preclinical setting so that we can make sure that end-to-end, the system is delivering on the performance criteria. Throughout the year, we intend to bring in surgeons and perform some work using either tissue models or where it could even be small-scale preclinical to gather feedback and also make it more of a testing a platform for—goes both ways. We need to know what the surgeons think and also, from a development point of view, we know that solution is robust.

I would say towards the middle of the year would be one milestone where we get surgeons and get feedback to further develop, and that will help us leading to the year-end milestone of doing a full system preclinical evaluation.

**Question – RK Ramakanth**

Then when do you need to do any sort of clinical testing as such before? Or basically, what's the regulatory pathway? I think that's the question I have.

**Response – Anthony Fernando**

Yes. I think, so for us, we intend to follow traditional 510(k) because we are a predicate. That's the current path we're following.

**Question – RK Ramakanth**

Okay. Then on the KARL STORZ, I know you're still working on this relationship. Can you give any additional color as to how close you are or what else needs to get done before both parties can sign on the dotted line?

**Response – Anthony Fernando**

Yes. It's a great question, RK. It's an extremely complicated agreement. As you can imagine, there is IP involved, there's R&D component, there's manufacturing then there's a whole business commercial aspect and regulatory, all being discussed on a global scale. It's not just for the U.S. It's the U.S., Europe and Asia. There are a lot of complexities and a lot of conversations going on. Both companies are very diligently working to try to wrap it up as soon as possible, but I'd say that progress is made. As soon as we get it finalized, we'll make sure we communicate that.

**Question – RK Ramakanth**

Perfect. Thank you very much Anthony. Good luck, and talk to you soon.

**Response – Anthony Fernando**

Thanks, RK.

**Operator**

Thank you. Ladies and gentlemen, this concludes our question-and-answer session. I'd like to turn the conference back over to the Management team for any final 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**

Thank you. Ladies and gentlemen, this concludes today's conference call. We thank you all for attending today's presentation. You may now disconnect your lines, and have a wonderful day.