



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

August 10, 2023

RESEARCH TRIANGLE PARK, N.C., Aug. 10, 2023 (GLOBE NEWSWIRE) -- 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.

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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	<u>1,081</u>	<u>994</u>	<u>2,057</u>	<u>2,060</u>
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	<u>3,074</u>	<u>2,347</u>	<u>6,021</u>	<u>4,170</u>
Gross loss	<u>(1,993)</u>	<u>(1,353)</u>	<u>(3,964)</u>	<u>(2,110)</u>
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	<u>18,870</u>	<u>18,214</u>	<u>39,247</u>	<u>36,410</u>
Operating loss	<u>(20,863)</u>	<u>(19,567)</u>	<u>(43,211)</u>	<u>(38,520)</u>
Interest income	431	260	870	515
Interest expense	—	(141)	—	(341)
Other expense, net	(242)	(86)	(460)	(232)
Total other income (expense), net	<u>189</u>	<u>33</u>	<u>410</u>	<u>(58)</u>
Loss before income taxes	<u>(20,674)</u>	<u>(19,534)</u>	<u>(42,801)</u>	<u>(38,578)</u>
Income tax benefit (expense)	12	(85)	(79)	(169)
Net loss	<u>(20,662)</u>	<u>(19,619)</u>	<u>(42,880)</u>	<u>(38,747)</u>
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	<u>\$ (20,388)</u>	<u>\$ (21,476)</u>	<u>\$ (41,749)</u>	<u>\$ (41,806)</u>

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

	June 30, 2023	December 31, 2022
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	54,910	86,873
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	\$ 78,371	\$ 116,053

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	10,647	10,414
Long Term Liabilities:		
Contingent consideration	1,564	1,256
Noncurrent operating lease liabilities	4,657	4,738
Total Liabilities	16,868	16,408
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	61,503	99,645
Total Liabilities and Stockholders' Equity	\$ 78,371	\$ 116,053

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	\$ 9,029	\$ 12,134

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)

	<u>Three Months Ended</u>		<u>Six Months Ended</u>	
	<u>June 30,</u>		<u>June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
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)	\$ (20,345)	\$ (17,252)	\$ (42,346)	\$ (33,864)
	<u>Three Months Ended</u>		<u>Six Months Ended</u>	
	<u>June 30,</u>		<u>June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
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)	\$ (0.09)	\$ (0.07)	\$ (0.18)	\$ (0.14)

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.

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