

Asensus Surgical, Inc. Reports Operating and Financial Results for the Third Quarter 2022

November 10, 2022

RESEARCH TRIANGLE PARK, N.C., Nov. 10, 2022 (GLOBE NEWSWIRE) -- Asensus Surgical, Inc. (NYSE American: ASXC), a medical device company that is digitizing the interface between the surgeon and the patient to pioneer a new era of Performance-Guided Surgery[™], today announced its operating and financial results for the third quarter 2022.

Recent Highlights

- Over 1,900 procedures were performed globally during the nine months ended September 30, 2022, representing growth of 27% over the prior year
- Five new Senhance program initiations year to date, 3 in Germany, 1 in Japan, 1 in CIS region
- Submitted FDA 510(k) application for pediatric indication in the U.S.
- Received the Society of Laparoscopic & Robotic Surgeons 2022 Innovation of the Year award for the Intelligent Surgical Unit™(ISU™
- The Company had cash, cash equivalents, short-term and long-term investments, excluding restricted cash, of approximately \$88.3 million at September 30, 2022

"We are very pleased with what we have accomplished this quarter, with impressive utilization metrics, a growing base of clinical evidence highlighting the benefits of the Senhance system and the ISU, and the growth of our installed base," said Anthony Fernando, Asensus Surgical President and CEO. "As we have made great progress towards the ongoing development of Performance-Guided Surgery and its suite of digital capabilities, we look forward to continuing to progress the platform to enable safer, more consistent surgery - resulting in better outcomes for hospitals and patients alike."

Digital Surgery Portfolio Expansion

Expanded Global ISU Machine Vision Capabilities

The Company continues to expand the utilization and applicability of the ISU globally. The Company is seeking CE Mark approval for expanded machine vision capabilities in Europe, which the Company continues to expect to receive in late 2022. The newest ISU features include: real-time 3D measurement, digital tagging, image enhancement, and enhanced camera control based on real-time data while performing surgery. The expanded machine vision capabilities have both U.S. FDA 510(k) clearance and Japanese PMDA approval.

This filing included a review of the entire Senhance System platform, and if successful, would represent one of the first robotic surgical systems to be approved through the new, more rigorous MDR process.

Articulating Instrument Launch

These instruments are currently in a pilot launch in the U.S. and Europe, and the Company continues to expect a full scale commercial launch by the end of 2022. Articulating Instruments offer better access to difficult-to-reach areas of the anatomy by providing two additional degrees of freedom.

U.S. Pediatric Regulatory Submission

The Company submitted its 510(k) application for pediatric clearance in the U.S. during the third quarter of 2022. The Senhance System's unique combination of the 3mm instrumentation with 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 nine months of 2022, over 1,900 procedures have been completed utilizing the Senhance System, a 27% increase over the same period in 2021. In the third quarter, surgeons performed over 600 procedures, representing an 18% increase over the third quarter of 2021. This growth was primarily driven by strong utilization trends as a result of an expanded installed base and a growth in new surgeon users at existing installations as well as a broader market recovery.

When a procedure is performed with a Senhance System, the Company is able to collect robust data, including surgical video. Over time, the accumulation of this digital surgical data library will enable the Company to generate powerful clinical insights that will fuel the development of Performance-Guided Surgery capabilities to help surgeons reduce surgical variability and drive consistently superior surgical outcomes.

Clinical Registry (TRUST)

The Company is leveraging its growing body of real-world clinical data through the utilization of its TRUSTTM clinical registry. The Company believes TRUST is the largest multi-specialty robotic-assisted laparoscopic registry in the industry. The Company continues to grow this body of clinical data to support its commercial strategy as well as help to facilitate an increasing number of high-quality clinical publications demonstrating the value of the Senhance System and Performance-Guided Surgery, with over 2,000 patients enrolled to date. The registered procedures consist of approximately 67% general surgery, including abdominal and thoracic, 15% GYN, and 18% urology.

Clinical Validation

During the quarter, there were three peer-reviewed clinical papers published providing further support for the clinical utility of the Senhance System across a variety of surgical specialties.

These papers can be found at the Company's website, www.senhance.com/us/resources.

During the quarter, the Company received the Society of Laparoscopic & Robotic Surgeons 2022 Innovation of the Year award for the ISU. Each year, The Society of Laparoscopic & Robotic Surgeons recognizes the most innovative products that have a multidisciplinary application in minimally invasive surgery.

New Program Initiations

During the third quarter, the Company announced four Senhance System initiations:

- Evangelical Hospital Goettingen-Weende in Göttingen, Germany
- Saiseikai Shiga Hospital in Ritto, Japan
- The Clinic for General and Visceral Surgery at the St. Bernhard Hospital in Kamp-Lintfort, Germany
- A hospital in the Commonwealth of Independent States (CIS) region

Subsequent to the end of the third quarter, the Company announced one additional Senhance System initiation, bringing the year to date total to five:

• The Dr. von Hauner Children's Hospital at the Ludwig Maximilians University of Munich, located in Munich, Germany.

For the full year 2022, the Company continues to expect to initiate 8 - 10 new Senhance Surgical Systems.

Third Quarter Financial Results

For the three months ended September 30, 2022, the Company reported revenue of \$2.6 million as compared to revenue of \$2.6 million in the three months ended September 30, 2021. Revenue in the third quarter of 2022 included \$1.2 million in system revenue, \$0.3 million in lease revenue, \$0.8 million in instruments and accessories, and \$0.3 million in services.

For the three months ended September 30, 2022, total operating expenses were \$17.2 million, as compared to \$16.7 million, in the three months ended September 30, 2021.

For the three months ended September 30, 2022, net loss was \$18.9 million, or \$0.08 per share, as compared to a net loss of \$16.1 million, or \$0.07 per share, in the three months ended September 30, 2021.

Adjusted net loss is a non-GAAP financial measure. See the reconciliation of GAAP to Non-GAAP Measures below. For the three months ended September 30, 2022, the adjusted net loss was \$16.9 million, or \$0.07 per share, as compared to an adjusted net loss of \$14.3 million, or \$0.06 per share in the three months ended September 30, 2021, after adjusting for the following charges: amortization of intangible assets, change in fair value of contingent consideration, and employee retention tax credit, all 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 \$88.3 million as of September 30, 2022.

Conference Call

Asensus Surgical, Inc. will host a conference call on Thursday, November 10, 2022, at 4:30 PM ET to discuss its third quarter 2022 operating and financial results. To listen to the conference call on your telephone, please dial 1-866-652-5200 for domestic callers and 1-412-317-6060 for international callers, and reference conference ID 10171489 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 at https://ir.asensus.com/events-and-presentations.

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. This builds upon the foundation of Digital Laparoscopy with the Senhance Surgical System powered by the Intelligent Surgical Unit (ISU) 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. Learn more about Performance-Guided Surgery and Digital Laparoscopy with the Senhance Surgical System here: www.senhance.com. 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. For more information, visit www.senhance.com/indications. For more

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Forward-Looking Statements

This press release includes statements relating to the Senhance System and our 2022 third 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 continue to progress the Company's platform to enable safer, more consistent surgery resulting in better outcomes for hospitals and patients alike; whether the Company will receive CE Mark approval for expanded machine vision capabilities in Europe in late 2022; whether the Company's articulating instruments will undergo a full scale commercial launch by the end of 2022; whether the Company will receive a pediatric clearance for the Senhance Surgical System from the FDA; whether the Company's TRUST clinical registry is the largest multi-specialty robotic-assisted laparoscopic registry in the industry and whether the Company will continue to grow the Trust registry data to support its commercial strategy; and whether we will initiate 8-10 new Senhance Surgical Systems placements in 2022. For a discussion of the risks and uncertainties associated with the Company's business, please review our filings with the Securities and Exchange Commission (SEC). You are cautioned not to place undue reliance on these forward-looking statements, which are based on our expectations as of the date of this press release and speak only as of the origination date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Asensus Surgical, Inc. Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except per share amounts) (Unaudited)

		Three Months Ended September 30,				Nine Months Ended June 30,				
	2022	2022		2021	2022		,	2021		
Revenue:										
Product	\$1,	964	\$	1,922	\$	2,565	\$	3,651		
Service		335		395		1,067		1,180		
Lease		264		254		991		925		
Total revenue	2,	563		2,571		4,623		5,756		
Cost of revenue:										
Product	3,	057		1,993		4,316		4,671		
Service		365		342		1,506		1,344		
Lease		982		1,015		2,752		2,794		
Total cost of revenue	4,	404		3,350		8,574		8,809		
Gross loss	(1,	841)		(779)		(3,951)		(3,053)		
Operating Expenses:		/		,		,		/		
Research and development	6,	741		4,469		20,422		12,773		
Sales and marketing	3.	615		3,551		10,936		10,166		
General and administrative	4,	853		5,557		15,378		13,397		
Amortization of intangible assets	2,	398		2,804		7,601		8,533		
Change in fair value of contingent consideration	(416)		278		(1,168)		1,013		
Property and equipment impairment		_		_		432		_		
Total Operating Expenses	17,	191		16,659		53,601		45,882		
Operating Loss		032)		(17,438)		(57,552)		(48,935)		
Other Income (Expense), net:		/		/		/		/		
Gain on extinguishment of debt		_		_		_		2,847		
Change in fair value of warrant liabilities		_		_		_		(1,981)		
Interest income		291		122		806		253		
Interest expense		(99)		(65)		(440)		(77)		
Employee retention tax credit		_		1,311		_		1,311		
Other (expense) income, net		(29)		33		(261)		(3)		
Total Other Income (Expense), net		163		1,401		105		2,350		
Loss before income taxes	(18,	869)		(16,037)		(57,447)		(46,585)		
Income tax (expense) benefit		, (55)		(32)		(224)		4		
Net loss	(18,	<u>,</u> 924)		(16,069)		(57,671)		(46,581)		
Comprehensive loss:		/		/		/		/		

Net loss Foreign currency translation loss Unrealized gain (loss) on available-for-sale investments	(18,924) (1,655) 86	(16,069) (931) (53)	(57,671) (4,018) (610)		(46,581) (2,397) (53)
Comprehensive loss	\$ (20,493)	\$ (17,053)	\$ (62,299)	\$	(49,031)
Net loss per common share attributable to common stockholders – basic and diluted	\$ (0.08)	\$ (0.07)	\$ (0.24)	\$	(0.21)
Weighted average number of shares used in computing net loss per common share – basic and diluted	 236,713	 234,337	 236,373	_	224,300

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

	Sep	September 30, 2022		cember 31, 2021
Assets				
Current Assets:				
Cash and cash equivalents	\$	13,870	\$	18,129
Short-term investments, available-for-sale		72,481		80,262
Accounts receivable, net		2,250		749
Inventories		9,035		8,634
Prepaid expenses		3,713		3,255
Employee retention tax credit receivable		1,147		1,311
Other current assets		1,034		957
Total Current Assets		103,530		113,297
Restricted cash		1,107		1,154
Long-term investments, available-for-sale		1,937		37,435
Inventories, net of current portion		3,441		7,074
Property and equipment, net		9,145		10,971
Intellectual property, net		1,529		9,892
Net deferred tax assets		227		288
Operating lease right-of-use assets, net		4,799		5,348
Other long-term assets		2,938		1,014
Total Assets	\$	128,653	\$	186,473
Liabilities and Stockholders' Equity		-,		
Current Liabilities:				
	\$	3,637	\$	2 4 4 9
Accounts payable	φ	3,868	Φ	3,448 3,559
Accrued employee compensation and benefits		-		-
Accrued expenses and other current liabilities		1,320 662		1,617 683
Operating lease liabilities – current portion				
Deferred revenue		357		543
Total Current Liabilities		9,844		9,850
Long Term Liabilities:		4 000		0.074
Contingent consideration		1,203		2,371
Noncurrent operating lease liabilities		4,630		5,006
Total Liabilities		15,677		17,227
Commitments and Contingencies				
Stockholders' Equity				
Common stock \$0.001 par value, 750,000,000 shares authorized at September 30, 2022 and December 31, 2021; 236,783,315 and				
235,218,552 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively		237		235
Preferred stock, \$0.01 par value, 25,000,000 shares authorized, no shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively		_		_
Additional paid-in capital		960,676		954,649
Accumulated deficit		(843,045)		(785,374)
Accumulated other comprehensive loss		(043,043) (4,892)		(264)
		(7,002)		(204)

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

		Nine Mont				
		Septem 2022	ber 3	<u>0,</u> 2021		
Operating Activities:						
Net loss	\$	(57,671)	\$	(46,581)		
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:						
Depreciation		2,481		2,416		
Amortization of intangible assets		7,601		8,533		
Amortization of discounts and premiums on investments, net		556		65		
Stock-based compensation		6,361		6,589		
Gain on extinguishment of debt		—		(2,847)		
Deferred tax expense (benefit)		224		(4)		
Change in inventory reserves		386		377		
Bad debt expense		9		—		
Property and equipment impairment		432		—		
Loss on disposal of property and equipment		97		—		
Change in fair value of warrant liabilities		—		1,981		
Change in fair value of contingent consideration		(1,168)		1,013		
Changes in operating assets and liabilities:						
Accounts receivable		(1,735)		113		
Inventories		(535)		(1,941)		
Operating lease right-of-use assets		237		(3,174)		
Prepaid expenses		(693)		1,220		
Employee retention tax credit receivable		164		(1,311)		
Other current and long-term assets		(2,123)		2,098		
Accounts payable		449		1,376		
Accrued expenses		236		(588)		
Deferred revenue		(139)		(81)		
Operating lease liabilities		(53)		3,259		
Net cash and cash equivalents used in operating activities		(44,884)		(27,487)		
Investing Activities:						
Purchase of available-for-sale investments		(25,588)		(88,232)		
Proceeds from maturities of available-for-sale investments		67,702		_		
Purchase of property and equipment		(904)		(838)		
Net cash and cash equivalents provided by (used in) investing activities		41,210		(89,070)		
Financing Activities:				,		
Proceeds from issuance of common stock, net of issuance costs		_		130,361		
Taxes paid related to net share settlement of vesting of restricted stock units		(350)		(1,058)		
Proceeds from exercise of stock options and warrants		18		30,838		
Net cash and cash equivalents (used in) provided by financing activities		(332)		160,141		
Effect of exchange rate changes on cash and cash equivalents		(300)		(181)		
Net (decrease) increase in cash, cash equivalents and restricted cash		(4,306)		43,403		
Cash, cash equivalents and restricted cash, beginning of period		19,283		17,529		
Cash, cash equivalents and restricted cash, end of period	\$	14,977	\$	60,932		
	<u>+</u>	,	<u>+</u>			
Supplemental Disclosure for Cash Flow Information:						
Cash paid for leases	\$	729	\$	781		
Cash paid for taxes	\$	79	\$	63		
Supplemental Schedule of Non-cash Investing and Financing Activities:						
Transfer of inventories to property and equipment	\$	1,293	\$	2,156		
Reclass of warrant liability to common stock and additional paid-in-capital	\$	—	\$	2,236		
Lease liabilities arising from obtaining right-of-use assets	\$	316	\$	3,857		

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

	Three Months Ended September 30,						 nths Ended nber 30,		
	2022		2021		2021 2022		 2021		
Net loss attributable to common stockholders (GAAP)	\$	(18,924)	\$	(16,069)	\$	(57,671)	\$ (46,581)		
Adjustments									
Amortization of intangible assets		2,398		2,804		7,601	8,533		
Change in fair value of contingent consideration		(416)		278		(1,168)	1,013		
Property and equipment impairment				—		432			
Gain on extinguishment of debt				—		_	(2,847)		
Change in fair value of warrant liabilities		—		_		_	1,981		
Employee retention tax credit				(1,311)		_	 (1,311)		
Adjusted net loss attributable to common stockholders (Non-GAAP)	\$	(16,942)	\$	(14,298)	\$	(50,806)	\$ (39,212)		

	Three Mo Septe	onths E mber 3	Nine Months Ended September 30,				
	 2022		2021		2022	20	21
Net loss per share attributable to common stockholders (GAAP)	\$ (0.08)	\$	(0.07)	\$	(0.24)	\$	(0.21)
Adjustments							
Amortization of intangible assets	0.01		0.01		0.03		0.04
Change in fair value of contingent consideration	0.00		0.01		0.00		0.01
Property and equipment impairment	—		_		0.00		_
Gain on extinguishment of debt	_		_		_		(0.01)
Change in fair value of warrant liabilities	_		_		_		0.01
Employee retention tax credit	—		(0.01)		_		(0.01)
Adjusted net loss per share attributable to common stockholders (Non-GAAP)	\$ (0.07)	\$	(0.06)	\$	(0.21)	\$	(0.17)

The non-GAAP financial measures for the three and nine months ended September 30, 2022 and 2021, which provide management with additional insight into the Company's results of operations from period to period without non-cash charges and are calculated using the following adjustments:

a) Intangible assets that are amortized consist of developed technology and purchased patent rights recorded at cost and amortized over 7 to 10 years.

b) Contingent consideration in connection with the acquisition of the Senhance System in 2015 is recorded as a liability and is the estimate of the fair value of potential milestone payments related to business acquisitions. Contingent consideration is measured at fair value using a Monte-Carlo simulation utilizing significant unobservable inputs including the probability of achieving each of the potential milestones, revenue volatility, EURO to USD exchange rate, and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.

c) Property and equipment impairment associated with returned Senhance Systems under operating leases that are not expected to generate future cash flows sufficient to recover their net book value.

d) During the second quarter of 2021, the Company received notification from the U.S. Small Business Administration that the principal amount of its Paycheck Protection Program loan of \$2.8 million and related interest had been forgiven. Gain on extinguishment of debt of \$2.8 million was recognized for the nine months ended September 30, 2021, in the consolidated statement of operations and comprehensive loss.

e) The Company's Series B Warrants were measured at fair value using a simulation model which took into account, as of the valuation date, factors including the current exercise price, the expected life of the warrant, the current price of the underlying stock, its expected volatility, holding cost and the risk-free interest rate for the term of the warrant. The warrant liability was revalued upon exercise and the final change in fair value was recognized in the first quarter of 2021.

f) During the third quarter of 2021, the Company submitted a refund for incurred employee payroll taxes of \$1.3 million under the Employee Retention Tax Credit provision as part of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). A corresponding tax credit receivable of \$1.3 million was recorded on the condensed consolidated balance sheet at September 30, 2021.

INVESTOR CONTACT:

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

OR

MEDIA CONTACT: Isabella Rodriguez, 708-833-1572 CG Life irodriguez@cqlife.com



Source: Asensus Surgical, Inc.