

Shockwave Medical Reports Fourth Quarter and Full Year 2020 Financial Results

February 17, 2021

SANTA CLARA, Calif., Feb. 17, 2021 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (Nasdaq: SWAV), a pioneer in the development and commercialization of Intravascular Lithotripsy (IVL) to treat complex calcified cardiovascular disease, today reported financial results for the three months and full year ended December 31, 2020.

Recent Highlights

- Recognized revenue of \$22.7 million for the fourth quarter of 2020 and \$67.8 million for the full year of 2020, representing increases of 59% and 58%, respectively, from the same periods in 2019
- Received FDA approval of IVL for severely calcified coronary artery disease
- Presented data for two large trials at late breaking sessions in the fourth quarter
- Granted four new codes by CMS that established specific payment for IVL procedures performed in an outpatient setting in arteries below the knee
- Granted eight codes by CMS for IVL performed in Ambulatory Surgery Centers
- Ended the year with over 100 issued patents

"The successes we achieved despite the myriad COVID challenges of 2020 are a testament to the team at Shockwave and to the clinical value of our proprietary IVL technology," said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. "With the recent FDA approval of our C² device, we will now be able to address a significant unmet need for patients with severely calcified coronary arteries in the United States. I want to thank our employees and our investigators for their hard work and persistence as they have fought through the pandemic to put us in this fortunate position."

Fourth Quarter 2020 Financial Results

Revenue for the fourth quarter of 2020 was \$22.7 million, an increase of \$8.4 million, or 59%, compared to the fourth quarter of 2019. The growth was primarily driven by sales force expansion in the U.S. and increased penetration in both U.S. and international markets.

Gross profit for the fourth quarter of 2020 was \$16.2 million compared to \$8.8 million for the fourth quarter of 2019. Gross margin for the fourth quarter of 2020 was 72%, as compared to 61% in the same period of last year. Contributors to gross margin expansion included continued improvement in manufacturing productivity and process efficiencies.

Operating expenses were \$32.1 million for the fourth quarter of 2020 compared to \$24.1 million in the corresponding prior year period, representing a 33% increase, primarily driven by increases in headcount since the year ago period.

Net loss was \$15.9 million in the fourth quarter of 2020, as compared to \$14.7 million in the corresponding period of the prior year. Net loss per share was \$0.46 in the fourth quarter of 2020.

Full Year 2020 Financial Results

Revenue for full year 2020 was \$67.8 million, an increase of \$24.9 million, or 58%, compared to the full year of 2019. The growth was primarily driven by the expansion of the U.S. sales force and international distributor network.

Gross profit for the full year 2020 was \$46.8 million compared to \$25.8 million for the full year 2019. The gross margin percentage for the full year 2020 increased to 69% compared to 60% in the full year 2019, driven primarily by improvements in production processes and greater absorption of fixed costs by higher production.

Operating expenses were \$112.5 million for the full year 2020 compared to \$77.6 million in the prior year, an increase of 45%, primarily driven by headcount increases.

Net loss was \$65.7 million for full year 2020, as compared to \$51.1 million in the prior year. Net loss per share was \$1.99 for full year 2020.

Cash, cash equivalents and short-term investments totaled \$202.4 million as of December 31, 2020.

Impact of COVID-19 Pandemic and 2021 Financial Guidance

The COVID-19 pandemic continues to create significant uncertainty globally, including in relation to (i) the scope and duration of the current global resurgence of COVID-19 cases, (ii) the impact of new mutations of the virus, (iii) the timing and efficacy of COVID-19 vaccines, and (iv) the timing and extent of a global recovery and economic normalization. Given this continued uncertainty, we cannot provide reasonable guidance as to Shockwave Medical's future results of operations and financial performance. As such, Shockwave is not issuing 2021 financial guidance at this time.

Conference Call

Shockwave Medical will host a conference call at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time on Wednesday, February 17, 2021 to discuss its fourth quarter and full year 2020 financial results. The call may be accessed through an operator by dialing (866) 795-9106 for domestic callers or (470) 495-9173 for international callers, using conference ID: 7854854. A live and archived webcast of the event will be available at https://ir.shockwavemedical.com/.

About Shockwave Medical, Inc.

Shockwave Medical is focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. Shockwave Medical aims to establish a new standard of care for the interventional treatment of atherosclerotic cardiovascular disease through differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which Shockwave Medical refers to as Intravascular Lithotripsy (IVL). IVL is a minimally invasive, easy-to-use and safe way to significantly improve patient outcomes. To view an animation of the IVL procedure and for more information, visit www.shockwavemedical.com.

Forward-Looking Statements

This press release contains statements relating to our expectations, projections, beliefs, and prospects, which are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue," and similar expressions, and the negative of these terms. You are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements are only predictions based on our current expectations, estimates, and assumptions, valid only as of the date they are made, and subject to risks and uncertainties, some of which we are not currently aware.

Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others: the impact of the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including the impact on our sales, expenses, supply chain, manufacturing, research and development activities, clinical trials, and employees; our ability to develop, manufacture, obtain and maintain regulatory approvals for, market and sell, our products; our expected future growth, including the size and growth potential of the markets for our products; our ability to obtain coverage and reimbursement for procedures performed using our products; our ability to scale our organizational culture; the impact of the development, regulatory approval, efficacy and commercialization of competing products; the loss of key scientific or management personnel; our ability to develop and maintain our corporate infrastructure, including our internal controls; our financial performance and capital requirements; and our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others. These factors, as well as others, are discussed in our filings with the Securities and Exchange Commission (SEC), including in Part I, Item IA - Risk Factors in our most recent Annual Report on Form 10-K filed with the SEC, and in our other periodic and other reports filed with the SEC. Except to the extent required by law, we do not undertake to update any of these forward-looking statements after the date hereof to conform these statements to actual results or revised expectations.

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SHOCKWAVE MEDICAL, INC. Balance Sheet Data (in thousands)

	December 31, 2020 (Unaudited)		December 31, 2019		
ASSETS					
CURRENT ASSETS:					
Cash and cash equivalents	\$	50,423	\$	139,045	
Short-term investments		151,931		56,304	
Accounts receivable, net		11,689		7,377	
Inventory		29,859		12,074	
Prepaid expenses and other current assets		2,398		1,897	
Total current assets		246,300		216,697	
Operating lease right-of-use assets		7,568		8,825	
Property and equipment, net		16,362		4,910	
Other assets		1,812		1,506	
TOTAL ASSETS	\$	272,042	\$	231,938	
LIABILITIES AND STOCKHOLDERS' EQUITY					
CURRENT LIABILITIES:					
Accounts payable	\$	1,466	\$	2,790	
Term notes, current portion		3,300		6,667	
Accrued liabilities		19,942		13,777	
Lease liability, current portion		873		774	
Total current liabilities		25,581		24,008	
Lease liability, noncurrent		7,488		8,125	
Term notes, noncurrent portion		13,319		7,152	
TOTAL LIABILITIES		46,388		39,285	

STOCKHOLDERS' EQUITY:			
Preferred stock	_		_
Common stock	35		31
Additional paid-in capital	469,283		370,561
Accumulated other comprehensive loss	9		35
Accumulated deficit	(243,673)		(177,974)
TOTAL STOCKHOLDERS' EQUITY	225,654		192,653
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 272.042	\$ <u> </u>	231.938

SHOCKWAVE MEDICAL, INC. Statement of Operations Data (Unaudited)

(in thousands, except share and per share data)

	Three Months Ended December 31,			Year Ended December 31,					
		2020		2019		2020		2019	
Revenue:									
Product revenue	\$	22,716	\$	14,312	\$	67,789	\$	42,927	
Cost of revenue:									
Cost of product revenue		6,471		5,553		20,991		17,159	
Gross profit		16,245		8,759		46,798		25,768	
Operating expenses:									
Research and development		9,044		10,075		36,926		32,853	
Sales and marketing		16,436		9,597		51,672		30,620	
General and administrative		6,631		4,450		23,863		14,134	
Total operating expenses		32,111		24,122		112,461		77,607	
Loss from operations		(15,866)		(15,363)		(65,663)		(51,839)	
Interest expense		(315)		(198)		(1,212)		(944)	
Change in fair value of warrant liability		_		_		_		(609)	
Other income, net		314		827		1,256		2,345	
Net loss before taxes		(15,867)		(14,734)		(65,619)		(51,047)	
Income tax provision		7		11		80		62	
Net loss	\$	(15,874)	\$	(14,745)	\$	(65,699)	\$	(51,109)	
Net loss per share, basic and diluted	\$	(0.46)	\$	(0.49)	\$	(1.99)	\$	(2.14)	
Shares used in computing net loss per share, basic and diluted		34,447,314		29,894,306		33,088,095		23,904,828	



Source: Shockwave Medical, Inc.