

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event Reported): February 17, 2021

**Shockwave Medical, Inc.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction of Incorporation)

**001-38829**  
(Commission File Number)

**27-0494101**  
(I.R.S. Employer Identification Number)

**5403 Betsy Ross Drive, Santa Clara, California 95054**  
(Address of Principal Executive Offices) (Zip Code)

**(510) 279-4262**  
(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:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)  
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)  
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))  
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	SWAV	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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 February 17, 2021, the Company issued a press release (the “Press Release”) announcing its financial results for the quarter and year ended December 31, 2020. A copy of the Press Release is attached as Exhibit 99.1 to this current report on Form 8-K.

The information under Item 2.02 in this current report on Form 8-K and the related information in the exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “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, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<b><u>Exhibit Number</u></b>	<b><u>Description of Exhibit</u></b>
<a href="#">99.1</a>	<a href="#">Press Release dated February 17, 2021</a>

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## 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 hereunto duly authorized.

**Shockwave Medical, Inc.**

Date: February 17, 2021

By: /s/ Dan Puckett  
Dan Puckett  
Chief Financial Officer

## Shockwave Medical Reports Fourth Quarter and Full Year 2020 Financial Results

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 C<sup>2</sup> 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

## 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](http://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
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
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
<b>TOTAL ASSETS</b>	<b>\$ 272,042</b>	<b>\$ 231,938</b>

**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	\$ 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