

**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): May 10, 2021**

**SHOCKWAVE MEDICAL, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or Other Jurisdiction of Incorporation)

**001-38829**

(Commission File Number)

**27-0494101**

(I.R.S. Employer Identification No.)

**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 (§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 10, 2021, the Company issued a press release (the “Press Release”) announcing its financial results for the quarter ended March 31, 2021. 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

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
<a href="#">99.1</a>	<a href="#">Press Release dated May 10, 2021</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**SIGNATURE**

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: May 10, 2021

By: /s/ Daniel K. Puckett  
Daniel K. Puckett  
Chief Financial Officer

## Shockwave Medical Reports First Quarter 2021 Financial Results

SANTA CLARA, Calif., May 10, 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 ended March 31, 2021.

### Recent Highlights

- Recognized revenue of \$31.9 million for the first quarter of 2021, representing an increase of 110% from the same period in 2020
- Received Pre-Market Approval for use of IVL in severely calcified coronary artery disease from the U.S. Food and Drug Administration, and subsequently launched our Shockwave C<sup>2</sup> device in the U.S.
- Announced formation of a joint venture with Genesis MedTech Group, an established entity whose management team has a solid track record of commercializing medical devices in mainland China
- Submitted Shonin application to PMDA for commercial approval of IVL for coronary use in Japan
- CMS proposed new technology add on codes, or NTAP, for inpatient coronary procedures where IVL is used

“This quarter has been a highly productive one for Shockwave and I could not be more impressed by the achievements of our team and the support of our customers,” said Doug Godshall, President and Chief Executive Officer of Shockwave Medical.

“With the recent FDA approval of our Shockwave C<sup>2</sup> device, followed by the proposed NTAP payment by CMS only eight weeks after approval, we are well positioned to continue to expand our reach in helping to treat patients with severely calcified arterial disease.”

### First Quarter 2021 Financial Results

Revenue for the first quarter ended March 31, 2021 was \$31.9 million, a 110% increase from \$15.2 million in the same period of 2020. The growth was primarily driven by the launch of the coronary product, Shockwave C<sup>2</sup>, in the U.S. in February and increased adoption of Shockwave products.

Gross profit for the first quarter of 2021 was \$24.0 million compared to \$9.5 million for the first quarter of 2020. Gross margin for the first quarter of 2021 was 75%, as compared to 63% in the first quarter of 2020. Contributors to gross margin expansion included the launch of Shockwave C<sup>2</sup> in the US, which has a higher selling price, and continued improvements in manufacturing productivity and process efficiencies.

Total operating expenses for the first quarter of 2021 were \$41.5 million, a 45% increase from \$28.5 million in the first quarter of 2020. The increase was primarily driven by salesforce expansion in the U.S. and higher headcount to support the growth of the business.

Net loss for the first quarter of 2021 was \$23.6 million, compared to a net loss of \$18.8 million in the same period of 2020. Net loss per share for the period was \$0.68.

Cash, cash equivalents and short-term investments totaled \$177.4 million as of March 31, 2021.

### 2021 Financial Guidance

Shockwave Medical projects revenue for the full year 2021 to range from \$195 million to \$205 million, which would represent 188% to 202% growth over the company’s prior year revenue.

### Conference Call

Shockwave Medical will host a conference call at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time on Monday, May 10, 2021 to discuss its first quarter 2021 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: 5446898. 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](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)**

	<b>March 31, 2021 (Unaudited)</b>	<b>December 31, 2020</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 57,006	\$ 50,423
Short-term investments	120,422	151,931
Accounts receivable, net	19,613	11,689
Inventory	33,538	29,859
Prepaid expenses and other current assets	2,533	2,398
<b>Total current assets</b>	<b>233,112</b>	<b>246,300</b>
Operating lease right-of-use assets	7,211	7,568
Property and equipment, net	20,233	16,362
Equity method investment	6,750	—
Other assets	1,764	1,812
<b>TOTAL ASSETS</b>	<b>\$ 269,070</b>	<b>\$ 272,042</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 3,728	\$ 1,466
Term notes, current portion	4,950	3,300
Accrued liabilities	23,918	19,942
Lease liability, current portion	898	873
<b>Total current liabilities</b>	<b>33,494</b>	<b>25,581</b>
Lease liability, noncurrent	7,213	7,488
Term notes, noncurrent portion	11,836	13,319
Related party contract liability, noncurrent portion	12,273	—
<b>TOTAL LIABILITIES</b>	<b>64,816</b>	<b>46,388</b>
<b>STOCKHOLDERS' EQUITY:</b>		

Preferred stock	—	—
Common stock	35	35
Additional paid-in capital	471,477	469,283
Accumulated other comprehensive loss	16	9
Accumulated deficit	(267,274)	(243,673)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>204,254</b>	<b>225,654</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 269,070</b>	<b>\$ 272,042</b>

**SHOCKWAVE MEDICAL, INC.**  
**Statement of Operations Data**  
**(Unaudited)**  
**(in thousands, except share and per share data)**

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2021</b>	<b>2020</b>
Revenue:		
Product revenue	\$ 31,900	\$ 15,197
Cost of revenue:		
Cost of product revenue	7,892	5,651
Gross profit	24,008	9,546
Operating expenses:		
Research and development	10,277	11,890
Sales and marketing	23,992	10,411
General and administrative	7,226	6,224
Total operating expenses	41,495	28,525
Loss from operations	(17,487)	(18,979)
Share in net loss of equity method investment	(5,523)	—
Interest expense	(312)	(277)
Other income (expense), net	(235)	504
Net loss before taxes	(23,557)	(18,752)
Income tax provision	44	23
Net loss	\$ (23,601)	\$ (18,775)
Net loss per share, basic and diluted	\$ (0.68)	\$ (0.59)
Shares used in computing net loss per share, basic and diluted	34,797,400	31,644,041