

**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, 2022

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 February 17, 2022, the Company issued a press release (the “Press Release”) announcing its financial results for the quarter and year ended December 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

Exhibit Number **Description**

99.1	Press Release dated February 17, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: February 17, 2022

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

Shockwave Medical Reports Fourth Quarter and Full Year 2021 Financial Results

SANTA CLARA, Calif., Feb. 17, 2022 (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, 2021.

Recent Highlights

- Recognized revenue of \$84.2 million for the fourth quarter of 2021 and \$237.1 million for the full year of 2021, representing increases of 271% and 250%, respectively, from the same periods in 2020
- Centers for Medicare & Medicaid Services (CMS) reassigned the payment for peripheral IVL procedures performed on above the knee (ATK) arteries in the hospital outpatient setting, thereby meaningfully increasing the payments hospitals receive for these procedures
- Enrolled the first patient in our Disrupt BTK II global post-market study that is designed to assess the long-term benefit of peripheral IVL on the most challenging calcified below the knee lesions
- Ended the year with 125 issued and 46 pending patents

“I continue to be humbled by the exceptional performance of the entire Shockwave team, despite the unpredictable and unprecedented challenges that are constantly being put in front of us,” said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. “2021 was another stellar year with significant achievements across the board - from regulatory and sales to reimbursement, marketing, and operations. I want to thank our employees for their hard work and persistence in helping us achieve these successes and our customers and investigators for supporting us as we pursue our mission to improve outcomes for patients with calcified vascular disease.”

Fourth Quarter 2021 Financial Results

Revenue for the fourth quarter of 2021 was \$84.2 million, an increase of \$61.5 million, or 271%, compared to the corresponding prior year period. Revenue growth was primarily driven by the launch of the coronary product, Shockwave C², in the U.S. in February, sales force expansion in the U.S. and increased penetration in both U.S. and international markets.

Gross profit for the fourth quarter of 2021 was \$71.5 million compared to \$16.2 million for corresponding prior year period. Gross margin for the fourth quarter of 2021 was 85%, as compared to 72% in the corresponding prior year period. Contributors to increased gross margin included product mix in addition to continued improvement in manufacturing productivity and process efficiencies.

Operating expenses for the fourth quarter of 2021 were \$57.5 million, compared to \$32.1 million for the corresponding prior year period, representing a 79% increase, primarily driven by increases in headcount to support growth in the business.

Net income was \$12.9 million in the fourth quarter of 2021, as compared to a net loss of \$15.9 million in the corresponding prior year period. Basic net income per share was \$0.37 in the fourth quarter of 2021. Diluted net income per share was \$0.34 in the fourth quarter of 2021.

Full Year 2021 Financial Results

Revenue for the full year 2021 was \$237.1 million, an increase of \$169.4 million, or 250%, compared to the full year of 2020. The growth was primarily driven by the launch of Shockwave C² in the U.S. in February, along with expansion of the U.S. sales force and international distributor network.

Gross profit for the full year 2021 was \$195.7 million compared to \$46.8 million for the full year 2020. The gross margin percentage for the full year 2021 increased to 83% compared to 69% in the full year 2020, driven primarily by product mix in addition to continued improvements in production processes and greater absorption of fixed costs by higher production.

Operating expenses were \$196.6 million for the full year 2021, compared to \$112.5 million in the full year 2020, an increase of 75% primarily driven by headcount increases.

Net loss was \$9.1 million for the full year 2021, as compared to \$65.7 million in the full year 2020. Net loss per share was \$0.26 for the full year 2021.

Cash, cash equivalents and short-term investments totaled \$201 million as of December 31, 2021.

2022 Financial Guidance

Shockwave Medical projects revenue for the full year 2022 to range from \$405 million to \$425 million, which represents 71% to 79% growth over the full year 2021 revenue.

Conference Call

Shockwave Medical will host a conference call at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time on Thursday, February 17, 2022, to discuss its fourth quarter and full year 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: 6866777. 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, uncertainties, assumptions and other factors that could cause our actual results, level of activity, performance, or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements.

Forward-looking statements contained in this press release include, but are not limited to the following, statements about: 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, 2021	December 31, 2020
	(Unaudited)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 89,209	\$ 50,423
Short-term investments	111,772	151,931
Accounts receivable, net	37,435	11,689
Inventory	42,978	29,859
Prepaid expenses and other current assets	4,508	2,398
Total current assets	285,902	246,300
Operating lease right-of-use assets	27,496	7,568
Property and equipment, net	24,361	16,362
Equity method investment	5,987	—

Other assets	1,936	1,812
TOTAL ASSETS	<u>\$ 345,682</u>	<u>\$ 272,042</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 3,520	\$ 1,466
Term notes, current portion	5,500	3,300
Accrued liabilities	40,870	19,942
Lease liability, current portion	1,738	873
Total current liabilities	<u>51,628</u>	<u>25,581</u>
Lease liability, noncurrent	28,321	7,488
Term notes, noncurrent portion	11,630	13,319
Related party contract liability, noncurrent portion	12,273	—
TOTAL LIABILITIES	<u>103,852</u>	<u>46,388</u>
STOCKHOLDERS' EQUITY:		
Preferred stock	—	—
Common stock	35	35
Additional paid-in capital	494,806	469,283
Accumulated other comprehensive income (loss)	(202)	9
Accumulated deficit	<u>(252,809)</u>	<u>(243,673)</u>
TOTAL STOCKHOLDERS' EQUITY	<u>241,830</u>	<u>225,654</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 345,682</u>	<u>\$ 272,042</u>

SHOCKWAVE MEDICAL, INC.

Statement of Operations Data

(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
Revenue:				
Product revenue	\$ 84,183	\$ 22,716	\$ 237,146	\$ 67,789
Cost of revenue:				
Cost of product revenue	12,663	6,471	41,438	20,991
Gross profit	<u>71,520</u>	<u>16,245</u>	<u>195,708</u>	<u>46,798</u>
Operating expenses:				
Research and development	14,717	9,044	50,544	36,926
Sales and marketing	33,190	16,436	111,288	51,672
General and administrative	9,630	6,631	34,747	23,863
Total operating expenses	<u>57,537</u>	<u>32,111</u>	<u>196,579</u>	<u>112,461</u>
Income (loss) from operations	13,983	(15,866)	(871)	(65,663)
Share in net loss of equity method investment	(421)	—	(6,286)	—
Interest expense	(301)	(315)	(1,096)	(1,212)
Other income (expense), net	(213)	314	(582)	1,256
Net income (loss) before taxes	<u>13,048</u>	<u>(15,867)</u>	<u>(8,835)</u>	<u>(65,619)</u>
Income tax provision	106	7	301	80
Net income (loss)	<u>\$ 12,942</u>	<u>\$ (15,874)</u>	<u>\$ (9,136)</u>	<u>\$ (65,699)</u>
Net income (loss) per share				
Basic	\$ 0.37	\$ (0.46)	\$ (0.26)	\$ (1.99)
Diluted	\$ 0.34	\$ (0.46)	\$ (0.26)	\$ (1.99)
Shares used in computing net income (loss) per share				
Basic	35,350,529	34,447,314	35,098,130	33,088,095
Diluted	37,614,385	34,447,314	35,098,130	33,088,095