

**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): November 8, 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 November 8, 2021, the Company issued a press release (the “Press Release”) announcing its financial results for the quarter ended September 30, 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 November 8, 2021
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: November 8, 2021

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

Shockwave Medical Reports Third Quarter 2021 Financial Results

SANTA CLARA, Calif., Nov. 08, 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 September 30, 2021.

Recent Highlights

- Recognized revenue of \$65.2 million for the third quarter of 2021, representing an increase of 233% from the same period in 2020
- DISRUPT PAD III observational study results of peripheral IVL featured as a late breaking presentation at the VIVA21 conference
- First one-year results, a new gender analysis and an OCT analysis from the Disrupt CAD coronary IVL clinical program presented in several sessions at the 32nd Transcatheter Cardiovascular Therapeutics (TCT) annual scientific symposium
- Centers for Medicare & Medicaid Services (CMS) increased payment for above the knee peripheral IVL procedures as part of the calendar year 2022 Medicare Hospital Outpatient Prospective Payment System (OPPS) final rule

“I have been encouraged to see the consistent clinical acceptance and penetration of IVL, as shown by our solid results in the third quarter, which were once again led by the broadening adoption of coronary IVL in the U.S.,” said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. “In addition, the ongoing generation of clinical data to support the use of IVL across indications, lesion types and demographics speaks volumes about the incredible consistency and reliability of IVL in treating these most complex calcified patients.”

Third Quarter 2021 Financial Results

Revenue for the third quarter ended September 30, 2021 was \$65.2 million, a 233% increase from \$19.6 million in the same period of 2020. The growth was primarily driven by the launch of the coronary product, Shockwave C², in the U.S. in February, continued recovery from the pandemic impact and increased adoption of Shockwave products.

Gross profit for the third quarter of 2021 was \$54.2 million compared to \$14.3 million for the third quarter of 2020. Gross margin for the third quarter of 2021 was 83%, as compared to 73% in the third quarter of 2020. Increase in gross margin was driven by product mix along with continued improvement in manufacturing productivity and process efficiencies.

Total operating expenses for the third quarter of 2021 were \$51.4 million, a 90% increase from \$27.1 million in the third 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 income for the third quarter of 2021 was \$1.9 million, compared to a net loss of \$12.9 million in the same period of 2020. Basic net income per share for the period was \$0.06. Diluted net income per share for the period was \$0.05.

Cash, cash equivalents and short-term investments totaled \$183 million as of September 30, 2021.

2021 Financial Guidance

Shockwave Medical projects revenue for the full year 2021 to range from \$227 million to \$228 million, which represents 235% to 236% growth over the company’s prior year revenue. This compares to previous revenue guidance of \$218 million to \$223 million.

Conference Call

Shockwave Medical will host a conference call at 2:00 p.m. Pacific Time / 5:00 p.m. Eastern Time on Monday, November 8, 2021 to discuss its third 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: 9166273. 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
(Unaudited)
(in thousands)

	September 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 91,195	\$ 50,423
Short-term investments	91,759	151,931
Accounts receivable, net	29,966	11,689
Inventory	38,744	29,859
Prepaid expenses and other current assets	4,364	2,398
Total current assets	<u>256,028</u>	<u>246,300</u>
Operating lease right-of-use assets	11,790	7,568
Property and equipment, net	23,085	16,362
Equity method investment	6,408	—
Other assets	1,684	1,812
TOTAL ASSETS	<u><u>\$ 298,995</u></u>	<u><u>\$ 272,042</u></u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 3,632	\$ 1,466
Term notes, current portion	2,750	3,300
Accrued liabilities	33,017	19,942
Lease liability, current portion	867	873
Total current liabilities	<u>40,266</u>	<u>25,581</u>
Lease liability, noncurrent portion	11,939	7,488
Term notes, noncurrent portion	14,226	13,319
Related party contract liability, noncurrent portion	12,273	—
TOTAL LIABILITIES	<u><u>78,704</u></u>	<u><u>46,388</u></u>
STOCKHOLDERS' EQUITY:		
Preferred stock	—	—

Common stock	35	35
Additional paid-in capital	486,014	469,283
Accumulated other comprehensive income	(7)	9
Accumulated deficit	(265,751)	(243,673)
TOTAL STOCKHOLDERS' EQUITY	220,291	225,654
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 298,995	\$ 272,042

SHOCKWAVE MEDICAL, INC.

Statement of Operations Data

(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Product revenue	\$ 65,155	\$ 19,590	\$ 152,963	\$ 45,073
Cost of revenue:				
Cost of product revenue	10,949	5,277	28,775	14,520
Gross profit	54,206	14,313	124,188	30,553
Operating expenses:				
Research and development	13,735	7,891	35,827	27,882
Sales and marketing	28,393	13,619	78,098	35,236
General and administrative	9,265	5,610	25,117	17,232
Total operating expenses	51,393	27,120	139,042	80,350
Income (Loss) from operations	2,813	(12,807)	(14,854)	(49,797)
Share in net loss of equity method investment	(342)	—	(5,865)	—
Interest expense	(165)	(314)	(795)	(897)
Other income (expense), net	(280)	218	(369)	942
Net income (loss) before taxes	2,026	(12,903)	(21,883)	(49,752)
Income tax provision	78	29	195	73
Net income (loss)	<u>\$ 1,948</u>	<u>\$ (12,932)</u>	<u>\$ (22,078)</u>	<u>\$ (49,825)</u>
Net income (loss) per share				
Basic	\$ 0.06	\$ (0.38)	\$ (0.63)	\$ (1.53)
Diluted	\$ 0.05	\$ (0.38)	\$ (0.63)	\$ (1.53)
Shares used in computing net income (loss) per share				
Basic	35,207,276	34,078,726	35,013,072	32,631,715
Diluted	37,567,176	34,078,726	35,013,072	32,631,715