

**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 7, 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 November 07, 2022, the Company issued a press release (the “Press Release”) announcing its financial results for the three months ended September 30, 2022. 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 7, 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: November 7, 2022

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

Shockwave Medical Reports Third Quarter 2022 Financial Results

SANTA CLARA, Calif., Nov. 07, 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 ended September 30, 2022.

Recent Highlights

- Recognized revenue of \$131.3 million for the third quarter of 2022, representing an increase of 102% from the same period in 2021
- Received FDA Clearance for the Shockwave IVL System with the Shockwave L⁶ Peripheral IVL Catheter
- Received CE marking for the Shockwave C²⁺ coronary catheter in Europe
- Granted reimbursement for the Shockwave C² Coronary IVL Catheter by the Japanese Ministry of Health, Labour and Welfare (MHLW) in Japan

“Our third quarter achievements were encouraging across the entire Shockwave organization. Sales of all products, both in the U.S. and international markets, outperformed expectations, and operationally our accomplishments continue to be the backbone of our success,” said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. “These results were particularly impressive in light of the many ongoing macro issues we have all seen across the globe. Despite these challenges, our team and our customers have been able to adapt and remain focused on using our IVL technology to treat patients suffering from calcified vascular disease.”

Third Quarter 2022 Financial Results

Revenue for the third quarter ended September 30, 2022, was \$131.3 million, a 102% increase from \$65.2 million in the same period of 2021. The growth was primarily driven by the launch of the coronary product, Shockwave C², in the U.S. in February 2021, continued recovery from the pandemic impact and increased adoption of Shockwave products.

Gross profit for the third quarter of 2022 was \$113.5 million compared to \$54.2 million for the third quarter of 2021. Gross margin for the third quarter of 2022 was 86%, as compared to 83% in the third quarter of 2021. The increase in gross margin was primarily driven by product mix along with continued improvement in manufacturing productivity and process efficiencies.

Total operating expenses for the third quarter of 2022 were \$76.7 million, a 49% increase from \$51.4 million in the third quarter of 2021. The increase was primarily driven by sales force expansion in the U.S. and higher headcount to support the growth of the business.

Net income for the third quarter of 2022 was \$35.0 million, compared to net income of \$1.9 million in the same period of 2021. Basic and diluted net income per share for the third quarter of 2022 was \$0.97 and \$0.92, respectively.

Cash, cash equivalents and short-term investments totaled \$250.7 million as of September 30, 2022.

2022 Financial Guidance

Shockwave Medical projects revenue for the full year 2022 to range from \$483 million to \$488 million, which represents 104% to 106% growth over the Company’s prior year revenue. This compares to previous revenue guidance of \$465 million to \$475 million.

Conference Call

Shockwave Medical will host a conference call at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time on Monday, November 7, 2022, to discuss its third quarter 2022 financial results. The call may be accessed by dialing 877-704-4453 for domestic callers or 201-389-0920 for international callers, using conference ID:13733213. 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)

	September 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 127,779	\$ 89,209
Short-term investments	122,888	111,772
Accounts receivable, net	64,224	37,435
Inventory	68,974	42,978
Prepaid expenses and other current assets	11,393	4,508
Total current assets	395,258	285,902
Operating lease right-of-use assets	33,107	27,496
Property and equipment, net	39,265	24,361
Equity method investment	4,573	5,987
Other assets	3,606	1,936
TOTAL ASSETS	\$ 475,809	\$ 345,682
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 3,469	\$ 3,520
Term notes, current portion	—	5,500
Accrued liabilities	49,492	40,870
Lease liability, current portion	1,260	1,738
Total current liabilities	54,221	51,628
Lease liability, noncurrent	38,532	28,321
Term notes, noncurrent portion	14,853	11,630

Related party contract liability, noncurrent portion	12,273	12,273
TOTAL LIABILITIES	119,879	103,852
STOCKHOLDERS' EQUITY:		
Preferred stock	—	—
Common stock	36	35
Additional paid-in capital	535,230	494,806
Accumulated other comprehensive loss	(1,612)	(202)
Accumulated deficit	(177,724)	(252,809)
TOTAL STOCKHOLDERS' EQUITY	355,930	241,830
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 475,809	\$ 345,682

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Revenue:				
Product revenue	\$ 131,330	\$ 65,155	\$ 345,707	\$ 152,963
Cost of revenue:				
Cost of product revenue	17,874	10,949	47,494	28,775
Gross profit	113,456	54,206	298,213	124,188
Operating expenses:				
Research and development	20,177	13,735	57,956	35,827
Sales and marketing	42,082	28,393	118,558	78,098
General and administrative	14,434	9,265	39,988	25,117
Total operating expenses	76,693	51,393	216,502	139,042
Income (loss) from operations	36,763	2,813	81,711	(14,854)
Income (loss) from equity method investment	97	(342)	(1,414)	(5,865)
Interest expense	(316)	(165)	(917)	(795)
Other expense, net	(1,423)	(280)	(3,206)	(369)
Net income (loss) before taxes	35,121	2,026	76,174	(21,883)
Income tax provision	118	78	1,089	195
Net income (loss)	\$ 35,003	\$ 1,948	\$ 75,085	\$ (22,078)
Net income (loss) per share, basic	\$ 0.97	\$ 0.06	\$ 2.10	\$ (0.63)
Net income (loss) per share, diluted	\$ 0.92	\$ 0.05	\$ 1.99	\$ (0.63)
Shares used in computing net income (loss) per share, basic	36,003,931	35,207,276	35,807,264	35,013,072
Shares used in computing net income (loss) per share, diluted	37,948,049	37,567,176	37,813,107	35,013,072