

**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 8, 2023

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	The Nasdaq Stock Market LLC

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 8, 2023, the Company issued a press release (the “Press Release”) announcing its financial results for the first quarter ended March 31, 2023. 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 May 8, 2023
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: May 8, 2023

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

Shockwave Medical Reports First Quarter 2023 Financial Results

SANTA CLARA, Calif., May 08, 2023 (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, 2023.

Recent Highlights

- Recognized revenue of \$161.1 million for the first quarter of 2023, representing an increase of 72% from the same period in 2022
- Announced the full U.S. commercial availability of the Shockwave L⁶ Peripheral IVL Catheter following clearance by the U.S. Food and Drug Administration (FDA)
- Centers for Medicare & Medicaid Services (CMS), as part of the calendar year 2024 Medicare Hospital Inpatient Prospective Payment System (IPPS) proposed rule, proposed three newly introduced MS-DRGs specific to IVL in order to address the higher average costs and generally longer lengths of stay associated with IVL compared with the cases in their previously assigned MS-DRGs
- Completed the acquisition of Neovasc Inc.

“Our global teams’ execution continues to be extraordinary, as demonstrated by our record results in all of our product and geographic areas,” said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. “The consistent high growth we have experienced over the past few years has further reinforced our drive to continue rapidly growing our core IVL business and to also innovate and develop additional solutions for patients with unmet needs. We look forward to continued collaboration with our customers to develop new solutions and enhance outcomes for their patients with problematic calcium and we are excited to begin the mission to address patients suffering from refractory angina.”

First Quarter 2023 Financial Results

Revenue for the first quarter ended March 31, 2023, was \$161.1 million, a 72% increase from \$93.6 million in the same period of 2022. The growth was primarily driven by an increase in the purchase volume of our catheters in both the United States and internationally.

Gross profit for the first quarter of 2023 was \$140.0 million compared to \$80.7 million for the first quarter of 2022. Gross margin for the first quarter of 2023 was 87%, as compared to 86% in the first quarter of 2022. The increase in gross margin was primarily driven by product mix in addition to continued improvement in manufacturing productivity and process efficiencies.

Total operating expenses for the first quarter of 2023 were \$100.2 million, a 53% increase from \$65.4 million in the first quarter of 2022. The increase was primarily driven by sales force expansion in the United States and higher headcount to support the growth of the business.

Net income for the first quarter of 2023 was \$39.1 million, compared to net income of \$14.5 million in the same period of 2022. Basic and diluted net income per share for the period was \$1.07 and \$1.03, respectively.

Cash, cash equivalents and short-term investments totaled \$416.9 million as of March 31, 2023.

2023 Financial Guidance

Shockwave Medical projects revenue for the full year 2023 to range from \$700 million to \$720 million, which represents 43% to 47% growth over the Company’s prior year revenue. This compares to previous revenue guidance for the full year of 2023 of \$660 million to \$680 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, May 8, 2023, to discuss its first quarter 2023 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: 13737254. A live and archived webcast of the event will be available at <https://ir.shockwavemedical.com/>.

About Shockwave Medical, Inc.

Shockwave Medical is a leader in the development and commercialization of innovative products that are transforming the treatment of cardiovascular disease. Its first-of-its-kind Intravascular Lithotripsy (IVL) technology has transformed the treatment of atherosclerotic cardiovascular disease by safely using sonic pressure waves to disrupt challenging calcified plaque, resulting in significantly improved patient outcomes. Shockwave has also recently acquired the Neovasc Reducer, which is under clinical investigation in the United States and is CE Marked in the European Union and the United Kingdom. By redistributing blood flow within the heart, the Reducer is designed to provide relief to the millions of patients worldwide suffering from refractory angina. Learn more at www.shockwavemedical.com and www.neovasc.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. Forward-looking statements in this press release include, but are not limited to, statements regarding our anticipated future operating results and financial position, including for the full year ending December 31, 2023, our business strategy and plans, our objectives for future operations and financial performance and other matters. 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 macroeconomic conditions, including inflation, rising interest rates, instability in the global banking system, and volatile market conditions, and geopolitical factors, including the ongoing conflict between Russia and Ukraine and responses thereto, supply chain disruptions, and the remaining effects of the COVID-19 pandemic, on our operations, financial results, liquidity, capital resources, expenses, supply chain, manufacturing, research and development activities, clinical trials, and employees; our ability to successfully execute our business and growth strategies; our ability to develop, manufacture, obtain and maintain regulatory approvals for, and 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; the success of any acquisitions that we make; 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 the sections titled “Risk Factors” in our most recent Annual Report on Form 10-K and any subsequently filed Quarterly Reports on Form 10-Q, and in our 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)

	March 31, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 280,932	\$ 156,586
Short-term investments	135,929	147,907
Accounts receivable, net	84,309	71,366
Inventory	83,256	75,112
Prepaid expenses and other current assets	6,399	8,292
Total current assets	590,825	459,263
Operating lease right-of-use assets	31,623	32,365
Property and equipment, net	54,057	48,152
Equity method investment	2,689	3,512
Deferred tax assets	97,941	97,568
Other assets	6,112	5,229
TOTAL ASSETS	\$ 783,247	\$ 646,089
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		

Accounts payable	\$	11,050	\$	6,721
Debt, current portion		80,000		—
Accrued liabilities		49,640		55,375
Lease liability, current portion		1,308		1,278
Total current liabilities		141,998		63,374
Lease liability, noncurrent portion		34,058		34,928
Debt, noncurrent portion		24,231		24,198
Related party contract liability, noncurrent portion		12,273		12,273
TOTAL LIABILITIES		212,560		134,773
STOCKHOLDERS' EQUITY:				
Preferred stock		—		—
Common stock		37		36
Additional paid-in capital		568,705		548,960
Accumulated other comprehensive loss		(367)		(867)
Retained earnings (accumulated deficit)		2,312		(36,813)
TOTAL STOCKHOLDERS' EQUITY		570,687		511,316
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	783,247	\$	646,089

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

	Three Months Ended	
	March 31,	
	2023	2022
Revenue:		
Product revenue	\$ 161,066	\$ 93,631
Cost of revenue:		
Cost of product revenue	21,066	12,890
Gross profit	140,000	80,741
Operating expenses:		
Research and development	26,971	17,019
Sales and marketing	54,011	35,961
General and administrative	19,204	12,389
Total operating expenses	100,186	65,369
Income from operations	39,814	15,372
Loss from equity method investment	(823)	(47)
Interest expense	(636)	(297)
Other income (expense), net	2,382	(310)
Net income before taxes	40,737	14,718
Income tax provision	1,612	197
Net income	\$ 39,125	\$ 14,521
Net income per share, basic	\$ 1.07	\$ 0.41
Net income per share, diluted	\$ 1.03	\$ 0.39
Shares used in computing net income per share, basic	36,427,263	35,587,337
Shares used in computing net income per share, diluted	37,979,448	37,623,477