

**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 12, 2020

Shockwave Medical, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-38829
(Commission File Number)

27-0494101
(I.R.S. Employer Identification Number)

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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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 12, 2020, Shockwave Medical, Inc. issued a press release (the “Press Release”) announcing its financial results for the quarter ended March 31, 2020. 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>
99.1	Press release dated May 12, 2020

SIGNATURES

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 12, 2020

By: /s/ Dan Puckett
Dan Puckett
Chief Financial Officer

Shockwave Medical Reports First Quarter 2020 Financial Results

SANTA CLARA, Calif., May 12, 2020 (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, 2020.

Recent Highlights

- Recognized revenue of \$15.2 million for the first quarter of 2020, representing an increase of 109% over the first quarter of 2019
- Completed enrollment in CAD III study of IVL for coronary use in the U.S.
- Completed enrollment in CAD IV pivotal study of IVL for coronary use in Japan
- Extended geographic reach and now commercial in 46 countries
- Expanded US field team from 61 to 78 members

“We are very pleased with our first quarter results, particularly given the COVID-19 pandemic that is so profoundly impacting the world. Our results reflect the continued growth and penetration of our IVL products and the hard work and dedication of our teams across the globe as we work to continue to help our customers and patients in any way we can,” said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. “The foundation of Shockwave remains strong and I want to thank each employee and business partner for the resiliency and dedication they have shown during this unprecedented time. Our hearts go out to those who have lost their lives to the COVID-19 pandemic and I want to express our gratitude to the healthcare workers – many of whom are friends and customers of Shockwave - who are on the front line fighting this pandemic.”

First Quarter 2020 Financial Results

Revenue for the first quarter of 2020 was \$15.2 million, an increase of \$7.9 million, or 109%, compared to the first quarter of 2019. The growth was primarily driven by continued sales force expansion in the U.S. and increased penetration in both U.S. and international markets.

Gross profit for the first quarter of 2020 was \$9.5 million compared to \$4.2 million for the first quarter of 2019. The gross margin percentage for the first quarter of 2020 increased to 63% compared to 58% in the first quarter of 2019, driven primarily by continued improvements in production processes to drive efficiencies and greater absorption of fixed costs from increased production.

Operating expenses were \$28.5 million for the first quarter of 2020 compared to \$16.4 million in the corresponding prior year period, an increase of 74%, primarily driven by sales force expansion and clinical costs from the CAD III and CAD IV studies.

Net loss was \$18.8 million in the first quarter of 2020, as compared to \$12.8 million in the corresponding period of the prior year. Net loss per share was \$0.59 in the first quarter of 2020.

Cash, cash equivalents and short-term investments totaled \$170.4 million as of March 31, 2020.

2020 Financial Guidance

Shockwave Medical withdrew its previously announced annual guidance for 2020 on April 6, 2020. The COVID-19 pandemic reduced IVL catheter sales toward the end of the first quarter of 2020 and is continuing to adversely impact sales in the second quarter of 2020. The pandemic could also significantly impact the financial health of our customers which could pressure hospital spending and impact pricing. As a result of these factors as well as the uncertain scope and duration of the COVID-19 pandemic, and uncertain timing of global recovery, we cannot, at this time, reliably estimate the future impact on IVL catheter sales, and in turn, our operations and financial results.

Conference Call

Shockwave Medical will host a teleconference at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time on Tuesday, May 12, 2020 to discuss its first quarter. The teleconference will be webcasted live and available in listen-only mode on the company’s investor relations website at <https://ir.shockwavemedical.com/>. An archived webcast of the event will be available following the teleconference.

About Shockwave Medical, Inc.

Shockwave Medical is focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. The company aims to establish a new standard of care for medical device treatment of atherosclerotic cardiovascular disease through their differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which they refer 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 Shockwave’s expectations, projections, beliefs, and prospects (including statements regarding Shockwave’s product development outlook), which are “forward-looking statements” within the meaning of the federal securities laws and by their nature are uncertain. Words such as “believe,” “may,” “will,” “estimate,” “continue,”

“anticipate,” “intend,” “expect,” “plans,” and similar expressions are intended to identify forward-looking statements. Such forward-looking statements are not guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements.

Forward-looking statements include, but are not limited to statements about: the impact of the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including on our sales, expenses, supply chain, manufacturing, research and development activities, clinical trials and employees; our ability to design, develop, manufacture and market innovative products to treat patients with challenging medical conditions, particularly in peripheral artery disease, coronary artery disease and aortic stenosis; our expected future growth, including growth in international sales; the size and growth potential of the markets for our products, and our ability to serve those markets; the rate and degree of market acceptance of our products; coverage and reimbursement for procedures performed using our products; the performance of third parties in connection with the development of our products, including third-party suppliers; regulatory developments in the United States and foreign countries; our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines; our plans to research, develop and commercialize our products and any other approved or cleared product; our ability to scale our organizational culture of cooperative product development and commercial execution; the development, regulatory approval, efficacy and commercialization of competing products; the loss of key scientific or management personnel; our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; our ability to develop and maintain our corporate infrastructure, including our internal controls; our financial performance and capital requirements; and our expectations regarding 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 forward-looking statements are only predictions based on our current expectations and projections about future events. There are important 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. These factors, as well as others, are discussed in greater detail 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. There may be additional risks of which we are not presently aware or that we currently believe are immaterial which could have an adverse impact on our business. Any forward-looking statements are based on our current expectations, estimates and assumptions regarding future events and are applicable only as of the dates of such statements. We make no commitment to revise or update any forward-looking statements in order to reflect events or circumstances that may change.

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SHOCKWAVE MEDICAL, INC.
Balance Sheet Data
(in thousands)

	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 123,111	\$ 139,045
Short-term investments	47,278	56,304
Accounts receivable, net	7,811	7,377
Inventory	15,921	12,074
Prepaid expenses and other current assets	3,485	1,897
Total current assets	<u>197,606</u>	<u>216,697</u>
Operating lease right-of-use assets	8,495	8,825
Property and equipment, net	13,084	4,910
Other assets	1,553	1,506
TOTAL ASSETS	<u><u>\$ 220,738</u></u>	<u><u>\$ 231,938</u></u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,150	\$ 2,790
Term notes, current portion	—	6,667

Accrued liabilities	15,826	13,777
Lease liability, current portion	787	774
Total current liabilities	18,763	24,008
Lease liability, noncurrent	8,077	8,125
Term notes, noncurrent portion	16,126	7,152
TOTAL LIABILITIES	42,966	39,285
STOCKHOLDERS' EQUITY:		
Preferred stock	—	—
Common stock	32	31
Additional paid-in capital	374,386	370,561
Accumulated other comprehensive loss	103	35
Accumulated deficit	(196,749)	(177,974)
TOTAL STOCKHOLDERS' EQUITY	177,772	192,653
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 220,738	\$ 231,938

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

	Three Months Ended	
	March 31,	
	2020	2019
Revenue:		
Product revenue	\$ 15,197	\$ 7,269
Cost of revenue:		
Cost of product revenue	5,651	3,072
Gross profit	9,546	4,197
Operating expenses:		
Research and development	11,890	7,484
Sales and marketing	10,411	5,871
General and administrative	6,224	3,001
Total operating expenses	28,525	16,356
Loss from operations	(18,979)	(12,159)
Interest expense	(277)	(245)
Change in fair value of warrant liability	—	(609)
Other income, net	504	221
Net loss before taxes	(18,752)	(12,792)
Income tax provision	23	7
Net loss	\$ (18,775)	\$ (12,799)
Net loss per share, basic and diluted	\$ (0.59)	\$ (1.37)
Shares used in computing net loss per share, basic and diluted	31,644,041	9,364,755