

**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 earliest event Reported: February 11, 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))

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.

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

Item 1.01. Entry into a Material Definitive Agreement.

On February 11, 2020, Shockwave Medical, Inc. (the “Company”) entered into the First Amendment (the “Amendment”) to its Loan and Security Agreement, dated as of February 26, 2018 (the “Existing Loan Agreement”), with Silicon Valley Bank (“SVB”), to refinance its existing term loan.

The Amendment provides the Company with a supplemental term loan in the amount of \$16.5 million. The Company expects to use \$13.2 million of the proceeds from the supplemental term loan to repay in full all amounts due under its existing term loan and to pay related expenses. In addition, the Amendment terminates the Company’s existing \$2.0 million revolving line of credit with SVB under the Existing Loan Agreement.

The principal amount outstanding under the supplemental term loan accrues interest, payable monthly in arrears, at a floating per annum rate equal to the greater of (A) the Wall Street Journal prime rate minus 1.25% and (B) 3.50%. No principal payments are due on the supplemental term loan until June 30, 2021; provided that such interest only period shall be extended to December 31, 2021 if the Company achieves specified revenue milestones and shall be extended further to June 30, 2022 if the Company achieves specified revenue and regulatory milestones (the date that such interest only period ends, the “Amortization Date”). Following the Amortization Date, the principal amount of the supplemental term loan shall be due in equal monthly installments through the maturity date, December 1, 2023. There is also a final payment equal to 9.5% of the original principal amount of the supplemental term loan, or \$1.6 million, due at maturity (or any earlier date of optional pre-payment or acceleration of principal due to an event of default). The Company may, at its option, prepay the supplemental term loan in full, subject to an additional prepayment fee ranging between 0% and 3% of the original principal amount of the supplemental term loan. The prepayment fee would also be due and payable in the event of an acceleration of the principal amount of the supplemental term loan due to an event of default.

The supplemental term loan is secured by all of the Company’s assets, excluding intellectual property and certain other assets. The supplemental term loan is subject to customary affirmative and restrictive covenants, including with respect to the Company’s ability to enter into fundamental transactions, incur additional indebtedness, grant liens, pay any dividend or make any distributions to stockholders, make investments and merge or consolidate with any other person or engage in transactions with affiliates, but is not subject to any financial covenants.

The foregoing descriptions of the Amendment is not complete, and is qualified in its entirety by the full text of the Amendment, a copy of which will be filed with the Securities and Exchange Commission as an exhibit to the Company’s Quarterly Report on Form 10-Q for the three months ended March 31, 2020.

Item 2.02. Results of Operations and Financial Condition.

On February 13, 2020, the Company issued a press release (the “Press Release”) announcing its financial results for the quarter and year ended December 31, 2019. 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 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information set forth under Item 1.01 of this Current Report on Form 8-K is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
99.1	Press release dated February 13, 2020

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 13, 2020

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

Shockwave Medical Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Full Year 2020 Financial Outlook

SANTA CLARA, Calif., Feb. 13, 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 and full year ended December 31, 2019.

Recent Highlights

- Recognized revenue of \$14.3 million for the fourth quarter and \$42.9 million for the full year of 2019, representing increases of 183% and 250%, respectively, over the corresponding periods of 2018
- Commenced the full commercial launch of S⁴ Peripheral IVL Catheter in the U.S.
- Initiated the CAD IV study of IVL in Japan
- Ended the year with total enrollment of 346 patients in the CAD III IDE study in the U.S.
- Entered into a new sublease agreement - more than doubling the Company's office space to approximately 85,200 square feet
- Completed an underwritten public offering raising \$97 million in net proceeds

"I am encouraged by the progress we have made at Shockwave over the course of 2019. Our team improved their performance across the board – from clinical to sales to operations – as we all worked together to advance the use of IVL and to help change the way calcified cardiovascular disease is treated," said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. "The growing use of IVL across many different vessels has exceeded our expectations and I believe that Shockwave is well positioned to continue to positively impact our customers and their patients into the future."

Fourth Quarter 2019 Financial Results

Revenue for the fourth quarter of 2019 was \$14.3 million, an increase of \$9.3 million, or 183%, compared to the fourth quarter of 2018. The growth was primarily driven by the expansion of the U.S. sales force and increased penetration in both U.S. and international markets.

Gross profit for the fourth quarter of 2019 was \$8.8 million compared to \$1.8 million for the fourth quarter of 2018. The gross margin percentage for the fourth quarter of 2019 increased to 61% compared to 35% in the fourth quarter of 2018, driven primarily by continued improvements in production processes and greater absorption of fixed costs by higher production.

Operating expenses were \$24.1 million for the fourth quarter of 2019 compared to \$12.9 million in the corresponding prior year period, an increase of 87%, primarily driven by sales force expansion and higher clinical costs from the CAD III IDE and CAD IV Japan studies.

Net loss was \$14.7 million in the fourth quarter of 2019, as compared to \$11.2 million in the corresponding period of the prior year. Net loss per share was \$0.49 in the fourth quarter of 2019.

Full Year 2019 Financial Results

Revenue for full year 2019 was \$42.9 million, an increase of \$30.7 million, or 250%, compared to the full year of 2018. The growth was primarily driven by the expansion of the U.S. sales force and international distributor network.

Gross profit for the full year 2019 was \$25.8 million compared to \$5.0 million for the full year 2018. The gross margin percentage for the full year 2019 increased to 60% compared to 41% in the full year 2018, driven primarily by continued improvements in production processes and greater absorption of fixed costs by higher production.

Operating expenses were \$77.6 million for the full year 2019 compared to \$46.2 million in the prior year, an increase of 68%, primarily driven by sales force expansion and higher clinical costs from the CAD III IDE and CAD IV Japan studies.

Net loss was \$51.1 million for full year 2019, as compared to \$41.1 million in the prior year. Net loss per share was \$2.14 for full year 2019.

Cash, cash equivalents and short-term investments totaled \$195.3 million as of December 31, 2019.

2020 Financial Guidance

Shockwave Medical projects revenue for the full year 2020 to range from \$74 million to \$77 million, which would represent 72% to 79% growth over the company's prior year 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 13, 2020 to discuss its fourth quarter and full year 2019 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: 5764306. 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. 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 financial and business 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. Our business and operations are subject to a variety of risks and uncertainties and, consequently, actual results may differ materially from those projected by any forward-looking statements. Factors that could cause actual results to differ from those projected include, but are not limited to: failure to achieve or sustain profitability; failure to effectively market existing products; failure to effectively introduce and market new products; delays in product introductions; significant competition; inability to further penetrate our current customer base and increase the frequency of use of our products by our customers; inability to achieve or maintain satisfactory pricing and margins; manufacturing difficulties; the inability to attain coverage and adequate reimbursement for procedures using our products; permanent write-downs or write-offs of our inventory; product defects or failures; unfavorable outcomes in clinical trials; inability to maintain our culture as we grow; fluctuations in foreign currency exchange rates; potential adverse regulatory actions; and potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. These risks and uncertainties, as well as others, are discussed in greater detail in our filings with the Securities and Exchange Commission (SEC), including under the section entitled “Risk Factors” in our Quarterly Report on Form 10-Q for the nine months ended September 30, 2019 and in our prospectus dated November 14, 2019. 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.

Investor Contact:

Debbie Kaster, Gilmartin Group
investors@shockwavemedical.com

SHOCKWAVE MEDICAL, INC.
Balance Sheet Data
(Unaudited)
(In thousands)

	December 31, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 139,045	\$ 39,643
Short-term investments	56,304	—
Accounts receivable, net	7,377	2,850
Inventory	12,074	5,131
Prepaid expenses and other current assets	1,897	1,112
Total current assets	216,697	48,736
Operating lease right-of-use assets	8,825	—
Property and equipment, net	4,910	2,619
Other assets	1,506	2,066
TOTAL ASSETS	\$ 231,938	\$ 53,421
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS’ EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,790	\$ 1,487
Term notes, current portion	6,667	1,667
Accrued liabilities	13,777	6,217
Lease liability, current portion	774	—
Total current liabilities	24,008	9,371
Lease liability, noncurrent	8,125	—
Term notes, noncurrent portion	7,152	13,383
Convertible preferred stock warrant liability	—	313

Other liabilities	—	136
TOTAL LIABILITIES	39,285	23,203
Convertible preferred stock	—	152,806
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock	—	—
Common stock	31	2
Additional paid-in capital	370,561	4,275
Accumulated other comprehensive loss	35	—
Accumulated deficit	(177,974)	(126,865)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	192,653	(122,588)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	\$ 231,938	\$ 53,421

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

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2019	2018	2019	2018
Revenue:				
Product revenue	\$ 14,312	\$ 5,062	\$ 42,927	\$ 12,263
Operating expenses:				
Cost of product revenue	5,553	3,304	17,159	7,250
Research and development	10,075	6,119	32,853	22,698
Sales and marketing	9,597	4,925	30,620	17,536
General and administrative	4,450	1,842	14,134	5,979
Total operating expenses	<u>29,675</u>	<u>16,190</u>	<u>94,766</u>	<u>53,463</u>
Loss from operations	(15,363)	(11,128)	(51,839)	(41,200)
Interest expense	(198)	(185)	(944)	(401)
Change in fair value of warrant liability	—	1	(609)	(52)
Other income, net	827	100	2,345	589
Net loss before taxes	(14,734)	(11,212)	(51,047)	(41,064)
Income tax provision	11	11	62	38
Net loss	<u>\$ (14,745)</u>	<u>\$ (11,223)</u>	<u>\$ (51,109)</u>	<u>\$ (41,102)</u>
Net loss per share, basic and diluted	<u>\$ (0.49)</u>	<u>\$ (6.23)</u>	<u>\$ (2.14)</u>	<u>\$ (23.39)</u>
Shares used in computing net loss per share, basic and diluted	<u>29,894,306</u>	<u>1,800,219</u>	<u>23,904,828</u>	<u>1,757,102</u>