

**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, 2019

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
(IRS Employer
Identification No.)

5403 Betsy Ross Drive
Santa Clara, California
(Address of principal executive offices)

95054
(Zip Code)

Registrant's telephone number, including area code: (510) 279-4262

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 (see General Instruction A.2. below):

- 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 7, 2019, ShockWave Medical, Inc. issued a press release (the “Press Release”) announcing its financial results for the quarter ended September 30, 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
99.1	Press release dated November 7, 2019

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: November 7, 2019

/s/ Dan Puckett

Dan Puckett

Chief Financial Officer



Shockwave Medical Reports Third Quarter 2019 Financial Results

Santa Clara, Calif. – November 7, 2019 – 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, 2019.

Recent Highlights

- Recognized revenue of \$11.3 million for the third quarter of 2019, representing a 215% increase over the third quarter of 2018
- Received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) for IVL System with the C² Coronary IVL Catheter, which is currently the subject of the DISRUPT CAD III Investigational Device Exemption (IDE) study designed to support FDA approval
- Unveiled results of the DISRUPT CAD II European post-market study of Coronary IVL at recent Transcatheter Cardiovascular Therapeutics (TCT) conference, confirming the low complication rates and strong safety and performance from the DISRUPT CAD I study
- Commenced full commercial launch of the S⁴ device at the Vascular Interventional Advances (VIVA) 2019 Annual Conference
- Initiated CAD IV study of Coronary IVL in Japan

“Our third quarter performance was marked by many key accomplishments as our team continues to deliver solid, balanced, results across our domestic and international businesses,” said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. “Additionally, we achieved several important operational successes, including doubling the number of patients enrolled in CAD III since last quarter, initiating our CAD IV study in Japan and completing the full launch of our S⁴ device to safely address the large number of patients who suffer from below the knee peripheral disease. We look forward to building on this progress as we continue our efforts to positively impact patient outcomes worldwide.”

Third Quarter 2019 Financial Results

Revenue for the third quarter of 2019 was \$11.3 million, an increase of \$7.7 million, or 215%, compared to the third quarter of 2018. The growth was primarily driven by the expansion of the U.S. salesforce and international distributor network.

Gross profit for the third quarter of 2019 was \$6.9 million compared to \$1.6 million for the third quarter of 2018. The gross margin percentage for the third quarter of 2019 increased to 61% compared to 45% in the third quarter of 2018, driven primarily by continued improvements in production processes and greater absorption of fixed costs by higher production.

Operating expenses were \$20 million for the third quarter of 2019 compared to \$11.7 million in the corresponding prior year period, an increase of 71%, primarily driven by salesforce expansion and higher clinical costs from the CAD III IDE and CAD IV Japan studies.

Net loss was \$13 million in the third quarter of 2019, as compared to \$10.2 million in the corresponding period of the prior year. Net loss per share was \$0.46 in the third quarter of 2019.

Cash, cash equivalents and short-term investments totaled \$114.1 million as of September 30, 2019.

2019 Financial Guidance

Shockwave Medical projects revenue for the full year 2019 to range from \$41 million to \$42 million, which represents 234% to 242% 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, November 7, 2019 to discuss its third quarter 2019 financial results. The call may be accessed through an operator by calling (866) 795-9106 for domestic callers and (470) 495-9173 for international callers using conference ID number 1427729. 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 treatment of calcified vascular disease by establishing a new standard of care with Intravascular Lithotripsy (IVL). IVL seeks to minimize trauma within the artery by delivering pulsatile sonic pressure waves locally to fracture both intimal and medial calcium in the artery wall, by pass through surrounding soft vascular tissue in a safe manner. To view an animation of 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 prospectus dated March 6, 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)

	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 39,452	\$ 39,643
Short-term investments	74,646	—
Accounts receivable, net	5,551	2,850
Inventory	9,227	5,131
Prepaid expenses and other current assets	2,199	1,112
Total current assets	131,075	48,736
Operating lease right-of-use assets	2,155	—
Property and equipment, net	4,111	2,619
Other assets	548	2,066
TOTAL ASSETS	<u>\$ 137,889</u>	<u>\$ 53,421</u>
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,486	\$ 1,487
Term notes, current portion	6,667	1,667
Accrued liabilities	9,496	6,217
Lease liability, current portion	742	—
Total current liabilities	19,391	9,371
Lease liability, noncurrent	1,543	—
Term notes, noncurrent portion	8,705	13,383
Convertible preferred stock warrant liability	—	313
Other liabilities	—	136
TOTAL LIABILITIES	<u>29,639</u>	<u>23,203</u>
Convertible preferred stock	—	152,806
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock	—	—
Common stock	28	2
Additional paid-in capital	271,394	4,275
Accumulated other comprehensive loss	57	—
Accumulated deficit	(163,229)	(126,865)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	<u>108,250</u>	<u>(122,588)</u>
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	<u>\$ 137,889</u>	<u>\$ 53,421</u>

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,	
	2019	2018	2019	2018
Revenue:				
Product revenue	\$ 11,333	\$ 3,600	\$ 28,615	\$ 7,201
Operating expenses:				
Cost of product revenue	4,401	1,973	11,606	3,946
Research and development	8,368	5,533	22,778	16,579
Sales and marketing	8,192	4,801	21,023	12,611
General and administrative	3,437	1,369	9,684	4,137
Total operating expenses	<u>24,398</u>	<u>13,676</u>	<u>65,091</u>	<u>37,273</u>
Loss from operations	(13,065)	(10,076)	(36,476)	(30,072)
Interest expense	(251)	(158)	(746)	(216)
Change in fair value of warrant liability	—	(104)	(609)	(53)
Other income, net	385	166	1,518	489
Net loss before taxes	(12,931)	(10,172)	(36,313)	(29,852)
Income tax provision	26	6	51	27
Net loss	<u>\$ (12,957)</u>	<u>\$ (10,178)</u>	<u>\$ (36,364)</u>	<u>\$ (29,879)</u>
Net loss per share, basic and diluted	<u>\$ (0.46)</u>	<u>\$ (5.73)</u>	<u>\$ (1.66)</u>	<u>\$ (17.15)</u>
Shares used in computing net loss per share, basic and diluted	<u>28,085,821</u>	<u>1,776,249</u>	<u>21,886,396</u>	<u>1,742,572</u>