

**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): August 5, 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))

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.

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 2.02. Results of Operations and Financial Condition.

On August 5, 2019, ShockWave Medical, Inc. issued a press release (the “Press Release”) announcing its financial results for the quarter ended June 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 August 5, 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: August 5, 2019

/s/ Dan Puckett

Dan Puckett

Chief Financial Officer



Shockwave Medical Reports Second Quarter 2019 Financial Results

Santa Clara, Calif. – August 5, 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 June 30, 2019.

Recent Highlights

- Recognized revenue of \$10.0 million for the second quarter of 2019, representing a 339% increase over the second quarter of 2018
- Appointed industry veterans Keith Dawkins M.D. to Chief Medical Officer and Hajime Tada as General Counsel
- Crossed the 100-patient enrollment threshold in CAD III, the Company's U.S. coronary IDE trial
- Had data from Company's CAD II European Registry accepted for presentation at Transcatheter Cardiovascular Therapeutics (TCT) 2019, to be held in September
- Completed the move of production facilities to the Santa Clara site, more than doubling capacity

"We continue to be encouraged by our results thus far in 2019 – both financially and operationally - as our organization continues to improve execution on all fronts," said Doug Godshall, President and Chief Executive Officer. "The balanced mix of our products, both geographically and clinically, combined with the strong interest from physicians, speaks to the versatility of our IVL technology and its ability to help patients with complex calcified cardiovascular disease. Our progress operationally, clinically and financially is encouraging and gives us confidence to continue expanding and enhancing our team."

Second Quarter 2019 Financial Results

Revenue for the second quarter of 2019 was \$10.0 million, an increase of \$7.7 million, or 339%, compared to the second quarter of 2018. The growth was primarily driven by the increased sales of our M⁵ IVL catheter in the U.S. and the growth of our C² international business.

Gross profit for the second quarter of 2019 was \$5.9 million compared to \$1.1 million for the second quarter of 2018. The gross margin percentage for the second quarter of 2019 increased to 59% compared to 48% in the second quarter of 2018, driven primarily by increased efficiencies and higher production volume, which improved the absorption of fixed costs.

Operating expenses were \$17.1 million for the second quarter of 2019 compared to \$11.3 million in the corresponding prior year period, an increase of 52%, primarily driven by commercial expansion, increased spend on clinical programs and costs associated with being a public company.

Net loss was \$10.6 million in the second quarter of 2019, as compared to \$10.1 million in the corresponding period of the prior year. Net loss per share was \$0.38 in the second quarter of 2019.

Cash, cash equivalents and short-term investments totaled \$125.1 million as of June 30, 2019.

2019 Financial Guidance

Shockwave Medical projects revenue for the full year 2019 to range from \$38 million to \$40 million, which represents 210% to 226% growth over the company's prior year revenue.

Conference Call

Shockwave Medical will host a conference call at 2:00 p.m. Pacific Time / 5:00 p.m. Eastern Time on Monday, August 5, 2019 to discuss its second 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 2399907. 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 by establishing a new standard of care with Intravascular Lithotripsy (IVL) technology. The company's differentiated and proprietary IVL approach to calcium modification uses sonic pressure waves to safely and effectively fracture problematic calcium throughout the cardiovascular system in a wide and growing number of applications. 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 sustain or grow 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>June 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 41,924	\$ 39,643
Short-term investments	83,213	—
Accounts receivable, net	5,242	2,850
Inventory	8,291	5,131
Prepaid expenses and other current assets	1,953	1,112
Total current assets	140,623	48,736
Operating lease right-of-use assets	2,398	—
Property and equipment, net	3,244	2,619
Other assets	542	2,066
TOTAL ASSETS	<u>\$ 146,807</u>	<u>\$ 53,421</u>
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,216	\$ 1,487
Term notes, current portion	5,000	1,667
Accrued liabilities	7,378	6,217
Lease liability, current portion	806	—
Total current liabilities	15,400	9,371
Lease liability, noncurrent	1,732	—
Term notes, noncurrent portion	10,262	13,383
Convertible preferred stock warrant liability	—	313
Other liabilities	—	136
TOTAL LIABILITIES	<u>27,394</u>	<u>23,203</u>
Convertible preferred stock	—	152,806
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock	—	—
Common stock	28	2
Additional paid-in capital	269,582	4,275
Accumulated other comprehensive loss	75	—
Accumulated deficit	(150,272)	(126,865)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	<u>119,413</u>	<u>(122,588)</u>
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	<u>\$ 146,807</u>	<u>\$ 53,421</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue:				
Product revenue	\$ 10,012	\$ 2,279	\$ 17,282	\$ 3,601
Operating expenses:				
Cost of product revenue	4,133	1,179	7,205	1,973
Research and development	6,926	5,530	14,410	11,046
Sales and marketing	6,961	4,372	12,831	7,810
General and administrative	3,245	1,392	6,247	2,768
Total operating expenses	21,265	12,473	40,693	23,597
Loss from operations	(11,253)	(10,194)	(23,411)	(19,996)
Interest expense	(250)	(40)	(495)	(58)
Change in fair value of warrant liability	—	10	(609)	51
Other income, net	913	138	1,133	323
Net loss before taxes	(10,590)	(10,086)	(23,382)	(19,680)
Income tax provision	18	21	25	21
Net loss	\$ (10,608)	\$ (10,107)	\$ (23,407)	\$ (19,701)
Net loss per share, basic and diluted	\$ (0.38)	\$ (5.79)	\$ (1.25)	\$ (11.42)
Shares used in computing net loss per share, basic and diluted	28,002,887	1,745,499	18,735,307	1,725,414