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): March 30, 2021

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 \Box

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 7.01. Regulation FD Disclosure.

On March 30, 2021, Shockwave Medical, Inc. issued a press release (the "Press Release") announcing its preliminary, unaudited, forecast, revenue for the quarter ending March 31, 2021. A copy of the Press Release is attached as Exhibit 99.1 to this current report on Form 8-K.

The information under Item 7.01 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 of Exhibit

<u>99.1</u> <u>Press Release dated March 30, 2021.</u>

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.

Date: March 30, 2021

Shockwave Medical, Inc.

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



SHOCKWAVE PROVIDES UPDATE ON U.S. LAUNCH OF CORONARY IVL SYSTEM

Announces Preliminary Revenue Range for the First Quarter of 2021

SANTA CLARA, CALIF. — March 30, 2021 — Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat severely calcified cardiovascular disease, today announced a preliminary forecast revenue range for the first quarter 2021, ahead of its participation in the Wells Fargo MedTech R&D Spotlight Call Series to be held at 1:00 p.m. Eastern Time on March 30, 2021.

"We are pleased by the encouraging performance in the first quarter and, in particular, with the excellent reception of our newly-launched C^2 Coronary IVL product in the United States," said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. "I commend our team on their extraordinary preparation and execution of the launch of C^2 and am so grateful for the collaborative partnership we have with our customers. The entire Shockwave Medical organization remains focused on our mission to deliver life changing products to patients suffering from calcified arterial disease."

Coronary Launch

The C^2 System was approved by the U.S. Food and Drug Administration on February 12, 2021 for use in calcified de-novo coronary arteries prior to implanting a stent. Subsequent to FDA approval, the company has achieved the following results with C^2 in the United States through March 29, 2021:

- Shockwave territory managers have launched an average of just over 1.5 U.S. accounts per month, consistent with the company's stated strategy of executing the launch in a disciplined and sustainable fashion.
- ^c C² clinical performance in the U.S. has been consistent with Shockwave's experience with C² in international markets.
- Over 120 U.S. customers have purchased the C^2 Launch Kit, with initial launch orders averaging approximately six C^2 units.
- Nearly 50% of U.S. accounts that have initiated launch have completed the launch activities and are able to use IVL independently.
- Five live cases utilizing C² in U.S. centers have been performed in conjunction with the recent Cardiovascular Research Technologies (CRT) and Scottsdale Interventional Forum (SIF) Conferences.
- Peripheral revenue in the U.S. has continued to grow month-over-month throughout the quarter.



First Quarter 2021 Results

Preliminary first quarter 2021 revenue is expected to be in the range of \$31.0 million to \$32.0 million, which would represent an increase of 104% to 111% over the first quarter of 2020. The first quarter 2021 revenue range included in this release is preliminary and prior to the completion of review procedures by Shockwave Medical's external auditors and is therefore subject to adjustment.

Shockwave to Participate in Wells Fargo R&D Spotlight Call

Shockwave will participate in the Wells Fargo MedTech R&D Spotlight Call Series on Tuesday, March 30, 2021 at 1:00 pm Eastern Time. A live and archived webcast of the event will be available at https://ir.shockwavemedical.com/.

About Shockwave Medical, Inc.

Shockwave is focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. Shockwave aims to establish a new standard of care for the interventional treatment of atherosclerotic cardiovascular disease through differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which the company refers 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 <u>www.shockwavemedical.com</u>.

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. 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 the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including the impact on our sales, expenses, supply chain, manufacturing, research and development activities, clinical trials, and employees; our ability to develop, manufacture, obtain and maintain regulatory approvals for, 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; the completion and review by our auditors of our financial results for the three months



ended March 31, 2021; our financial performance and capital requirements; 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 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. 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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