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 9, 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** (I.R.S. Employer Identification No.)

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 (§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.

Item 2.02. Results of Operations and Financial Condition.

On August 9, 2021, the Company issued a press release (the "Press Release") announcing its financial results for the quarter ended June 30, 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 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>	Description of Exhibit
<u>99.1</u> 104	<u>Press Release dated August 9, 2021</u> Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 9, 2021

By: <u>/s/ Daniel K. Puckett</u> Daniel K. Puckett Chief Financial Officer

Shockwave Medical Reports Second Quarter 2021 Financial Results

SANTA CLARA, Calif., Aug. 09, 2021 (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 June 30, 2021.

Recent Highlights

- Recognized revenue of \$55.9 million for the second quarter of 2021, representing an increase of 444% from the same period in 2020
- Granted approval for a Transitional Pass-Through (TPT) payment for Shockwave C² Coronary IVL device, which became effective July 1, 2021 for procedures in the outpatient setting
- Featured in three publications in the *Journal of the American College of Cardiology: Cardiovascular Interventions (JACC CI)*, which supported the clinical safety and efficacy of Shockwave Intravascular Lithotripsy
- Granted New Technology Add-On Payment (NTAP) for coronary IVL, which will become effective October 1, 2021 for procedures in the inpatient setting

"Our second quarter results reflect the continued hard work and perseverance of our teams across the globe in not only launching our Shockwave C² device in the United States, but in achieving exceptional results across our entire product portfolio and operational infrastructure throughout the Shockwave organization. Our business showed substantial growth, despite the challenges related to the COVID-19 pandemic," said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. "The growing clinical acceptance of IVL continues to validate the importance of IVL for our customers and their patients and for the treatment of calcified arterial disease."

Second Quarter 2021 Financial Results

Revenue for the second quarter of 2021 was \$55.9 million, a 444% increase from \$10.3 million in the second quarter of 2020. The growth was primarily driven by the launch of the coronary product, Shockwave C², in the United States in February, increased adoption of Shockwave products, and the continued recovery from the trough of the COVID-19 pandemic impact in 2020.

Gross profit for the second quarter of 2021 was \$46 million compared to \$6.7 million for the second quarter of 2020. Gross margin for the second quarter of 2021 was 82%, as compared to 65% in the second quarter of 2020. Contributors to gross margin expansion included the launch of Shockwave C^2 in the United States and continued improvements in manufacturing productivity and process efficiencies.

Total operating expenses for the second quarter of 2021 were \$46.2 million, an 87% increase from \$24.7 million in the second quarter of 2020. The increase was primarily driven by salesforce expansion in the United States and higher headcount to support the growth of the business.

Net loss for the second quarter of 2021 was \$0.4 million, compared to a net loss of \$18.1 million in the second quarter of 2020. Net loss per share for the period was \$0.01.

Cash, cash equivalents and short-term investments totaled \$174.7 million as of June 30, 2021.

2021 Financial Guidance

Shockwave Medical projects revenue for the full year 2021 to range from \$218 million to \$223 million, which represents 222% to 229% growth over the company's prior year revenue. This compares to previous revenue guidance of \$195 million to \$205 million.

Conference Call

Shockwave Medical will host a conference call at 5:30 a.m. Pacific Time / 8:30 a.m. Eastern Time on Monday, August 9, 2021 to discuss its second quarter 2021 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: 1687208. A live and archived webcast of the event will be available at <u>https://ir.shockwavemedical.com/</u>.

About Shockwave Medical, Inc.

Shockwave Medical is focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. Shockwave Medical 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 Shockwave Medical 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 www.shockwavemedical.com.

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; 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 subsequent quarterly reports on form 10Q, and in our other reports, each as 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.

Media Contact: Rob Fletcher rfletcher@shockwavemedical.com

Investor Contact: Debbie Kaster dkaster@shockwavemedical.com

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

	June 30, 2021		December 31, 2020		
ASSETS					
CURRENT ASSETS:					
Cash and cash equivalents	\$	84,268	\$	50,423	
Short-term investments		90,478		151,931	
Accounts receivable, net		24,955		11,689	
Inventory		36,149		29,859	
Prepaid expenses and other current assets		3,781		2,398	
Total current assets		239,631		246,300	
Operating lease right-of-use assets		6,825		7,568	
Property and equipment, net		21,467		16,362	
Equity method investment		6,750		—	
Other assets		1,686		1,812	
TOTAL ASSETS	\$	276,359	\$	272,042	
LIABILITIES AND STOCKHOLDERS' EQUITY					
CURRENT LIABILITIES:					
Accounts payable	\$	2,633	\$	1,466	
Term notes, current portion		4,125		3,300	
Accrued liabilities		28,317		19,942	
Lease liability, current portion		920		873	
Total current liabilities		35,995		25,581	
Lease liability, noncurrent portion		6,911		7,488	
Term notes, noncurrent portion		12,833		13,319	

Related party contract liability, noncurrent portion	12,273		—
TOTAL LIABILITIES	 68,012		46,388
STOCKHOLDERS' EQUITY:			
Preferred stock	_		
Common stock	35		35
Additional paid-in capital	476,001		469,283
Accumulated other comprehensive income	10		9
Accumulated deficit	(267,699)		(243,673)
TOTAL STOCKHOLDERS' EQUITY	 208,347		225,654
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 276,359	\$	272,042
		-	

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,				
		2021		2020		2021		2020
Revenue:								
Product revenue	\$	55,908	\$	10,286	\$	87,808	\$	25,483
Cost of revenue:								
Cost of product revenue		9,934		3,592		17,826		9,243
Gross profit		45,974		6,694		69,982		16,240
Operating expenses:								
Research and development		11,815		8,101		22,092		19,991
Sales and marketing		25,713		11,206		49,705		21,617
General and administrative		8,626		5,398		15,852		11,622
Total operating expenses		46,154		24,705		87,649		53,230
Loss from operations		(180)		(18,011)		(17,667)		(36,990)
Share in net loss of equity method investment						(5,523)		—
Interest expense		(318)		(306)		(630)		(583)
Other income (expense), net		146		220		(89)		724
Net loss before taxes		(352)		(18,097)		(23,909)		(36,849)
Income tax provision		73		21		117		44
Net loss	\$	(425)	\$	(18,118)	\$	(24,026)	\$	(36,893)
Net loss per share, basic and diluted	\$	(0.01)	\$	(0.56)	\$	(0.69)	\$	(1.16)
Shares used in computing net loss per share, basic and diluted		35,030,036		32,156,476	_	34,914,361		31,900,259