

REVA MEDICAL, INC.

FORM 8-K (Current report filing)

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Address	5751 COPLEY DRIVE SAN DIEGO, CA, 92111
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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: November 7, 2017
(Date of earliest event reported)

REVA MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-54192
(Commission
File Number)

33-0810505
(I.R.S. Employer
Identification No.)

5751 Copley Drive, San Diego, CA
(Address of principal executive offices)

92111
(Zip Code)

(858) 966-3000
(Registrant's telephone number, including area code)

(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.

Item 2.02 Results of Operations and Financial Condition.

On November 7, 2017, REVA Medical, Inc. issued a press release announcing its financial results for the three and nine months ended September 30, 2017. A copy of the press release is furnished as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated November 7, 2017

In accordance with General Instruction B.2. of Form 8-K, the information in Item 2.02 of this report and Exhibit 99.1 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 liability of that section, nor shall it be deemed incorporated by reference in any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

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.

REVA Medical, Inc.

Date: November 7, 2017

/s/ Brandi L. Roberts
Brandi L. Roberts
Chief Financial Officer and Corporate Secretary



REVA MEDICAL REPORTS THIRD QUARTER 2017 FINANCIAL RESULTS

San Diego, California (Tuesday, November 7, 2017, PST) – REVA Medical, Inc. (ASX: RVA) (“REVA” or the “Company”) , a leader in bioresorbable polymer technologies for vascular medical applications, today reported financial results for the quarter ended September 30, 2017.

Third Quarter 2017 Operating Results

The Company initiated commercial sales of the *Fantom* bioresorbable scaffold and reported total billings for shipped product of \$105,000 with \$17,000 of revenue recognized for the third quarter of 2017 compared to no billings or revenue for the same period in 2016. Shipped product included a combination of new customer orders and reorders from existing customers.

Also in the quarter, Carmelo Mastrandrea joined REVA as the Vice President, Europe. Mr. Mastrandrea has been working to build out the commercial team and we are pleased that our first two sales managers started on November 1, 2017. We are in active discussions with three additional candidates that we anticipate will join REVA in the first quarter of 2018. The commercial team will focus on building product utilization and opening new accounts in Germany, Switzerland, Austria, Belgium, the Netherlands, Luxembourg and Denmark, which are the initial countries identified as part of REVA’s targeted launch. The Company plans to broaden its commercial team as it expands sales in Europe.

“REVA reached a monumental milestone with the first commercial sales of the *Fantom* bioresorbable scaffold, and I thank the REVA team and our collaborators for their hard work and dedication in getting us to this point,” stated Reggie Groves, Chief Executive Officer of REVA Medical. “The physician community has been receptive to bioresorbable scaffold technology and *Fantom* in particular. We are in close communication with our customers and have received positive feedback based on *Fantom*’s deliverability, radiopacity, and ease-of-use features.”

Gross profit for the third quarter of 2017 was \$10,000 or approximately 59%. Gross profit this quarter was higher than expected due to a portion of our manufacturing costs being allocated to research and development (R&D) expenses as they were incurred prior to CE Mark in April 2017. We anticipate that our future gross profits will be lower than our third quarter results and industry standards until we can achieve higher sales volumes to accommodate larger manufacturing batches and allocations of overhead.

R&D expenses were \$3.1 million for the third quarter of 2017, a decrease of \$1.1 million, or 27%, compared to \$4.2 million for the same period in 2016. The decrease was due primarily to net decreases in personnel costs of \$0.4 million, material costs and testing services of \$0.4 million related to our transition from research and development to commercialization and overhead allocations of \$0.3 million as we continue to assess our overhead rates during this initial period of commercial activities.

Selling, general and administrative (SG&A) expenses were \$1.7 million for the third quarter of 2017, a decrease of \$0.2 million, or 13%, compared to \$1.9 million for the same period in 2016. The decrease of \$0.2 million was due primarily to a decrease in personnel costs of \$0.7 million, of which a significant portion is related to the forfeiture of performance based stock awards in connection with executive retirements and the reduction in force that occurred in the third quarter of 2017. This decrease was offset by increases of \$0.3 million in audit related and legal fees attributed to the accounting for our convertible notes payable and warrants issued in 2017 (“2017 Notes”) and \$0.2 million in sales and marketing expenses.

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Interest expense was \$1.5 million for the third quarter of 2017, compared to \$0.5 million for the same period in 2016. The increase is due to a full quarter of interest on both the convertible notes payable issued in 2014 (“2014 Notes”) and 2017 Notes in the third quarter of 2017 as compared to a full quarter of interest on only the 2014 Notes in the third quarter of 2016.

Gain on change in fair values of convertible notes and warrant liability was \$12.3 million for the third quarter of 2017, compared to a loss of \$17.3 million for the same period in 2016. The gain/(loss) on change in fair values of convertible notes is impacted by the number of Notes outstanding for each period, as well as other factors that drive fair value, including the market trading price of our stock.

The Company’s net income was \$6.1 million for the third quarter of 2017, or \$0.15 per share (basic) and a loss of \$0.04 per share (diluted), compared to a net loss of \$23.9 million, or \$0.56 per share (basic and diluted), for the same period in 2016.

Year-to-Date Financial Results

The Company reported \$17,000 of revenue for the nine months ended September 30, 2017 compared to no revenue for the same period in 2016.

Cost of revenue was \$7,000 for the nine months ended September 30, 2017 compared to no cost of revenue for the same period in 2016.

R&D expenses were \$10.1 million for the nine months ended September 30, 2017, a decrease of \$4.1 million, or 28%, compared to \$14.2 million for the same period in 2016. The decrease was due primarily to net decreases in personnel costs of \$1.4 million, material costs and testing services of \$1.3 million related to our transition from research and development to commercialization and clinical costs of \$1.1 million as our FANTOM II study completed enrollment in March 2016 and patient follow-ups with invasive imaging were substantially complete by March 2017.

SG&A expenses were \$5.8 million for the nine months ended September 30, 2017, a decrease of \$0.7 million, or 11%, compared to \$6.5 million for the same period in 2016. The decrease was due primarily to net decreases in personnel costs of \$1.1 million, of which a significant portion is related to the forfeiture of performance based stock awards in connection with executive retirements and the reduction in force that occurred in the third quarter of 2017. This decrease was offset by increases of \$0.4 million in sales and marketing expenses and \$0.3 million in audit related and legal fees attributed to the accounting for our 2017 Notes.

Interest expense was \$5.2 million for the nine months ended September 30, 2017, compared to \$1.5 million for the same period in 2016. The nine months ended September 30, 2017 included transaction expenses of \$2.1 million related to the 2017 Notes as well as interest expense on the 2017 Notes for four to five months and interest expense on the 2014 Notes for nine months. The nine months ended September 30, 2016 included interest expense for the 2014 Notes only for nine months.

Gain on change in fair values of convertible notes and warrant liability was \$28.6 million for the nine months ended September 30, 2017, compared to a loss of \$47.1 million for the same period in 2016. The gain/(loss) on change in fair values of convertible notes is impacted by the number of Notes outstanding for each period, as well as other factors that drive fair value, including the market trading price of our stock.

The Company’s net income was \$7.0 million for the nine months ended September 30, 2017, or \$0.17 per share (basic) and a loss of \$0.30 per share (diluted), compared to a net loss of \$69.3 million, or \$1.65 per share (basic and diluted), for the same period in 2016.

About Fantom

Fantom is a sirolimus-eluting bioresorbable scaffold (BRS) developed as an alternative to metallic stents for the treatment of coronary artery disease. Scaffolds provide restoration of blood flow, support the artery through the healing process, and then disappear (or “resorb”) from the body over a period of time. This resorption is intended to allow the return of natural movement and function of the artery. *Fantom* is the only bioresorbable scaffold made from Tyrocore, REVA’s proprietary tyrosine-derived polymer designed specifically for vascular scaffold applications. Tyrocore is inherently radiopaque, making *Fantom* the first and only BRS that is visible under fluoroscopy. *Fantom* is designed with thin struts while maintaining strength and with distinct ease-of-use features such as expansion with one continuous inflation.

About REVA Medical

REVA Medical is a medical device company focused on the development and commercialization of bioresorbable polymer technologies for vascular applications. The Company’s lead product, the *Fantom* bioresorbable scaffold, received European CE Mark on April 3, 2017 for the treatment of coronary artery disease. REVA is located in San Diego, California, USA and employs over 50 people in the U.S. and Europe.

Fantom, Fantom Encore, and Tyrocore are trademarks of REVA Medical, Inc.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions, and expectations and on information currently available to management. All statements that are not statements of historical fact, including those statements that address future operating plans or performance and events or developments that may occur in the future, are forward-looking statements, such as those statements regarding the projections and timing surrounding commercial operations and sales, clinical trials, pipeline product development, and future financings. No undue reliance should be placed on forward-looking statements. Although management believes forward-looking statements are reasonable as and when made, forward-looking statements are subject to a number of risks and uncertainties that may cause actual results to vary materially from those expressed in forward-looking statements, including the risks and uncertainties that are described in the "Risk Factors" section of our Annual Report on Form 10-K filed with the US Securities and Exchange Commission (the “SEC”) on February 28, 2017, and as updated in our periodic reports thereafter. Any forward-looking statements in this announcement speak only as of the date when made. REVA does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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[Tables to Follow]

REVA Medical, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except per share data)

	Three months ended September 30, (Unaudited)		Nine months ended September 30, (Unaudited)	
	2017	2016	2017	2016
Revenue	\$ 17	\$ —	\$ 17	\$ —
Cost of revenue	7	—	7	—
Gross profit	10	—	10	—
Operating expenses:				
Research and development	3,092	4,212	10,139	14,165
Selling, general and administrative	1,687	1,937	5,766	6,496
Total operating expenses	4,779	6,149	15,905	20,661
Loss from operations	(4,769)	(6,149)	(15,895)	(20,661)
Interest income (expense), net	(1,465)	(511)	(5,133)	(1,519)
Loss on issuance of convertible notes payable and warrants to purchase common stock	—	—	(520)	—
Gain (loss) on change in fair value of convertible notes payable and warrant liability	12,304	(17,269)	28,620	(47,067)
Other expense	(17)	(14)	(98)	(49)
Net income (loss)	<u>\$ 6,053</u>	<u>\$ (23,943)</u>	<u>\$ 6,974</u>	<u>\$ (69,296)</u>
Net loss per share – basic	<u>\$ 0.15</u>	<u>\$ (0.56)</u>	<u>\$ 0.17</u>	<u>\$ (1.65)</u>
Weighted average shares – basic	41,197,348	42,681,176	42,001,898	41,909,945
Net loss per share – diluted	<u>\$ (0.04)</u>	<u>\$ (0.56)</u>	<u>\$ (0.30)</u>	<u>\$ (1.65)</u>
Weighted average shares – diluted	52,703,504	42,681,176	53,508,054	41,909,945

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REVA Medical, Inc.
Balance Sheet Data
(In thousands)

	September 30, 2017	December 31, 2016
Cash, cash equivalents and investment securities	\$ 24,083	\$ 6,674
Total assets	26,683	9,483
Convertible notes payable and accrued interest	112,955	95,859
Total liabilities	120,699	99,076
Stockholders' deficit	(94,016)	(89,593)

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