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: August 7, 2018
(Date of earliest event reported)

REVA MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-54192**	**33-0810505**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(I.R.S. Employer Identification No.)*

5751 Copley Drive, San Diego, CA	**92111**
(Address of principal executive offices)	*(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 August 7, 2018, REVA Medical, Inc. issued a press release announcing its financial results for the three and six months ended June 30, 2018. 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 August 7, 2018

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: August 7, 2018

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

REVA MEDICAL REPORTS SECOND QUARTER 2018 FINANCIAL RESULTS

San Diego, California and Sydney, Australia (Tuesday, 7 August 2018 - AEST) – REVA Medical, Inc. (ASX: RVA) ("REVA" or the "Company"), a leader in bioresorbable polymer technologies for vascular medical applications, today provided a business update and reported financial results for the second quarter ended June 30, 2018.

"In the second quarter of 2018, we delivered on many milestones that we outlined last quarter to drive commercial growth and expand the use of Fantom," said Reggie Groves, CEO, REVA Medical. "We entered our first distribution partnership to expand use of Fantom to Turkey, presented new 2-year clinical results from our FANTOM II trial, initiated our post market trial, and secured CE Mark for the full Fantom Encore product line. As a result, we are continuing to see growth in product shipments and reorders, which is one of our most important metrics of commercial momentum."

The Company completed on-boarding and training of its direct sales force in Germany, Switzerland, and Austria during the second quarter of 2018. Additionally, REVA began its planned geographic expansion of Fantom by entering into a first commercial distribution partnership with Kardionet in Turkey. In July 2018, REVA announced a second commercial distribution partnership with Bio Vascular Group in Italy and hired a part-time consultant to support direct sales in Belgium, the Netherlands and Luxembourg. REVA will continue to expand geographically with direct sales in select countries and distribution partnerships in countries that are more favorable for these partnerships (generally due to conditions such as high tender volume and extended payment terms).

During the second quarter of 2018, REVA released two-year data from the FANTOM II trial at the EuroPCR conference in Paris, France demonstrating sustained safety and efficacy of Fantom. The results included a low 5.0% rate of major adverse cardiac events ("MACE") in 240 patients. MACE is a stringent definition of safety and efficacy combining all events related to cardiac death, myocardial infarction, and target lesion revascularization. The endpoint of target lesion failure ("TLF") is similar to MACE but only includes myocardial infarction events that are related to the treated vessel. The two-year TLF rate from 240 patients in the FANTOM II trial was 4.6%. This compares favorably to the two-year TLF rates for Absorb of 11.0% and Xience of 7.9% in the 2,008-patient ABSORB III trial. During the second quarter of 2018, REVA also initiated the Fantom post market trial in Europe. The first patient was enrolled in May and the Company is working to add new hospitals to the study. The Company is currently targeting enrollment of 1,500 patients at 50 to 100 hospitals in the post market trial.

In June 2018, REVA obtained CE Mark for the full Fantom Encore product line. Fantom Encore, like Fantom, is used for the treatment of coronary artery disease. The approval includes Fantom Encore in the 3.0 and 3.5 mm diameters, expanding the approved product line beyond the 2.5 mm diameter scaffold which was approved in February 2018. The Fantom Encore product line has thinner struts than Fantom. Reduction in strut thickness is associated with improved outcomes and ease-of-use, which are critical for broader adoption of bioresorbable scaffolds. REVA plans to launch the Fantom Encore product line later this year.

The Company also continues to make progress on new products for use outside the coronary arteries. REVA's first product for below-the-knee peripheral artery disease, called MOTIV, received CE Mark approval in July 2018. Over the next few months, REVA will identify select centers to assess MOTIV's performance, inform future

product development activities, and determine MOTIV's complete commercial strategy in peripheral vascular applications. The Company expects MOTIV's first use in patients to be in late 2018 or early 2019. The Company is also applying its Tyrocore technology to embolic beads, which are intended to treat tumors such as hepatocellular carcinoma and uterine fibroids. REVA is currently evaluating the best path to take this technology forward for development and commercialization.

Second Quarter 2018 Operating Results

REVA recognized $91,000 of net revenue during the three months ended June 30, 2018 compared to no revenue for the same period in 2017. Net revenue during the three months ended June 30, 2018 grew by 72% as compared to net revenue during the three months ended March 31, 2018, due to an increase in estimated customer usage. Total product shipments for the three months ended June 30, 2018 were $149,000, a 16% increase as compared to total product shipments for the three months ended March 31, 2018. Additionally, the Company saw a 38% increase in the total number of customers as of June 30, 2018 versus March 31, 2018.

Gross margin for the three months ended June 30, 2018 was negative $30,000. Cost of goods sold for the three months ended June 30, 2018 included an additional charge of $52,000 for potential excess and obsolete inventory. REVA has increased its reserves in anticipation of the transition from Fantom to Fantom Encore which the Company believes will occur by the end of 2018. Excluding this charge, gross profit would have been $22,000 or 24% of net revenue. REVA anticipates that the gross profit will continue to be lower than industry standards until higher sales and manufacturing volumes are reached.

Research and development ("R&D") expenses were $2.5 million for the second quarter of 2018, a decrease of $0.6 million, or 19%, compared to $3.1 million for the same period in 2017. The decrease was due primarily to net decreases in personnel costs of $0.3 million and licensing fees of $0.3 million. The decrease in personnel costs was related to the reduction in force that occurred in the third quarter of 2017 and the decrease in licensing fees was related to reduced activities in this area as REVA transitioned from R&D to commercialization.

Selling, general and administrative ("SG&A") expenses were $3.1 million for the second quarter of 2018, an increase of $1.1 million, or 59%, compared to $2.0 million for the same period in 2017. The increase was due primarily to increases in personnel costs of $0.8 million, legal and consulting fees of $0.2 million and facility costs of $0.1 million. These increases related to the expansion of REVA's sales force and corporate infrastructure to support the commercialization of Fantom and Fantom Encore and the ongoing needs of being a public company.

Interest expense was $1.6 million for the second quarter of 2018, compared to $3.1 million for the same period in 2017. The decrease was due to the absence of $2.1 million in transaction costs related to the 2017 convertible notes issued in the second quarter of 2017, offset by an increase in interest expense of $0.6 million related to the convertible notes the Company issued in May and June 2017. During the 2018 period the Company had a full quarter of interest related to such notes as compared to a partial quarter of interest during the 2017 period.

Gain on change in fair value of convertible notes and warrant liability was $9.1 million for the second quarter of 2018, compared to a gain of $8.2 million for the same period in 2017. The fair value of convertible notes is impacted by the number of convertible notes outstanding for each period, as well as the market price of the Company's common stock and other factors that drive fair value.

The Company's net income was $1.9 million for the second quarter of 2018, or $0.05 per share (basic) and a loss of $0.13 per share (diluted), compared to a net loss of $0.5 million, or $0.01 per share (basic and diluted), for the same period in 2017.

Year-to-Date Financial Results

REVA recognized $144,000 of net revenue during the six months ended June 30, 2018 compared to no revenue for the same period in 2017. Total product shipments for the six months ended June 30, 2018 were $277,000.

Gross margin for the six months ended June 30, 2018 was negative $33,000. Cost of goods sold for the six months ended June 30, 2018 included an additional charge of $66,000 for potential excess and obsolete inventory. The Company has increased its reserves in anticipation of the transition from Fantom to Fantom Encore which the Company anticipates will occur by the end of 2018. Excluding this charge, gross profit would have been $33,000 or 23% of net revenue. REVA anticipates that gross profit will continue to be lower than industry standards until higher sales and manufacturing volumes are reached.

R&D expenses were $4.9 million for the six months ended June 30, 2018, a decrease of $2.1 million, or 30%, compared to $7.0 million for the same period in 2017. The decrease was due primarily to a $0.9 million decrease in personnel costs, a $0.5 million decrease in licensing fees, a $0.3 million decrease in depreciation and a $0.2 million decrease in R&D materials. The decrease in personnel costs was related to the reduction in force that occurred in the third quarter of 2017. The decrease in licensing fees, R&D materials and depreciation were each related to reduced activities in those areas as REVA transitioned from R&D to commercialization.

SG&A expenses were $6.4 million for the six months ended June 30, 2018, an increase of $2.3 million, or 58%, compared to $4.1 million for the same period in 2017. The increase was due primarily to increases in personnel costs of $1.6 million, legal and consulting fees of $0.3 million, travel costs of $0.1 million and facility costs of $0.1 million. These increases were related to the expansion of REVA's sales force and corporate infrastructure to support the commercialization of Fantom and Fantom Encore and the ongoing needs of being a public company.

Interest expense was $3.1 million for the six months ended June 30, 2018, a decrease of $0.6 million, or 16%, compared to $3.7 million for the same period in 2017. The decrease was due to the absence of $2.1 million in transaction costs related to the 2017 convertible notes issued in the second quarter of 2017, offset by an increase in interest expense of $1.5 million related to the convertible notes REVA issued in May and June 2017. During the 2018 period the Company had a full six months of interest related to such notes, as compared to a partial six-month period of interest during the 2017 period.

Gain on change in fair value of convertible notes and warrant liability was $39.7 million for the six months ended June 30, 2018, compared to a gain of $16.3 million for the same period in 2017. The fair value of convertible notes is impacted by the number of convertible notes outstanding for each period, as well as the market price of REVA's common stock and other factors that drive fair value.

The Company's net income was $25.3 million for the six months ended June 30, 2018, or $0.61 per share (basic) and a loss of $0.16 per share (diluted), compared to net income of $0.9 million, or $0.02 per share (basic) and a loss of $0.31 per share (diluted), for the same period in 2017.

About Fantom and Fantom Encore

Fantom and Fantom Encore are sirolimus-eluting bioresorbable scaffolds developed as alternatives 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 function of the artery and reduce risk of adverse events associated with a permanent metallic implant. Fantom and Fantom Encore are the only bioresorbable scaffolds made from Tyrocore, REVA's proprietary tyrosine-derived polymer designed specifically for vascular scaffold applications. Tyrocore is inherently radiopaque, making Fantom and Fantom Encore the first and only bioresorbable scaffolds that are visible under fluoroscopy. Fantom and Fantom Encore are designed with thin struts while maintaining strength and with distinct ease-of-use features such as x-ray visibility, a large expansion range. expansion with one continuous inflation, and room-temperature storage stability.

About MOTIV

MOTIV is a sirolimus-eluting bioresorbable scaffolds developed for the treatment of below the knee ("BTK") peripheral artery disease ("PAD"). Treatment options for BTK patients are very limited and many patients progress to amputation. MOTIV is intended to expand treatment options to the millions of patients suffering from PAD.

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 products are the Fantom and Fantom Encore bioresorbable vascular scaffolds for the treatment of coronary artery disease. REVA is currently selling Fantom in Germany, Switzerland, Austria, Italy and Turkey. REVA is based in San Diego, California, and employs more than 50 people in the U.S. and Europe.

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

Conference Call

The Company will conduct a conference call to review its second quarter 2018 financial results and provide a business update. The call is scheduled for 2:30 p.m. PDT on Tuesday, August 7, 2018 (which is 7:30 a.m. AEST on Wednesday, 8 August 2018) and may be accessed within the United States and Canada by dialing 1-877-312-5413 five minutes prior to the scheduled start time. Callers in Australia may access the call toll-free by dialing 1800 005 989. The conference ID is 3186589 for all locations.

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 March 7, 2018, 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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REVA Medical, Inc.

Unaudited Condensed Consolidated Statements of Operations

(In thousands, except per share data)

	Three Months Ended June 30		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue, net	$ 91	$ —	$ 144	$ —
Cost of revenue	121	—	177	—
Gross margin	(30)	—	(33)	—
Operating expenses:				
Research and development	2,505	3,083	4,940	7,047
Selling, general and administrative	3,135	1,977	6,429	4,079
Total operating expenses	5,640	5,060	11,369	11,126
Loss from operations	(5,670)	(5,060)	(11,402)	(11,126)
Other income (expense):				
Interest income	26	—	45	2
Interest expense	(1,562)	(3,079)	(3,069)	(3,670)
Loss on issuance of convertible notes payable and warrants to purchase common stock	—	(520)	—	(520)
Gain on change in fair value of convertible notes and warrant liability	9,125	8,178	39,716	16,316
Other income (expense)	8	(22)	(20)	(81)
Total other income	7,597	4,557	36,672	12,047
Net income (loss)	$ 1,927	$ (503)	$ 25,270	$ 921
Net income (loss) per share – basic	$ 0.05	$ (0.01)	$ 0.61	$ 0.02
Weighted average shares outstanding – basic	41,274,839	41,988,220	41,260,410	42,410,841
Net loss per share – diluted	$ (0.13)	$ (0.01)	$ (0.16)	$ (0.31)
Weighted average shares outstanding - diluted	52,780,955	41,988,220	52,766,566	55,295,755

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

	June 30, 2018	December 31, 2017
Cash, cash equivalents and investment securities	$ 10,874	$ 20,014
Total assets	14,537	22,661
Convertible notes payable and accrued interest	75,305	108,147
Total liabilities	79,659	115,474
Stockholders' deficit	(65,122)	(92,813)