**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 5, 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, Suite B, 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 November 5, 2018, REVA Medical, Inc. issued a press release announcing its financial results for the three and nine months ended September 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 November 5, 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: November 5, 2018

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

**Exhibit 99.1**

# REVA MEDICAL REPORTS THIRD QUARTER 2018 FINANCIAL RESULTS

**San Diego, California and Sydney, Australia** (Tuesday, 6 November 2018 - AEDT) – 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 third quarter ended September 30, 2018.

"REVA has achieved two technological milestones in bioresorbable scaffolds ("BRS"): the launch of Fantom ® Encore, with the thinnest strut profiles of any commercially available BRS in Europe and CE Mark of MOTIV™, the first bioresorbable scaffold approved for the treatment of arteries below-the-knee," said Reggie Groves, CEO, REVA. "These products illustrate the advantages of our Tyrocore™ polymer, which we are leveraging to create significant advancements in areas of coronary artery disease, peripheral artery disease and embolization therapies."

"We continued to see growth in product shipments and new customers for Fantom in the third quarter of 2018 despite the increasing challenges in the European BRS market," continued Ms. Groves. "In August 2018, the European Society of Cardiology ("ESC") published updated clinical guidelines for percutaneous coronary intervention procedures that included a recommendation that BRS should not be used outside of well-controlled clinical studies. As a result, we will focus on generating the clinical evidence needed to support our commercialization efforts and a modification to the ESC guidelines in the future. Additionally, we are shifting resources to advance our peripheral and embolization therapy programs. These markets are growing quickly and with reasonable investment, we believe we can make significant progress in the next few years."

**Recent Corporate Highlights**

- Fantom Encore Launch – The Company recently announced the launch of Fantom Encore, its third-generation coronary bioresorbable scaffold with a market-leading thin strut profile compared to other commercially available, CE Mark BRS. Fantom Encore offers differentiated features including thinner strut profiles, improved ease-of-use, and full x-ray visibility. These advantages are derived from REVA's Tyrocore polymer and have been associated with improved outcomes and ease-of-use, which are critical for the broader adoption of bioresorbable scaffold technology.

- Fantom Commercial Activities – During the third quarter of 2018, the Company completed on-boarding of its new Italian distributor as well as a part-time consultant in The Netherlands, Belgium and Luxembourg. As a result, Fantom and Fantom Encore are now commercially available in eight countries including Germany, Switzerland, Austria, The Netherlands, Belgium, Luxembourg, Italy and Turkey.

- Clinical Data – Key data sets demonstrating the capabilities of the Company's Fantom® BRS were presented at the Transcatheter Cardiovascular Therapeutics ("TCT") conference held in San Diego, California in September 2018. The presentations included new procedural data from an indication expansion study in patients experiencing acute heart attacks as well as positive clinical and imaging results of the Fantom BRS through two years.

- New Product – REVA's first product for below-the-knee peripheral artery disease ( "BTK-PAD"), called MOTIV, received CE Mark approval in July 2018. BTK PAD is a large and growing medical issue. Treatment options for BTK PAD patients are very limited and many patients progress to amputation. The Company will identify select centers to assess MOTIV's performance and inform on commercial and product development plans.

- New Therapies – The Company is also applying its Tyrocore technology to embolization therapies, which are intended to treat malignant and non-malignant tumors such as hepatocellular carcinoma and uterine fibroids, respectively. Tyrocore is uniquely suited to embolization therapies because, to the Company's knowledge, there are no x-ray visible, bioresorbable embolization products available in the world. Embolization products generally possess established reimbursement, attractive margins, and a relatively straight-forward regulatory path relative to bioresorbable scaffolds. The Company is evaluating the 510k process as a pathway for U.S. clearance.

**Third Quarter 2018 Operating Results**

REVA's cash balance as of September 30, 2018, was $7.1 million. The Company believes this cash balance will be sufficient to fund operating and capital needs through the first quarter of 2019, assuming the Company achieves certain minimum levels of sales of Fantom and Fantom Encore scaffolds between now and the first quarter of 2019 and implements certain cost reductions in the fourth quarter of 2018. Accordingly, the Company will need to raise further capital to support commercialization activities, and to conduct additional clinical trials, if the Company determines to do so. REVA plans to address the Company's capital needs by pursuing business development and strategic opportunities and pursuing equity or debt financing options.

REVA recognized $93,000 of net revenue during the three months ended September 30, 2018, compared to $17,000 of net revenue for the same period in 2017, the Company's first quarter of product sales. Net revenue during the three months ended September 30, 2018, was consistent with net revenue during the three months ended June 30, 2018. Total product shipments for the three months ended September 30, 2018, were $185,000, a 24% increase as compared to total product shipments for the three months ended June 30, 2018. Additionally, the Company saw an 18% increase in the total number of customers as of September 30, 2018, versus June 30, 2018.

Gross margin for the three months ended September 30, 2018, was negative $48,000. Cost of goods sold for the three months ended September 30, 2018, included an additional charge of $45,000 for potential excess and obsolete inventory, a write off of $8,000 in raw materials and $36,000 of standard cost variances, all primarily related to the Company's transition from Fantom to Fantom Encore. REVA does not anticipate selling many additional Fantom scaffolds or producing additional Fantom scaffolds as the Company launched Fantom Encore on November 1, 2018. Excluding these charges, gross profit would have been $41,000 or 44% of net revenue. The Company anticipates that gross profit will continue to be lower than industry standards until REVA reaches higher sales and manufacturing volumes.

Research and development ("R&D") expenses were $1.7 million for the third quarter of 2018, a decrease of $1.4 million, or 44%, compared to $3.1 million for the same period in 2017. The decrease was due primarily to net decreases in licensing fees of $0.8 million and materials of $0.3 million. The decrease in licensing fees was related to the reversal of accrued extension fees per the July 2018 Rutgers license amendment as well as the absence of fees paid in 2017 related to CE approval. The decrease in materials was related to decreased R&D activity as the Company has focused on commercialization in 2018.

Selling, general and administrative ("SG&A") expenses were $2.8 million for the third quarter of 2018, an increase of $1.1 million, or 67%, compared to $1.7 million for the same period in 2017. The increase was due primarily to increases in personnel costs of $1.1 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 third quarter of 2018, compared to $1.5 million for the same period in 2017. The increase of $0.1 million in interest expense was related to the compounding of interest for the 2014 and 2017 convertible notes.

Loss on change in fair value of convertible notes and warrant liability was $2.9 million for the third quarter of 2018, compared to a gain of $12.3 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 the Company's common stock and other factors that drive fair value.

**Year-to-Date Financial Results**

REVA recognized $237,000 of net revenue during the nine months ended September 30, 2018, compared to $17,000 of net revenue for the same period in 2017. The increase is primarily due to nine months of selling activities in 2018 versus three months of selling activities in 2017, as well as growth in the Company's customer base. Total product shipments for the nine months ended September 30, 2018, were $462,000.

Gross margin for the nine months ended September 30, 2018, was negative $81,000. Cost of goods sold for the nine months ended September 30, 2018, included an additional charge of $111,000 for potential excess and obsolete inventory, a write off of $15,000 in raw materials and $58,000 in standard cost variances, primarily related to the Company's transition from Fantom to Fantom Encore. REVA does not anticipate selling many additional Fantom scaffolds or producing additional Fantom scaffolds as the Company launched Fantom Encore on November 1, 2018. Excluding these charges, gross profit would have been $103,000 or 43% of net revenue. REVA anticipates that the Company's gross profit will continue to be lower than industry standards until the Company reaches higher sales and manufacturing volumes.

R&D expenses were $6.7 million for the nine months ended September 30, 2018, a decrease of $3.4 million, or 34%, compared to $10.1 million for the same period in 2017. The decrease was due primarily to a $1.3 million decrease in licensing fees, a $0.8 million decrease in personnel costs, a $0.5 million decrease in overhead allocations and a $0.4 million decrease in depreciation. The decrease in licensing fees was related to the reversal of accrued extension fees per the July 2018 Rutgers license amendment as well as the absence of fees paid in 2017 related to CE approval. 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 $9.3 million for the nine months ended September 30, 2018, an increase of $3.5 million, or 60%, compared to $5.8 million for the same period in 2017. The increase was due primarily to increases in personnel costs of $2.7 million, legal and consulting fees of $0.4 million, travel costs of $0.2 million and facility costs of $0.2 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 $4.7 million for the nine months ended September 30, 2018, a decrease of $0.5 million, or 9%, compared to $5.2 million for the same period in 2017. The decrease was due primarily 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 $1.6 million related to the convertible notes issued in May and June 2017. During the 2018 period, the Company had a full nine 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 $36.9 million for the nine months ended September 30, 2018, compared to a gain of $28.6 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.

**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. After the restoration of blood flow, bioresorbable scaffolds 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 scaffold 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, the Netherlands, Belgium, Luxembourg, Italy and Turkey. REVA is based in San Diego, California, and employs 45 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 third quarter 2018 financial results and provide a business update. The call is scheduled for 2:00 p.m. PST on Monday, November 5, 2018 (which is 9:00 a.m. AEDT on Tuesday, 6 November 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 2589856 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 Company's ability to create advancements in areas of coronary artery disease, peripheral artery disease and embolization therapies, the Company's ability to generate the clinical evidence needed to support our commercialization efforts and a modification to the ESC guidelines, 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.*

**United States**

**Investor & Media Enquiries:**
REVA Medical, Inc.
Brandi Roberts
Chief Financial Officer
+1 858-966-3003

David Schull
Russo Partners
+1 858-717-2310
david.schull@russopartnersllc.com

**Australia**

**Investor Enquiries:**
Perpetuity Capital Pty Ltd
Kim Jacobs
+61 438 217 279
Andrew Cohen
+61 408 333 452

**Australia**

**Media Enquiries:**
Buchan Consulting
Rebecca Wilson
+61 3 9866 4722

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

| | Three Months Ended September 30, | | Nine months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Revenue, net | $ 93 | $ 17 | $ 237 | $ 17 |
| Cost of revenue | 141 | 7 | 318 | 7 |
| Gross margin | (48) | 10 | (81) | 10 |
| Operating expenses: | | | | |
| Research and development | 1,729 | 3,092 | 6,669 | 10,139 |
| Selling, general and administrative | 2,821 | 1,687 | 9,250 | 5,766 |
| Total operating expenses | 4,550 | 4,779 | 15,919 | 15,905 |
| Loss from operations | (4,598) | (4,769) | (16,000) | (15,895) |
| | | | | |
| Other income (expense): | | | | |
| Interest income | 19 | 34 | 64 | 36 |
| Interest expense | (1,617) | (1,499) | (4,686) | (5,169) |
| Loss on issuance of convertible notes payable and warrants to purchase common stock | — | — | — | (520) |
| (Loss) gain on change in fair value of convertible notes and warrant liability | (2,853) | 12,304 | 36,863 | 28,620 |
| Other income (expense) | 13 | (17) | (7) | (98) |
| Total other income (expense) | (4,438) | 10,822 | 32,234 | 22,869 |
| Net income (loss) | $ (9,036) | $ 6,053 | $ 16,234 | $ 6,974 |
| | | | | |
| Net income (loss) per share – basic | $ (0.22) | $ 0.15 | $ 0.39 | $ 0.17 |
| Weighted average shares outstanding – basic | 41,456,349 | 41,197,348 | 41,326,441 | 42,001,898 |
| | | | | |
| Net loss per share – diluted | $ (0.22) | $ (0.08) | $ (0.31) | $ (0.33) |
| Weighted average shares outstanding – diluted | 41,456,349 | 58,525,654 | 52,832,597 | 56,547,761 |

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

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Cash, cash equivalents and investment securities | $ 7,094 | $ 20,014 |
| Total assets | 10,626 | 22,661 |
| Convertible notes payable and accrued interest | 79,676 | 108,147 |
| Total liabilities | 83,896 | 115,474 |
| Stockholders' deficit | (73,270 ) | (92,813 ) |