

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: July 30, 2018
(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 July 30, 2018 (Australian Eastern Standard Time), REVA Medical, Inc. (“REVA” or the “Company”) filed its Appendix 4C Quarterly Report (“Quarterly Report”) for the three months ended June 30, 2018 with the Australian Securities Exchange (the “ASX”). A copy of the Quarterly Report is furnished hereto as Exhibit 99.1.

The Quarterly Report includes a statement of cash flows prepared in compliance with the requirements of Australian law and the ASX Listing Rules.

Cash as of June 30, 2018 as reported in the Quarterly Report was approximately \$10.1 million. The Company also had \$735,000 of investment securities as of June 30, 2018.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	<u>Australian Appendix 4C Quarterly Report for the quarter ended June 30, 2018</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.

REVA Medical, Inc.

Date: July 30, 2018

/s/ Brandi L. Roberts

Brandi L. Roberts

Chief Financial Officer

(principal financial and accounting officer)



REVA Medical Provides Quarterly Cashflow Report for the Quarter Ended 30 June 2018

San Diego, California and Sydney, Australia (Monday, 30 July 2018 - AEST) – REVA Medical, Inc. (ASX: RVA) (“REVA” or the “Company”), a leader in bioresorbable polymer technologies for vascular medical applications, is pleased to provide the attached Appendix 4C Quarterly Cashflow Report for the quarter ended 30 June 2018. The Appendix 4C is unaudited.

Appendix 4C Summary

As of 30 June 2018, the Company’s cash, cash equivalents and investment securities balance was US \$10.9 million. This balance was broken out between cash of US \$10.1 million and investment securities of US \$735,000. The 30 June 2018 cash balance of \$10.1 million is a decrease of US \$8.4 million from the 31 December 2017 balance of US \$18.5 million, and a decrease of US \$3.5 million from the 31 March 2018 balance.

Our second quarter cash flow activity primarily consisted of: US \$4.2 million in disbursements related to normal operating activities and purchases of US \$488,000 of capital equipment and leasehold improvements, offset by US \$135,000 in cash receipts from customers, \$524,000 in reimbursements for leasehold improvements in accordance with our amended lease for our corporate headquarters and US \$490,000 in maturities of investment securities.

We believe that our cash, cash equivalents and investment securities balance of \$10.9 million as of 30 June 2018 will be sufficient to fund our operating and capital needs through the first quarter of 2019. Accordingly, the Company will need to raise further capital to support our commercialization activities, and to conduct a U.S. clinical trial, if we determine to do so. We have a plan to address our capital needs, which includes accelerating our revenue by pursuing sales expansion and executing business development and strategic opportunities. We are also evaluating public or private sales of our equity or debt securities.

The Company currently plans to file its Form 10-Q Quarterly Report with the U.S. Securities and Exchange Commission and with the Australian Securities Exchange on or before the due date of 9 August 2018. The Quarterly Report provides financial statements, along with Management’s Discussion and Analysis of Financial Condition and Results of Operations for the quarter ended 30 June 2018.

Recent Corporate Highlights

- **Fantom Commercial Activities** – During the second quarter of 2018, we continued to support direct sales in Germany, Switzerland and Austria with our 5-person sales force. We recorded \$149,000 in product shipments and recognized revenue of \$91,000 in the second quarter of 2018. From the first quarter to the second quarter, our product shipments increased 16% and our recognized revenue increased 72%. We recognize revenue when we believe that Fantom has been utilized in a surgical procedure and is no longer subject to exchange rights.

In July 2018, we received CE Mark approval for twelve-month shelf life for Fantom. This will enable us to provide extended use-by dates to our customers and will also allow us to begin phasing out our product exchange program by the end of 2018. At that time, we also intend to simplify our revenue recognition policy by recognizing revenue upon product shipment and maintaining a reserve against potential future product returns based on historical activity.

In the second quarter of 2018, we began our planned expansion into distributor markets with the announcement of our first commercial distributor partnership with Kardionet in Turkey. In July 2018, we announced our second commercial distribution partnership with Bio Vascular Group in Italy. Also in July 2018, we hired a part-time consultant to support direct sales in Belgium, the Netherlands, and Luxemburg. We will continue to expand geographically with direct sales in select countries and distributor partnerships in countries that are more favorable for these partnerships (generally the result of conditions such as high tender volume and extended payment terms).

- **New Product Development** – In June 2018, we obtained CE Mark for our full Fantom Encore product line. Fantom Encore, like Fantom, is used for the treatment of coronary artery disease (“CAD”). Annually, approximately 5.6 million stents are used to treat CAD and the worldwide sales of stents is estimated to be \$4 billion¹. Our recent CE approval now encompasses 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 (95, 105 and 115 microns for the 2.5, 3.0 and 3.5 diameter sizes, respectively, versus 125 microns for all Fantom diameter sizes). Fantom Encore is made with Tyrocore, REVA’s proprietary radiopaque bioresorbable polymer, making Fantom Encore the most advanced bioresorbable scaffold. Thin struts are associated with better healing and clinical outcomes. Reduction in strut thickness is considered by physicians to be one of the most important improvements for bioresorbable scaffolds.

In July 2018, we expanded beyond the coronary arteries into the treatment of below the knee (“BTK”) peripheral artery disease (“PAD”) with the receipt of CE Mark for the MOTIV bioresorbable scaffold. PAD in the lower extremities is a large and growing medical issue. According to the Center for Disease Control, more than 8.5 million Americans suffer from PAD. Invasive medical treatments including drug coated balloons and drug eluting metal stents are an increasing treatment option. Drug eluting bioresorbable scaffolds present a significant opportunity to improve the treatment of patients suffering from PAD because of the potential to extend drug delivery and to enable retreatment without the risks associated with a metal stent. We estimate that the worldwide market for drug eluting bioresorbable scaffolds in BTK could reach \$1.5 billion². Over the next few months, we will identify select centers to assess MOTIV’s performance, inform future product development activities and determine its complete commercial strategy in peripheral vascular applications. We expect MOTIV’s first use in patients to be in late 2018 or early next year.

We also continue to make progress on a new vascular application, embolics. Embolic beads are used to occlude arteries that feed tumors, such as liver cancer or uterine fibroids. Our technology is uniquely suited to embolic beads because there are no x-ray visible, bioresorbable embolic products currently available on the US market. Embolic beads are interesting because of the established reimbursement, attractive margins, and relatively straight-forward regulatory path relative to bioresorbable scaffolds. We are currently evaluating the best path to take this technology forward for development and commercialization.

- **Clinical Data** – We released two-year data from our FANTOM II trial at EuroPCR in May 2018 which demonstrated sustained safety and efficacy of Fantom. Our 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

¹ JP Morgan Equity Research Interventional Cardiology Market Model Dec. 2016.

² Nehler M, et al. Epidemiology of peripheral arterial disease and critical limb ischemia in an insured national population. JVS 2014; Population data from United Nations online database.

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infarction events that are related to the treated vessel. Following this definition, the two-year TLF rate from 240 patients in the FANTOM II trial was 4.6%. This compares favorably to two-year TLF rates for Absorb of 11.0% and Xience of 7.9% in the 2,008-patient ABSORB III trial.

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.

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.

United States

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[Appendix to Follow]

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Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

REVA Medical, Inc.

ABN

ARBN 146 505 777

Quarter ended ("current quarter")

30 June 2018

Consolidated statement of cash flows	Current quarter (Q2) \$'000 USD	Year to date (6 months) \$'000 USD
1. Cash flows from operating activities		
1.1 Receipts from customers	135	282
1.2 Payments for		
(a)research and development	(754)	(1,649)
(b)product manufacturing and operating costs	(463)	(931)
(c)advertising and marketing	(67)	(186)
(d)leased assets	—	—
(e)staff costs	(1,974)	(4,998)
(f)administration and corporate costs	(925)	(1,727)
1.3 Dividends received (see note 3)	—	—
1.4 Interest received	30	47
1.5 Interest and other costs of finance paid	—	—
1.6 Income taxes paid	—	—
1.7 Government grants and tax incentives	—	—
1.8 Other (provide details if material)	524	524
1.9 Net cash from / (used in) operating activities	(3,494)	(8,638)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a)property, plant and equipment	(488)	(552)
(b)businesses (see item 10)	—	—
(c)investments	—	—
(d)intellectual property	—	—
(e)other non-current assets	—	—

+ See chapter 19 for defined terms
1 September 2016 Page 1

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows		Current quarter (Q2) \$'000 USD	Year to date (6 months) \$'000 USD
2.2	Proceeds from disposal of:		
	(a)property, plant and equipment	—	50
	(b)businesses (see item 10)	—	—
	(c)investments	490	735
	(d)intellectual property	—	—
	(e)other non-current assets	—	—
2.3	Cash flows from loans to other entities	—	—
2.4	Dividends received (see note 3)	—	—
2.5	Other (provide details if material)	—	—
2.6	Net cash from / (used in) investing activities	2	233
Cash flows from financing activities			
3.			
3.1	Proceeds from issues of shares	—	—
3.2	Proceeds from issue of convertible notes	—	—
3.3	Proceeds from exercise of share options	—	—
3.4	Transaction costs related to issues of shares, convertible notes or options	—	—
3.5	Proceeds from borrowings	—	—
3.6	Repayment of borrowings	—	—
3.7	Transaction costs related to loans and borrowings	—	—
3.8	Dividends paid	—	—
3.9	Other (repurchase of common stock)	—	—
3.10	Net cash from / (used in) financing activities	—	—
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	13,631	18,544
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,494)	(8,638)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	2	233
4.4	Net cash from / (used in) financing activities (item 3.10 above)	—	—
4.5	Effect of movement in exchange rates on cash held	—	—
4.6	Cash and cash equivalents at end of quarter	10,139	10,139

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

5. Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$'000 USD	Previous quarter \$'000 USD
5.1 Bank balances	9,989	13,481
5.2 Call deposits	150	150
5.3 Bank overdrafts	—	—
5.4 Other (provide details)	—	—
5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)	10,139	13,631

1.8 Reimbursement of leasehold improvements of corporate headquarters

6. Payments to directors of the entity and their associates	Current quarter \$'000 USD
6.1 Aggregate amount of payments to these parties included in item 1.2	85
6.2 Aggregate amount of cash flow from loans to these parties included in item 2.3	—
6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2	

Australian Director fees (1 non-executive directors)	USD \$13
U.S. Director fees (6 non-executive directors)	USD \$72

7. Payments to related entities of the entity and their associates	Current quarter \$'000 USD
7.1 Aggregate amount of payments to these parties included in item 1.2	—
7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3	—
7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2	

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

8. Financing facilities available <i>Add notes as necessary for an understanding of the position</i>	Total facility amount at quarter end \$'000 USD	Amount drawn at quarter end \$'000 USD
8.1 Loan facilities	—	—
8.2 Credit standby arrangements	—	—
8.3 Other (please specify)	—	—
8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.		

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9. Estimated cash outflows for next quarter	\$'000 USD
9.1 Research and development	750
9.2 Product manufacturing and operating costs	450
9.3 Advertising and marketing	150
9.4 Leased assets	—
9.5 Staff costs	2,100
9.6 Administration and corporate costs	850
9.7 Other (costs of financing transaction)	—
9.7 Other (capital equipment)	—
9.8 Total estimated cash outflows	4,300

10. Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1 Name of entity	N/A	N/A
10.2 Place of incorporation or registration		
10.3 Consideration for acquisition or disposal		
10.4 Total net assets		
10.5 Nature of business		

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Sign here: /s/ Brandi L. Roberts Date: 30 July 2018
(Director/Company secretary)

Print name: Brandi L. Roberts

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.