

REVA MEDICAL, INC.

FORM 8-K (Current report filing)

Filed 10/28/16 for the Period Ending 10/27/16

Address	5751 COPLEY DRIVE SAN DIEGO, CA 92111
Telephone	(858) 966-3000
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Sector	Healthcare
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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: October 27, 2016
(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))
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Item 2.02 Results of Operations and Financial Condition

On October 28, 2016 (Australian Eastern Daylight Time), REVA Medical, Inc. filed its Appendix 4C Quarterly Report (“Quarterly Report”) for the three months ended September 30, 2016 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 September 30, 2016 as reported in the Quarterly Report was approximately \$11.6 million.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Australian Appendix 4C Quarterly Report for the quarter ended September 30, 2016.

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: October 28, 2016

/s/ Katrina L. Thompson

Katrina L. Thompson
Chief Financial Officer
(principal financial and
accounting officer)

Index to Exhibits

**Exhibit
Number**

Description of Exhibits

99.1 Australian Appendix 4C Quarterly Report for the quarter ended September 30, 2016.



Appendix 4C

Quarter Ended 30 September 2016

San Diego, California and Sydney, Australia (Friday, 28 October 2016, AEDT) – REVA Medical, Inc. (ASX: RVA) (“REVA” or the “Company”) is pleased to provide the attached Appendix 4C Quarterly Report for the quarter ended 30 September 2016. The Appendix 4C is unaudited.

Third Quarter Highlights

The Company completed an application for CE Marking of its *Fantom* scaffold in August 2016, continues to collect data from its clinical trials, and is preparing for commercialization. *Fantom* is a bioresorbable drug-eluting scaffold that utilizes REVA’s advanced proprietary polymer to allow thinner strut thickness and enhanced deliverability, while offering its unique property of being visible under x-ray.

During the first quarter of 2016, the Company completed enrollment of the FANTOM II clinical trial with a total of 240 patients enrolled. During the second quarter of 2016, the Company completed the primary endpoint of an imaging assessment at a six-month time point on patients in Cohort A of the trial and released positive data from those patients. During the third quarter of 2016, the Company achieved the following:

- Finalized data analyses on patients in the FANTOM II clinical trial through the six-month primary endpoint and completed the application for regulatory approval to commercialize under the CE Mark in Europe. The endpoint data was obtained from the 117 patients in Cohort A of the trial and showed favorable results, including a Major Adverse Cardiac Events rate of 2.56% and a Late Lumen Loss of 0.25mm (± 0.40 mm) in scaffold and 0.17mm (± 0.34 mm) in segment. Low late loss is a desirable result that historically corresponds to positive long-term outcomes; permanent drug-eluting stents and competitive bioresorbable scaffolds generally have late loss values in the range of 0.20mm to 0.40mm.
- Initiated primary nine-month endpoint assessments on the remaining 123 patients enrolled in trial and began analyzing and compiling that data. Patients are scheduled to complete the nine-month imaging assessments in January 2017.
- Continued to prepare manufacturing operations for commercialization, which includes refining the processes, conducting verification on the processes, and other commercial preparation aspects for *Fantom*.
- Successfully completed the first of two on-site audits required for the CE Marking process in August, with no audit findings. The independent notified body conducted the second on-site audit this week and results are pending. In addition to these audits, the Company expects to receive the initial response to the data and other documentation submitted with the application by early December, with the possibility of receiving CE Mark by year end.

HEAD OFFICE : 5751 Copley Drive, San Diego, CA 92111 • +1 (858) 966-3000 • +1 (858) 966-3099 (FAX) • www.reva-medical.com

AUSTRALIAN OFFICE : Suite 4, Level 14, 6 O’Connell Street, Sydney NSW 2000 • +61 2 9237 2800

ARBN 146 505 777 • REVA Medical, Inc., is a foreign company incorporated in Delaware, USA, whose stockholders have limited liability

- Continued to identify and pursue sources of follow-on financing to secure additional capital. In addition to evaluating these options, the Company continues to support its plan to pursue a listing of its securities on NASDAQ or another U.S. exchange no later than 30 June 2017.

Appendix 4C

As of 30 September 2016, the Company's cash balance was US\$11,553,000. The current quarter end cash balance reflects a decrease of US\$4,996,000 from the 30 June 2016 balance of US\$16,549,000. This decrease reflects US\$4,742,000 in disbursements related to normal operating activities and capital equipment purchases of US\$254,000.

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 10 November 2016. 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 September 2016.

About REVA

REVA is a clinical stage medical device company located in San Diego, California, USA, that is working to commercialize its proprietary bioresorbable scaffolds, as an alternative to metal stents, to treat coronary artery disease. Scaffolds provide restoration of blood flow, support the artery through the healing process, then disappear (or "resorb") from the body over a period of time. This resorption allows the return of natural movement and function of the artery, a result not attainable with permanent metal stents. The Company's *Fantom*® scaffold has been designed to offer an ideal balance of thinness and strength, with distinct ease-of-use features including complete scaffold visibility under x-ray, expansion with one continuous inflation, and no procedural time limitations. REVA will require regulatory approval before it can commercialize *Fantom* or any other product.

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 performance and events or developments that we expect or anticipate will occur in the future, are forward-looking statements, such as those statements regarding our ability to obtain regulatory approvals, timely and successfully complete our clinical trials, protect our intellectual property position, commercialize our products if and when approved, develop and commercialize new products, recruit and retain our key personnel, and estimates regarding our capital requirements and financial performance. You should not place undue reliance 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 our 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 10, 2016, and as may be 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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Appendix 4C

Quarterly report for entities admitted on the basis of commitments

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

Name of entity

REVA Medical, Inc.

ABN

ARBN 146 505 777

Quarter ended ("current quarter")

30 September 2016

Consolidated statement of cash flows

Cash flows related to operating activities

	Current Quarter (Q3) \$'000 USD	Year to date (9 months) \$'000 USD
Receipts from customers	0	0
Payments for(a) staff costs	(1,995)	(6,568)
(b) advertising and marketing	0	0
(c) research and development	(2,317)	(7,841)
(d) leased assets	0	0
(e) other working capital	(431)	(1,740)
Dividends received	0	0
Interest and other items of a similar nature received	1	3
Interest and other costs of finance paid	0	0
Income taxes paid	0	0
Other (provide details if material)	0	0
Net operating cash flows	(4,742)	(16,146)

+ See chapter 19 for defined terms.

Appendix 4C
Quarterly report for entities
admitted on the basis of commitments

	Current Quarter (Q3) \$'000 USD	Year to date (9 months) \$'000 USD
Net operating cash flows (carried forward)	(4,742)	(16,146)
Cash flows related to investing activities		
Payment for acquisition of:		
(a) businesses (item 5)	0	0
(b) equity investments	0	0
(c) intellectual property	0	0
(d) physical non-current assets	(254)	(624)
(e) other non-current assets	0	0
0 Proceeds from disposal of:		
(a) businesses (item 5)	0	0
(b) equity investments	0	0
(c) intellectual property	0	0
(d) physical non-current assets	0	0
(e) other non-current assets	0	0
1 Loans to other entities	0	0
2 Loans repaid by other entities	0	0
3 Other: Maturities of Certificates of Deposit	0	0
Net investing cash flows	(254)	(624)
4 Total operating and investing cash flows	(4,996)	(16,770)
Cash flows related to financing activities		
5 Proceeds from issues of shares, options, etc.	0	11,428
6 Proceeds from sale of forfeited shares	0	0
7 Proceeds from borrowings	0	0
8 Repayment of borrowings	0	0
9 Dividends paid	0	0
10 Other (costs of financing transaction)	0	0
Net financing cash flows	0	11,428
Net increase (decrease) in cash held	(4,996)	(5,342)
11 Cash at beginning of quarter/year to date	16,549	16,895
12 Exchange rate adjustments to item 1.20	0	0
13 Cash at end of quarter	11,553	11,553

+ See chapter 19 for defined terms.

Payments to directors of the entity and associates of the directors

Payments to related entities of the entity and associates of the related entities

		Current Quarter (Q3) \$'000 USD
14	Aggregate amount of payments to the parties included in item 1.2	86
15	Aggregate amount of loans to the parties included in item 1.11	0
16	Explanation necessary for an understanding of the transactions	
Australian Director fees (2 non-executive directors) 25 U.S./British Director fees (5 non-executive directors) 61		

Non-cash financing and investing activities

Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

N/A

Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

N/A

Financing facilities available

Add notes as necessary for an understanding of the position.

	Amount available \$'000 USD	Amount used \$'000 USD
Loan facilities	0	0
Credit standby arrangements	0	0

+ See chapter 19 for defined terms.

Appendix 4C
Quarterly report for entities
admitted on the basis of commitments

Reconciliation of cash

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.

	Current Quarter (Q3) \$'000 USD	Previous Quarter (Q2) \$'000 USD
4.1 Cash on hand and at bank	23	90
4.2 Deposits at call (including time deposits)	11,530	16,459
4.3 Bank overdraft	0	0
4.4 Other (provide details)	0	0
Total: cash at end of quarter (item 1.23)	11,553	16,549

Acquisitions and disposals of business entities

	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1 Name of entity	N/A	N/A
5.2 Place of incorporation or registration		
5.3 Consideration for acquisition or disposal		
5.4 Total net assets		
5.5 Nature of business		

Compliance statement

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.

Sign here: ..s/ Katrina L. Thompson.....Date: 28 October 2016
 (Chief Financial Officer/Company Secretary)

Print name: Katrina L. Thompson

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 wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
2. The definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report except for any additional disclosure requirements requested by AASB 107 that are not already itemised in this report.
3. **Accounting Standards.** ASX will accept, for example, the use of International Financial Reporting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

+ See chapter 19 for defined terms.