

# REVA MEDICAL, INC.

## **FORM 8-K** (Current report filing)

Filed 01/30/17 for the Period Ending 01/30/17

Address	5751 COPLEY DRIVE SAN DIEGO, CA 92111
Telephone	(858) 966-3000
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Industry	Advanced Medical Equipment & Technology
Sector	Healthcare
Fiscal Year	12/31

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: January 30, 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))
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**Item 2.02 Results of Operations and Financial Condition**

On January 31, 2017 (Australian Eastern Daylight Time), REVA Medical, Inc. filed its Appendix 4C Quarterly Report (“Quarterly Report”) for the three months ended December 31, 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 December 31, 2016 as reported in the Quarterly Report was approximately \$6.67 million.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
99.1	Australian Appendix 4C Quarterly Report for the quarter ended December 31, 2016.

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## 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: January 30, 2017

/s/ Katrina L. Thompson

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

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**Index to Exhibits**

<b>Exhibit Number</b>	<b>Description of Exhibits</b>
99.1	Australian Appendix 4C Quarterly Report for the quarter ended December 31, 2016.



## Appendix 4C Quarter Ended 31 December 2016

**San Diego, California and Sydney, Australia (Tuesday, 31 January 2017, AEDT)** – REVA Medical, Inc. (ASX: RVA) (“REVA” or the “Company”) is pleased to provide the attached Appendix 4C Quarterly Report for the quarter ended 31 December 2016. The Appendix 4C is unaudited.

### **Fourth Quarter Highlights**

The Company completed an application for CE Marking of its *Fantom* scaffold in August 2016 and successfully completed both on-site audits required for the approval process in October 2016, with no audit findings. *Fantom* is REVA’s bioresorbable drug-eluting scaffold that utilizes the Company’s advanced proprietary polymer to allow thinner strut thickness and enhanced deliverability, while offering its unique property of being visible under x-ray.

The Company is awaiting *Fantom’s* approval from the European notified body. Upon receipt, the CE Mark will allow REVA to sell in European and other countries that accept the CE Mark. The Company had anticipated approval in December 2016, but has not received final approval to-date. Based on recent inquiries to the notified body, final approval is expected early this year.

While the Company awaits the CE Mark approval, it continues to perform follow-up assessments of patients enrolled in its clinical trials and prepare for commercialization.

Enrollment of the FANTOM II clinical trial was completed in March 2016, with a total of 240 patients who will be followed for five years. The primary endpoints of the trial are six-month Major Adverse Cardiac Events (“MACE”), a safety measurement determined by an independent clinical events committee, and six-month Late Lumen Loss (“LLL”), which indicates the effectiveness of the device. The FANTOM II trial data obtained to-date includes:

- MACE rate of 2.1% through six months on all patients. Permanent drug-eluting stents and competitive bioresorbable scaffolds generally have MACE rates ranging from 3% to 7% for the six-month time point.
- Mean LLL on the 117 Cohort A patients at six months of 0.25mm (±0.40mm) in-scaffold and 0.17mm (±0.34mm) in-segment. Low LLL is a desirable result that historically corresponds to positive long-term outcomes. Permanent drug-eluting stents and competitive bioresorbable scaffolds generally have LLL values in the range of 0.20mm to 0.40mm for the six-month time point.

The Company plans to manufacture the *Fantom* scaffold for commercial purposes at its current facility in San Diego, California. The facility includes a sophisticated polymer manufacturing laboratory, three cleanrooms, and numerous testing laboratories. The Company continues to refine the manufacturing processes, with a current capacity to produce at least 10,000 scaffolds per shift annually, and to optimize the cost structure of production.

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

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Additionally, the Company has set its commercial sales strategy, with launch planned for the first half of 2017 in a targeted number of centers that participated in the FANTOM II clinical trials. A small direct sales team is being sourced, to be based in Europe.

Lastly, during the fourth quarter of 2016, the Company continued to pursue a financing that would provide working capital for commercialization, follow-on clinical trials, and general operations, with the goal to complete the financing during the first quarter of 2017. In addition to the current financing activities, the Company continues to support its plan to pursue a listing of its securities on NASDAQ or another U.S. exchange by mid-2017.

#### **Appendix 4C**

As of 31 December 2016, the Company’s cash balance was US\$6,674,000. The current quarter end cash balance reflects a decrease of US\$4,879,000 from the 30 September 2016 balance of US\$11,553,000. This decrease reflects US\$5,106,000 in disbursements related to normal operating activities and capital equipment purchases of US\$11,000.

The Company currently plans to lodge its Appendix 4E Preliminary Final Report with the Australian Securities Exchange on or before the due date of 28 February 2017 and file its Annual Report on Form 10-K, including audited financial statements, with the U.S. Securities and Exchange Commission on or before the due date of 16 March 2017.

#### **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 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.*

<b>United States Investor &amp; Enquiries:</b>	<b>Australia MediaInvestor Enquiries:</b>	<b>Australia Media Enquiries:</b>
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# Appendix 4C

## Quarterly report for entities admitted on the basis of commitments

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")

31 December 2016

### Consolidated statement of cash flows

<b>Cash flows related to operating activities</b>	Current Quarter (Q4) \$'000 USD	Year to date (12 months) \$'000 USD
1.1 Receipts from customers	0	0
1.2 Payments for(a) staff costs	(1,660)	(8,228)
(b) advertising and marketing	0	0
(c) research and development	(2,699)	(10,540)
(d) leased assets	0	0
(e) other working capital	(747)	(2,487)
1.3 Dividends received	0	0
1.4 Interest and other items of a similar nature received	0	3
1.5 Interest and other costs of finance paid	0	0
1.6 Income taxes paid	0	0
1.7 Other (provide details if material)	0	0
<b>Net operating cash flows</b>	<b>(5,106)</b>	<b>(21,252)</b>

+ See chapter 19 for defined terms.

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

	Current Quarter (Q4) \$'000 USD	Year to date (12 months) \$'000 USD
1.8 Net operating cash flows (carried forward)	(5,106)	(21,252)
<b>Cash flows related to investing activities</b>		
1.9 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	(111)	(735)
(e) other non-current assets	0	0
1.10 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
1.11 Loans to other entities	0	0
1.12 Loans repaid by other entities	0	0
1.13 Other: Maturities of Certificates of Deposit	0	0
<b>Net investing cash flows</b>	(111)	(735)
<b>1.14 Total operating and investing cash flows</b>	(5,217)	(21,987)
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	338	11,766
1.16 Proceeds from sale of forfeited shares	0	0
1.17 Proceeds from borrowings	0	0
1.18 Repayment of borrowings	0	0
1.19 Dividends paid	0	0
1.20 Other (costs of financing transaction)	0	0
<b>Net financing cash flows</b>	338	11,766
<b>Net increase (decrease) in cash held</b>	(4,879)	(10,221)
1.21 Cash at beginning of quarter/year to date	11,553	16,895
1.22 Exchange rate adjustments to item 1.20	0	0
1.23 <b>Cash at end of quarter</b>	6,674	6,674

+ 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 (Q4) \$'000 USD
1.24	Aggregate amount of payments to the parties included in item 1.2	86
1.25	Aggregate amount of loans to the parties included in item 1.11	0
1.26	Explanation necessary for an understanding of the transactions <div style="border: 1px solid black; padding: 5px;">             Australian Director fees (2 non-executive directors) 25              U.S. Director fees (5 non-executive directors) 61           </div>	

**Non-cash financing and investing activities**

- 2.1 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
- 2.2 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**

*necessary for an understanding of the position.*

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

+ See chapter 19 for defined terms.

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

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**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 (Q4) \$'000 USD	Previous Quarter (Q3) \$'000 USD
4.1 Cash on hand and at bank	19	23
4.2 Deposits at call (including time deposits)	6,655	11,530
4.3 Bank overdraft	0	0
4.4 Other (provide details)	0	0
<b>Total: cash at end of quarter (item 1.23)</b>	<b>6,674</b>	<b>11,553</b>

**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: 31 January 2017  
 (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.

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+ See chapter 19 for defined terms.