

REVA MEDICAL, INC.

FORM 8-K (Current report filing)

Filed 10/31/17 for the Period Ending 10/31/17

Address	5751 COPLEY DRIVE SAN DIEGO, CA, 92111
Telephone	(858) 966-3000
CIK	0001496268
Symbol	RVALL
SIC Code	3842 - Orthopedic, Prosthetic, and Surgical Appliances and Supplies
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: October 31, 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))

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 7.01 Regulation FD Disclosure

On October 31, 2017, REVA Medical, Inc. (“REVA” or the “Company” announced that Dr. Ricardo A. Costa, trial investigator for the Company’s FANTOM II clinical trial from Institute Dante Pazzanese of Cardiology in Sao Paulo, Brazil, presented 24-month data from a subset of patients in the trial. These results were reported at the Transcatheter Cardiovascular Therapeutics 2017 (“TCT”) interventional cardiology conference, which is being held October 29th through November 2nd in Denver, CO.

The presentation materials delivered by Dr. Costa at the conference are attached hereto as Exhibit 99.1. A copy of the presentation is also posted under the *Investor Relations* section of REVA’s website at www.revamedical.com.

Limitation of Incorporation by Reference

In accordance with General Instruction B.2 of Form 8-K, this information including the Exhibit is furnished pursuant to Item 7.01 and shall not be deemed to be “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in this Item 7.01 of this Current Report on Form 8-K will not be deemed an admission as to the materiality of any information that is required to be disclosed solely by Regulation FD.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Presentation entitled “ FANTOM II Trial: First Report on Initial 24 Month Outcomes ”

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 31, 2017

/s/ Brandi L. Roberts

Brandi L. Roberts

Chief Financial Officer and Corporate Secretary

TCT 332: FANTOM II Trial: Safety & Performance Study of the Fantom Sirolimus-Eluting Bioresorbable Coronary Scaffold – First Report on Initial 24 Month Outcomes

Fantom II Clinical Trial Investigators

Fantom®

Optimal Drug Eluting Bioresorbable Coronary Scaffold

- 1st and Only BRS Made with Tyrosene™
- Designed specifically for bioresorbable scaffolds
- Derived from naturally occurring tyrosine amino acid
- Resist failure for restenosis
- Proprietary patent portfolio and manufactured by TCTA Medical

RADIOPAC

Advanced X-ray contrast agent for enhanced visualization

STRONG

High-strength alloy for structural support

BIODEGRADABLE

Resorbable leading to natural revascularization

TCTA107

FANTOM II Study Design and Endpoints

Study Design

- Safety and Performance Trial
- 240 patients in 2 cohorts
- 2 Sites to 3 Sites vessels
- Lesion length < 20mm
- Angiographic Follow-up
 - Cohort A: 6 weeks (177 pts)
 - Cohort B: 2 weeks (122 pts)
- Core imaging sub-study
 - Cohort A: 24 months (33 pts)
 - Cohort B: 24 months (33 pts)

TCTA111

FANTOM II – Cohort A & B Safety Results

Comparative of Overall Primary Endpoint (overall ITT)

	8 Weeks (n=177)	12 Weeks (n=118)	24 Months (n=66)
MACE	3.1%	4.2% (1%)	8.4% (2%)
Cardiac Death	0.6%	0.8%	1.5%
MI	1.2%	1.7%	1.4%
Stent Thrombosis	0.6%	2.6%	3.0%

TCTA112

FANTOM Program Clinical Summary

- Fantom offers new and clinically important features
 - Ease-of-use
 - Relatively wide stentable scaffold delivery
 - Low crossing profile with high flexibility
 - Staple-free delivery, no need for long guide-wire
 - Thin struts and radial strength to facilitate vessel healing
- Data demonstrates continued safety through 24 mo.
 - Low MACE Rate (3.1%)
- Imaging sub-study shows sustained results
 - No change in average lumen loss from 8 to 24 months
 - No evidence of late or chronic scaffold recoil

TCTA113

Fantom Ease of Use Features

Makes It Important Procedure Easier

TCTA114

FANTOM II – Cohorts A & B Study Overview and Baseline Characteristics

Study Overview

- 240 Patients
- 177 Patients (Cohort A)
- 122 Patients (Cohort B)

Baseline Characteristics (n=240)

Female (%)	28.3%
Mean Age (range)	65.7 (4-91)
Diabetes (%)	23.8%
Current/Former Smoker (%)	65.0%
Hyperlipidemia (%)	73.8%
Hypercholesterolemia (%)	74.6%
Previous PCI (%)	43.3%
Previous CABG (%)	3.0%
Previous MI (%)	25.0%
Previous VTE/AFIB (%)	0.8%

TCTA115

FANTOM II Angiographic – QCA Results

In-Scaffold Angiography	Baseline (n=237)	Cohort A - 6 Mo. (n=176)	Cohort B - 24 Mo. (n=66)
IRL (%)	5.7% ± 0.3*	5.7% ± 0.5*	5.8% ± 0.5*
MLL (%)	5.0% ± 0.2*	5.0% ± 0.4*	5.1% ± 0.5*
Reference Vessel (%)	36.5 ± 11.5	35.3 ± 8.2	35.8 ± 10.3
Acute Stenosis (%)	1.8% ± 0.1*		
ACR (%)	4.2 ± 0.2*		
Mean LLL (mm)		0.76 ± 0.23	0.50 ± 0.18
Mean LLL (mm)		0.17 ± 0.34	0.21 ± 0.10

TCTA116

Fantom Global Clinical Program

Global Clinical Program Overview

- USA: TCTA117
- Canada: TCTA118
- Europe: TCTA119
- Asia: TCTA120
- Latin America: TCTA121
- Australia: TCTA122

TCTA123

FANTOM II Study Investigators

- Australia:** Dr. Stefan D. Jansen, Dr. Richard
- Belgium:** Dr. De Bruyne
- Brazil:** Dr. Almeida, Dr. Costa, Dr. Chaves, Dr. Pado
- Denmark:** Dr. Sørensen, Dr. Lassen, Dr. Østerby
- France:** Dr. Guiraud, Dr. Chavalier, Dr. Hosten, Dr. Galle
- Germany:** Dr. Rottler, Dr. Müller, Dr. Kahlert, Dr. Gellera, Dr. Gellera, Dr. Gellera
- Netherlands:** Dr. Bovenland, Dr. Serruys, Dr. Serruys, Dr. Serruys
- Poland:** Dr. Szymanski, Dr. Kozłowski, Dr. Kozłowski, Dr. Lesiak, Dr. Wójcik

TCTA124

FANTOM II – Cohorts A & B Lesion Characteristics and Procedural Outcomes

Lesion Characteristics

Target Lesion Location – QCA	
LD	18.7% (116)
LD	31.3% (194)
SL	28.3% (176)

ACQWA Lesion Core (n=237)

Type A	18.6% (84)
Type B1	48.5% (214)
Type B2	28.4% (130)
Type C	3.9% (16)

Initial Outcomes

Acute Procedural Success (%)	98.8%
Stable Procedural Success (%)	98.1%
Delayed Procedural Success (%)	98.5%

TCTA125

FANTOM II Long Term Follow-up Case Sample

TCTA126

Fantom Product Evolution

Next Generation: Fantom Encore

- Thinner struts without compromising radial strength
- 95 micron or 0.9 micrometer
- No changes to Tyrosene™ polymer composition or scaffold design
- Improved polymer processing and manufacturing techniques
- European approval and launch anticipated in 2018

Dimension	Fantom	Fantom Encore
Strut Height	125 µm	95 µm
Strut Thickness	125 µm	125 µm
Strut Spacing	125 µm	125 µm

TCTA127