REVA MEDICAL, INC.

FORM 8-K
(Current report filing)

Filed 05/19/17 for the Period Ending 05/17/17

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
REVA MEDICAL, INC.
(Exact name of registrant as specified in its charter)

5751 Copley Drive, San Diego, CA
(Address of principal executive offices)

(858) 966-3000
(Registrant’s telephone number, including area code)

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))

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. ☐
REVA Medical, Inc. ("REVA" or the "Company") announced that it had sponsored a symposium at the Paris Course on Revascularization, or EuroPCR 2017, being held in Paris, France, this week. The symposium, entitled, *Fantom: performance gains and clinical data for a next generation BRS*, highlights the Company’s recently announced clinical data from its *FANTOM II* trial. Information regarding the Company’s newly initiated clinical trials and plans for expansion is also presented. The announcement and presentation materials are attached hereto as Exhibits. A copy of the presentation materials are posted under the *Investor Relations* section of REVA’s website at [www.revamedical.com](http://www.revamedical.com).

**Limitation of Incorporation by Reference**

In accordance with General Instruction B.2 of Form 8-K, this information including the Exhibits are 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.

<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>99.1</td>
<td>Cover Announcement entitled, “REVA Symposium Showcases Clinical Data”</td>
</tr>
<tr>
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<td>Presentation entitled, “REVA FANTOM II Performance and healing patterns by OCT”</td>
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<td>Presentation entitled, “The FANTOM Scaffold Expanding the use of Fantom BRS in worldwide markets: REVA’s global clinical trial programme and beyond”</td>
</tr>
</tbody>
</table>
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: May 19, 2017

/s/ Katrina L. Thompson
Katrina L. Thompson
Chief Financial Officer
(principal financial and accounting officer)
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REVA Symposium Showcases Clinical Data

Company discusses positive long-term data, expanded clinical trials, and plans for growth

San Diego, California and Sydney, Australia (Thursday, 18 May 2017, AEST) – Today at the Paris Course on Revascularization (“EuroPCR”), REVA Medical, Inc. (ASX: RVA) (“REVA” or the “Company”) sponsored a symposium entitled, Fantom: performance gains and clinical data for a next generation BRS, which highlighted the recently announced clinical data from the FANTOM II trial. Information regarding the Company’s newly initiated clinical trials and plans for expansion was also presented.

Dr. Alexandre Abizaid, Director of Invasive Cardiology at Institute Dante Pazzanese of Cardiology in Sao Paulo, Brazil, provided a thorough review of the 12-month clinical results from the FANTOM II trial, which were released by the Company yesterday. The results, which included a very low 4.2% rate of Major Adverse Cardiac Events (“MACE”), demonstrate a strong safety profile for Fantom through a sustained timeframe.

Dr. Neils Holm from the Skejby-Aarhus University Hospital in Aarhus, Denmark expanded on the nine-month Optical Coherence Tomography (“OCT”) results that were also released by the Company yesterday. The OCT imaging results in a subset of patients treated with Fantom demonstrated vessel patency (maintenance of a wide open artery) and sustained healing with greater than 99% strut coverage at nine months.

Dr. Lukasz Koltowski from the Medical University of Warsaw in Poland and Dr. Matthias Lutz from Universitätsklinikum Schleswig-Holstein in Kiel Germany presented a selection of patient case examples from REVA’s recently initiated clinical trials. The FANTOM II Cohort C trial is evaluating the use of Fantom in longer lesions and in multiple vessels. FANTOM AMI is evaluating Fantom in patients that present with an acute myocardial infarction (“AMI”). Each of these trials is designed to evaluate the safety and performance of Fantom in more complex cases. Positive results will support indication expansion for Fantom, allowing physicians to confidently expand their use of the product in their patients.

Dr. Gregg Stone from the Columbia University Medical Center and the Cardiovascular Research Foundation closed the symposium with an overview of REVA’s future plans for geographic expansion, including information regarding the Company’s proposed trials in the United States and Japan. In addition, Dr. Stone announced REVA’s plans for a thinner version of Fantom (sub-100 micron strut thickness) that is targeted for 2018. This device is being developed to address the issues associated with the use of bioresorbable scaffolds in smaller vessels, and will be a significant addition to the Fantom family of products.

The presentation materials delivered at the symposium are attached hereto and available in the Investor Relations section of REVA’s website at www.revamedical.com.
About REVA

REVA is a medical device company located in San Diego, California, USA, that has developed a proprietary bioresorbable scaffold, 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.

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 the projections and timing surrounding our plans to commence commercial operations and sell products, conduct clinical trials, develop pipeline products, incur losses from operations, list our securities for sale on a U.S. stock exchange, and assess and obtain future financings for operating and capital requirements. Readers 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 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 February 28, 2017, 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.
REVA FANTOM II

Performance and healing patterns by OCT

Niels Ramsing Holm
Aarhus University Hospital, Denmark

JO SIMONSEN, EMIL NIELSEN HOLCK, DIDIER CARRIÉ, NOBERT FREY, MATTHIAS LUTZ, JOACHIM WEBER-ALBERS, DARIUS DUDEK, BERNARD CHEVALIER, JOUKE DIJKSTRA, JENS LASSENG, JEFFREY ANDERSON, EVALD HØJ CHRISTIANSEN, ALEXANDRE ABIZAID, NIELS RAMSING HOLM

On behalf of the FANTOM II investigators
The FANTOM BRS

- Desaminotyrosine based polycarbonate backbone
- Strut thickness 125µm
- Sirolimus eluting for 3 months
- Full resorption within 3-4 years
FANTOM angiographic signature

- Radiopacity
- Covalently bound iodine in the polycarbonate backbone
FANTOM OCT signature

Baseline 6 month FU 9 month FU

PCI Research Aarhus University Hospital, Skejby • Denmark
FANTOM BRS by 3D OCT

3D OCT by St Jude OPTIS

PCI Research
Aarhus University Hospital, Skejby • Denmark
REVA FANTOM II – OCT analysis
OCT billede af baseline og FU strut
Customized analysis
OCT analysis optimized and validated by micro-CT

Strut thickness by micro-CT
OCT analysis optimized and validated by micro-CT
Baseline

FU
FANTOM in bifurcations

Micro-CT
FANTOM II Study Population
N= 240 Total Patients Enrolled

Cohort A - Study Population
N= 117 Patients

6 Month Follow-up
Clinical & Imaging

Angiographic
N=105

OCT
n=80

6 Month Follow-up
Clinical (n=108)

Long Term Follow-up
Clinical (annual through 5 years)

Cohort B - Study Population
N= 123 Patients

6 Month Follow-up
Clinical FU

9 Month Follow-up
Clinical & Imaging

Angiographic
N=43

OCT
n=80

Long Term Follow-up
Clinical (annual through 5 years)
Mean stent area

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Follow-up</th>
<th>Difference</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohort A Mean stent area (mm²)</td>
<td>7.1 (1.5)</td>
<td>7.2 (1.4)</td>
<td>0.1 (-0.02;0.24)</td>
<td>0.12</td>
</tr>
<tr>
<td>Cohort B Mean stent area (mm²)</td>
<td>7.4 (1.6)</td>
<td>7.3 (1.5)</td>
<td>-0.1 (-0.2;0.0)</td>
<td>0.16</td>
</tr>
</tbody>
</table>
Minimal stent area

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Follow-up</th>
<th>Difference</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal stent area (mm²)</td>
<td><strong>Cohort A</strong></td>
<td>7.1 (1.5)</td>
<td>7.2 (1.4)</td>
<td>0.1 (-0.02;0.24)</td>
</tr>
<tr>
<td></td>
<td><strong>Cohort B</strong></td>
<td>6.1 (1.4)</td>
<td>6.0 (1.3)</td>
<td>-0.1(-0.2;0.1)</td>
</tr>
</tbody>
</table>
Mean lumen area

<table>
<thead>
<tr>
<th>Mean luminal area (mm²)</th>
<th>Cohort A</th>
<th>Follow-up</th>
<th>Difference</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>6.8 (1.7)</td>
<td>5.7 (1.4)</td>
<td>-1.1 (-1.3; -0.9)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Cohort B</td>
<td>7.1 (1.6)</td>
<td>5.6 (1.5)</td>
<td>-1.6 (-1.7; -1.4)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
### Minimal lumen area

#### Minimal luminal area, Cohort A

<table>
<thead>
<tr>
<th>Minimal lumen area, mm²</th>
<th>Baseline</th>
<th>Follow-up</th>
<th>Difference (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohort A</td>
<td>6.8 (1.7)</td>
<td>5.7 (1.4)</td>
<td>-1.1 (-1.3; -0.9)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Cohort B</td>
<td>5.7 (1.4)</td>
<td>4.0 (1.4)</td>
<td>-1.7 (-1.9; -1.4)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

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**FANTOM II**

Minimal luminal area, Cohort A Minimal luminal area, Cohort B 6m follow-up 9m follow-up Baseline Baseline
Malapposition

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malapposition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cohort A</td>
<td>0.8% (0.0;3.5)</td>
<td>0.0% (0.0;0.0)</td>
</tr>
<tr>
<td>Cohort B</td>
<td>1.6% (0.1;5.2)</td>
<td>0.0% (0.0;0.0)</td>
</tr>
</tbody>
</table>
Extra-stent lumen

<table>
<thead>
<tr>
<th>Extra stent lumen area (mm²)</th>
<th>Baseline</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohort A</td>
<td>0.05 (0.02;0.13)</td>
<td>0.00 (0.00;0.02)</td>
</tr>
<tr>
<td>Cohort B</td>
<td>0.08 (0.03;0.18)</td>
<td>0.00 (0.00;0.02)</td>
</tr>
</tbody>
</table>
Neointimal area

<table>
<thead>
<tr>
<th></th>
<th>6 months <strong>Cohort A</strong></th>
<th>9 months <strong>Cohort B</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean neointimal area (mm²)</td>
<td>1.2 (1.0;1.4)</td>
<td>1.4 (1.2;1.7)</td>
</tr>
</tbody>
</table>
Neointimal thickness

<table>
<thead>
<tr>
<th>6 months Cohort A</th>
<th>9 months Cohort B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean neointimal thickness (µm)</td>
<td>57 (40;77)</td>
</tr>
</tbody>
</table>

FANTOM II

PCI Research
Aarhus University Hospital, Skejby • Denmark
Strut coverage

Cohort A
Coverage

Cohort B
Coverage

6 months Cohort A
Covered struts 98.1% (95.9;99.4)

9 Months Cohort B
Covered struts 99.0% (98.3;100.0)
Conclusion

The Fantom BRS show promising healing patterns after 6 and 9 months

- OCT properties allows for in-procedure 3D evaluation
- Expected slight decrease in lumen area after 9 months
- No stent area reduction – no late recoil
- High completeness of strut coverage
- Limited neointimal growth
- Excellent resolution of acute extra-stent lumen and malapposition
Fantom: performance gains and clinical data for a next-generation BRS

Lukasz Koltowski
1st Department of Cardiology
Medical University of Warsaw
Potential conflicts of interest

Speaker’s name: Lukasz Koltowski

I have the following potential conflicts of interest to report:

Receipt of grants / research supports: REVA Medical

Receipt of honoraria or consultation fees: Medtronic, REVA Medical
BRS in STEMI: Rationale so far...

Patient
- Younger patients
- Low atherosclerosis burden

Lesion
- Proximal segments
- Lipid-rich soft plaque
- Less calcifications
- More focal/shorter lesion

Scaffold
- Snow shoe effect
### BRS in STEMI

**BVS-RAI & BVS-EXAMINATION**

<table>
<thead>
<tr>
<th>Event</th>
<th>p-Value</th>
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<tr>
<td>ST</td>
<td>0.37</td>
</tr>
<tr>
<td>TLR</td>
<td>0.44</td>
</tr>
<tr>
<td>Death</td>
<td>0.06</td>
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<tr>
<td>DOCE</td>
<td>0.38</td>
</tr>
<tr>
<td>POCE</td>
<td>0.84</td>
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<tr>
<td>Dev. Compl.</td>
<td>0.40</td>
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</tbody>
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**BVS-RAI** Cortese et al. *Am J Card.* 2015

**BVS-EXAMINATION** Brugaletta et al. *JACC Card. Interv.* 2015
Still, BRS in STEMI needs improvement

In-scaffold neovascularization 24 months after bioresorbable vascular scaffold implantation in STEMI patient

Tomaniak, Kochman, Koltowski et al, JACC Cardiovasc. Int 2017 (in print)
Fantom in STEMI: Rationale

1. Snow shoe effect

<table>
<thead>
<tr>
<th>Thickness</th>
<th>PLLA scaffold</th>
<th>Fantom scaffold</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 μm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>32% (2.5 mm)</td>
<td>33% (2.5 mm)</td>
</tr>
<tr>
<td></td>
<td>27% (3.0 mm)</td>
<td>31% (3.0 mm)</td>
</tr>
<tr>
<td></td>
<td>27% (3.5 mm)</td>
<td>27% (3.5 mm)</td>
</tr>
<tr>
<td>125 μm</td>
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</tbody>
</table>

Greater thickness, smaller surface coverage

Lower thickness, greater surface coverage

Source: 1) PLLA scaffold IFU, 2) Data of file, REVA
Fantom in STEMI: Rationale

2. Low recoil & high radial strength

![Bar chart showing recoil and radial strength comparison]

**Recoil**
- PLLA scaffold, 150 um struts
- Fantom scaffold, 125 um struts

**Radial Strength**
- PLLA scaffold, 150 um struts
- Fantom scaffold, 125 um struts

**Low recoil**
- Tested on final scaffold 4.0% 3.5% 3.0% 2.5% systems (crimped, 2.0% sterilized and deployed) at 37°C in H2O

**Adequate radial strength**
- Force to permanently deform scaffold in IRIS compression in 37°C H2O
Fantom in STEMI: Rationale

3. Substantial expansion range
   - 0.75 - 1.0 mm depending upon device size
   - Able to adjust for vessel taper & dilatation

**3.0 mm Nominal Device**

Polymer enables expansion to 3.75 mm without fracture
Fantom in STEMI: Rationale

4. Radiographic Visibility
   - Precise scaffold placement & lesion coverage
   - Proper structural assessment after implantation
   - Less dependent on IVUS/OCT imaging compared to other BVS

Koltowski L (unpublished image)
Fantom in STEMI: Rationale

5. Improved healing profile

Example of Good Healing
- Mature, oriented cells
- Few platelets

Fantom @ 3 Months
- Mature, oriented cells
- Few platelets

Example of Poor Healing
- Immature cells
- Persistent platelets

PLL A Scaffold @ 3 Months
- Mature & Immature cells
- Persistent platelets

Fewer residual platelets @3 months

Data on file, Reva Corp.
First Fantom implantation in STEMI

Case:
- 2 hour CP
- ECG: STEMI inferior
- ASA
- Ticagrelor
- UFH
- Occluded RCA
- Large thrombus

[VIDEO]

Huczek Z (unpublished data)
First Fantom implantation in STEMI

Thrombectomy + pre-dilatation + Fantom (3.5 x 24 mm)

[VIDEO]

Post-dilatation NC 3,5 x 8 (20 atm.)

[VIDEO]

Huczek Z (unpublished data)
First Fantom implantation in STEMI

- ST resolution
- No chest pain
- Procedural success
- OCT evaluation

[Huczek Z (unpublished data)]

[VIDEO]
First Fantom implantation in STEMI

[VIDEO]

Huczek Z (unpublished data)
FANTOM STEMI pilot study

Design:
- Single-arm, prospective
- STEMI (de novo, 2.5-3.5 RVD, <20 mm, no bif., no calc.)
- Proper implantation technique (PSP, 1:1 NC)
- Intravascular imaging follow-up

Study flow:

<table>
<thead>
<tr>
<th>QoL</th>
<th>QoL</th>
<th>QoL</th>
<th>QoL</th>
</tr>
</thead>
<tbody>
<tr>
<td>OCT</td>
<td>OCT</td>
<td>OCT</td>
<td>OCT</td>
</tr>
<tr>
<td>NIRS/IVUS</td>
<td>NIRS/IVUS</td>
<td>NIRS/IVUS</td>
<td>NIRS/IVUS</td>
</tr>
<tr>
<td>Clinical</td>
<td>Clinical</td>
<td>Clinical</td>
<td>Clinical</td>
</tr>
<tr>
<td>Baseline</td>
<td>6 mo</td>
<td>18 mo</td>
<td>36 mo</td>
</tr>
</tbody>
</table>

Koltowski L (unpublished design)
"In theory, theory and practice are the same. In practice, they are not."
[Albert Einstein]

Thank you.
Studies beyond CE-mark: Fantom in long lesion & Multi-Vessel Disease

Matthias Lutz
University Medical Center Schleswig-Holstein,
Campus Kiel, Germany
Speaker’s name: Matthias Lutz

I have the following potential conflicts of interest to report:

- Receipt of grants / research supports: REVA Medical, St. Jude Medical
- Receipt of honoraria or consultation fees: Abbott, St. Jude Medical
FANTOM II
Study Design and Endpoints

- **Current Study Design**
  - Safety and Performance Trial
  - 240 patients in 2 cohorts
  - 2.5mm to 3.5mm vessels
  - **Single De novo Lesions**
    - Lesion length ≤ 20mm
  - Angiographic follow-up
    - Cohort A: 6 months.
    - Cohort B: 9 months.
FANTOM II
Expanded Study Design

Study Design – Cohort A & B
- Safety and Performance Trial
- 240 patients in 2 cohorts
- 2.5mm to 3.5mm vessels
- Single De novo Lesions
  - Lesion length ≤ 20mm
- Angiographic follow-up
  - Cohort A: 6 months
  - Cohort B: 9 months

Study Design – Cohort C
- Safety and Performance Trial
- 50 patients in single cohort
- 2.5mm to 3.5mm vessels
- Long Lesions and multiple vessel disease
  - Lesion length ≥ 20mm
  - Treatment of 2 – 3 vessel disease
- Angiographic follow-up
  - Cohort C: 6 months
FANTOM II Study Design

FANTOM II Study Population

Cohort A & B
- 28 Clinical Centers
- 8 Countries
  - 117 Patients - Enrolled
  - 6 Mo Clinical Follow-up (MACE)
  - 6 Mo Angiographic Follow-up (LII)
    - OCT & IVUS (Optional)
  - Annual Clinical Follow-up (5 yrs)

Cohort B
- 123 Patients - Enrolled
  - 6 Mo Clinical Follow-up (MACE)
  - 9 Mo Angiographic Follow-up (LII)
    - OCT & IVUS (Optional)
  - Annual Clinical Follow-up (5 yrs)

Cohort C
- 50 Patients - Enrolled
  - 6 Mo Clinical Follow-up (MACE)
  - 6 Mo Angiographic Follow-up (LII)
    - Includes OCT All Patients
  - Annual Clinical Follow-up (5 yrs)

Cohort A & B
- 28 Clinical Centers
- 8 Countries

Cohort C
- 5 Clinical Centers
- Single Country

Annual Clinical Follow-up (5 yrs)
First patient

Case:
58 y/o male

PCI prox. LAD 02/17
LV-EF 50%
CRF:
  - HTN
  - Hlip
  - Smoker

[VIDEO]
First patient - RCA

NC 3.0 x 15 mm @ 14 bar
[VIDEO]

Delivery 3.0 x 24 mm Fantom
[VIDEO]
First patient - RCA

NC 3.0 x 15 mm @ 14 bar

3.0 x 24 mm Fantom @ 12 bar

[VIDEO]
First patient - RCA

[VIDEO]

2. Fantom crossing
First patient - RCA

3.0 x 24 mm Fantom @ 16 bar

[VIDEO]
First patient - RCA

3.5 x 24 mm Fantom @12 bar

NC 3.5 x 20 mm @16 bar
First patient - RCA

distal overlapping

[VIDEO]
First patient - RCA

[VIDEO]

proximal „scaffold to scaffold“
First patient - RCA

final result

[VIDEO]
Case observations:

- Able to deliver multiple scaffolds in a single vessel
- Radiopacity makes visualisation of edge to edge or slight overlap possible
- Acute performance in first case positive - clinical study ongoing
The FANTOM Scaffold

Expanding the use of Fantom BRS in worldwide markets: REVA’s global clinical trial programme and beyond

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Potential conflicts of interest

Speaker's name: Dr. Gregg W. Stone

I have the following potential conflicts of interest to report:
Consultant to REVA Medical, Inc.
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Clinical Programs & Beyond

- Clinical Trials that have Reached Their Primary Endpoint
- New Clinical Programs: Now Enrolling
- Planned Future Clinical Programs
- New Product Advancements
- Potential Product Applications
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Clinical Trials that have Reached Their Primary Endpoint

• FANTOM I
  – 7 patient single center pilot study
  – Primary endpoint
    • Ischemic-driven target lesion revascularization (TLR) at 6 months
  – Outcomes
    
    |                      | MACE @ 12 months | OCT imaging @ 4 months | Scaffold Thrombosis @ 24 months |
    |----------------------|-----------------|------------------------|-------------------------------|
    | 0% MACE               | 99% strut coverage | 0% ST                 |
    | No ID-TLR            |                 |                        |
    | Primary endpoint met  |                 |                        |

  – Status
  • All patients now beyond 24-month follow-up; data analysis in process
  • Continued follow-up through 60 months ongoing
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Clinical Trials that have Reached Their Primary Endpoint

• FANTOM II (cohorts A and B)
  - 240 patient multi-center safety and performance study
  - Primary endpoints
    • Major Adverse Cardiac Events (MACE) and Late Lumen Loss at 6 Months
  - Outcomes

<table>
<thead>
<tr>
<th>Primary Endpoints / OCT Imaging</th>
<th>Secondary Endpoints</th>
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<tbody>
<tr>
<td>2.1% MACE through 6-month follow-up</td>
<td>4.2% MACE through 12-month follow-up</td>
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<tr>
<td>Late Lumen Loss 0.17 mm in-segment (0.25 mm in-scaffold) at 6 months</td>
<td>0.4% Scaffold Thrombosis (1 event) with more than 150 patients through 18-month follow-up</td>
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<tr>
<td>&gt;98% scaffold coverage at 6 months by OCT</td>
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• Status
  • All patients now beyond 12-month follow-up
  • Serial imaging sub-study analysis ongoing (cohort A: 24M, cohort B: 48M)
  • Continued follow-up through 60 months ongoing
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New Clinical Programs: Enrolling More Complex Patients

- **FANTOM II (Cohort C) – Long Lesions / Multiple Vessels**
  - 50 patient multicenter study
  - Population
    - Patients with lesions >20 mm in length requiring two or more scaffolds in the same vessel, and patients requiring treatment of multiple lesions in more than one vessel
  - PrimaryEndpoints
    - Major Adverse Cardiac Events (MACE) at 6 Months
    - Late Lumen Loss at 6 Months
  - Status
    - Initiated April 2017, enrollment ongoing
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New Clinical Programs: Enrolling AMI Patients

• FANTOM AMI
  – 20 patient single center pilot study
  – Primary Endpoint
    • Procedural success defined as acute angiographic success without in-hospital MACE
  – Secondary Endpoints
    • QCA and OCT serial imaging assessments at 6, 18 and 36 months
  – Status
    • Initiated May 2017, enrollment ongoing
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Planned Future Clinical Programs

• FANTOM III (US Pivotal Trial)
  – Randomized controlled multicenter study
    • Sample size: 1800 – 2200 patients
    • Control: Metallic drug-eluting stent
  – Primary Endpoint:
    • Target Lesion Failure (TLF) at 12 months (non-inferiority)
  – Secondary Endpoints (tentative):
    • QCA & OCT derived parameters at 3 years
  – Status
    • Currently in active discussions with FDA on study design
  – Planned Initiation: Q1/Q2 2018
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Planned Future Clinical Programs

- **FANTOM Japan**
  - Trial design currently in early planning phase
  - Typical pivotal trial design
    - Randomized controlled multi-center study
      - Sample size: 350 - 400 patients
      - Control: Metallic drug-eluting stent
    - Primary Endpoint: Target Lesion Failure at 12 Months
  - Status
    - Actively evaluating trial design options
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New Product Advancements

• Fantom Gen 2
  – Advanced Fantom scaffold with sub-100 micron strut thickness
  – Designed for use in smaller vessels (≤2.5 mm)
    • First product size 2.5 mm diameter in multiple lengths
  – Status
    • Actively qualifying design enhancements
  – Planned introduction
    • Q1/Q2 2018; pending regulatory approval


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Potential New Product Applications

- **FANTOM Peripheral**
  - Fantom scaffold with design features needed for peripheral applications
  - Design Considerations
    - Evaluating potential use in SFA application
    - Evaluating potential use in BTK application
  - Status
    - Actively qualifying design enhancements
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Global Clinical Trial Programme and Device Development

**Conclusions**

- **Fantom has demonstrated initial device safety through 12 months**
  - 4.2% MACE
  - 0.4% scaffold thrombosis

- **Good late lumen loss, with excellent strut coverage at 6 months**
  - 0.17 mm in-segment, 0.25 mm in-scaffold
  - >98% scaffold coverage at 6 months by OCT

- **Fantom clinical program & product development expanding**
  - Expanding geographical approvals
  - Evaluating coronary and non-coronary indication expansion
  - Evaluating design enhancements (e.g. thinner struts)