REVA MEDICAL, INC.

FORM 8-K
(Current report filing)

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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: August 2, 2016
(Date of earliest event reported)

REVA MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-54192**	**33-0810505**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(I.R.S. Employer Identification No.)*

5751 Copley Drive, San Diego, CA	**92111**
(Address of principal executive offices)	*(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))

Item 7.01 Regulation FD Disclosure

On August 3, 2016 (Australian Eastern Standard Time), REVA Medical, Inc. announced it had completed an application for CE Marking of its *Fantom* ® bioresorbable drug-eluting scaffold. The CE Mark, if approved, would allow the Company to sell the product in Europe and other countries that recognize the CE Mark. A copy of the announcement is furnished hereto as Exhibit 99.1.

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	Announcement entitled, " *Submission of CE Mark Application* "

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: August 3, 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	Announcement entitled, " *Submission of CE Mark Application* "

EXHIBIT 99.1

Submission of CE Mark Application

Sydney, Australia and San Diego, California (Wednesday, 3 August 2016 AEST) – REVA Medical, Inc. (ASX: RVA) ("REVA" or the "Company") is pleased to announce that it has submitted an application for CE Marking of its *Fantom* scaffold, following completion of clinical data analyses and required testing. The regulatory approval process generally spans several months and includes evaluation of the clinical, preclinical, and bench test data submitted, as well as audits of the Company's quality assurance system and related processes. Accordingly, the Company expects it would receive CE Mark approval, or notice of any issues with the application, prior to 31 December 2016. This regulatory approval would allow commercial sales in Europe and other countries that recognize the CE Mark.

The clinical data used in the application was obtained from the 117 patients in Cohort A of the FANTOM II clinical trial, which is being conducted in 28 hospitals in eight countries outside the United States. The primary endpoint in the trial was a combined clinical assessment of Major Adverse Cardiac Events ("MACE") and an invasive imaging assessment of Late Lumen Loss ("LLL") at six months. The adjudicated clinical data showed a MACE rate of 2.56%, which is consistent with the low preliminary rates previously reported for these patients. Additionally, the clinical data showed a final in-scaffold LLL of 0.25mm (±0.35 mm) and an in-segment LLL of 0.17 mm (±0.29 mm), which compare favorably to the rates of commercially available competitive bioresorbable scaffolds and drug-eluting stents.

The Company will continue to follow and evaluate patients in the trial for five years. The 123 patients enrolled in Cohort B of the trial will undergo clinical safety evaluations at six months and invasive imaging assessments at nine months. As these patients completed enrollment in March 2016, the imaging evaluations will be ongoing into the first quarter of 2017.

The clinical data and any additional data from Cohort A, as well as any available data from Cohort B patients in the trial, are planned to be reported at the Transcatheter Cardiovascular Therapeutics ("TCT") conference, which will be held October 29 th through November 2 nd in Washington D.C.

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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