

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: July 25, 2018
(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 8.01 Other Events

On July 25, 2018, REVA Medical, Inc. (“REVA” or the “Company”) announced that its bioresorbable scaffold MOTIV™ had received CE Mark approval for treatment of below the knee peripheral arterial disease. A copy of the press release is attached as Exhibit 99.1 to this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release entitled “ REVA Enters Peripheral Artery Disease Space with First-Ever CE Mark of a Bioresorbable Scaffold for Below the Knee Therapy ”

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: July 25, 2018

/s/ Brandi L. Roberts

Brandi L. Roberts

Chief Financial Officer and Corporate Secretary



REVA ENTERS PERIPHERAL ARTERY DISEASE SPACE WITH FIRST-EVER CE MARK OF A BIORESORBABLE SCAFFOLD FOR BELOW THE KNEE THERAPY

Sydney, Australia and San Diego, California (Thursday, 26 July 2018 - AEST) – REVA Medical, Inc. (ASX: RVA) (“REVA” or the “Company”), a leader in bioresorbable polymer technologies for vascular applications, today announced that its MOTIV™ bioresorbable scaffold is the first drug-eluting bioresorbable scaffold to receive CE Mark approval for treatment of below the knee peripheral artery disease. Late last year, REVA announced its plans to expand use of its bioresorbable scaffold technology in peripheral artery disease. The approval of MOTIV delivers that milestone and for the first time brings bioresorbable technology to this patient population.

MOTIV is made from Tyrocore, REVA’s proprietary polymer designed specifically for vascular scaffolds. Tyrocore is inherently radiopaque, making MOTIV visible under x-ray to ensure accurate placement in the artery. The Company will identify over the next few months select centers to assess the product’s performance, inform future product development activities and determine its complete commercial strategy in peripheral vascular applications. REVA expects MOTIV’s first use in patients to be in late 2018 or early next year.

“REVA did not just achieve its own milestone with CE Mark of MOTIV, we achieved a therapeutic milestone for patients with critical limb ischemia (“CLI”),” said Reggie Groves, REVA’s CEO. “Tyrocore and our polymer technology have a broad range of therapeutic applications. This is our first step beyond the coronary arteries, and we look forward to bringing a new treatment option to peripheral artery disease patients and their physicians.”

The most common indication for patients receiving below the knee (“BTK”) revascularization is CLI. If left untreated, CLI can progress to severe infection and amputation. Patients with CLI below the knee are a substantially underserved population. It is estimated that approximately 1.5 million people are affected by CLI, but only 150,000 interventional revascularization procedures are performed every year.

Research has shown that early-stage intervention is cost-effective and efficacious compared to late stage treatments like amputation. These interventions are intended to restore blood flow to the blocked artery in order to reduce pain and save the limb. Drug-eluting bioresorbable scaffolds such as MOTIV present a significant opportunity to improve the treatment of patients suffering from CLI because of the potential to extend drug delivery and to enable retreatment without the risks associated with metal stents.

About MOTIV

MOTIV is a sirolimus-eluting bioresorbable scaffold developed for the treatment of BTK peripheral artery disease (“PAD”). Treatment options for BTK patients are very limited, and many patients progress to amputation. MOTIV has the potential to expand treatment options for millions of patients suffering from PAD.

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

About REVA Medical

REVA Medical is a medical device company focused on the development and commercialization of bioresorbable polymer technologies for vascular applications. The Company's lead products are the Fantom and Fantom Encore bioresorbable vascular scaffolds for the treatment of coronary artery disease. REVA is currently selling Fantom in Germany, Switzerland, Austria, Turkey and Italy. REVA is based in San Diego, California, and employs more than 50 people in the U.S. and Europe.

Fantom, Fantom Encore, MOTIV, and Tyrocore are trademarks of REVA Medical, Inc.

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 plans or performance and events or developments that may occur in the future, are forward-looking statements, such as those statements regarding the projections and timing surrounding commercial operations and sales, clinical trials, pipeline product development, and future financings. No undue reliance should be placed 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 March 7, 2018, 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.

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