
**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**

**February 26, 2018
Date of report (Date of earliest event reported)**

Surmodics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Minnesota
(State of
Incorporation)

0-23837
(Commission
File Number)

41-1356149
(I.R.S. Employer
Identification No.)

**9924 West 74th Street
Eden Prairie, Minnesota**
(Address of Principal Executive Offices)

55344
(Zip Code)

(952) 500-7000
(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):

- 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 1.01 Entry into a Material Definitive Agreement.

On February 26, 2018, Surmodics, Inc. (the “Company” or “Surmodics”) entered into a Development and Distribution Agreement (the “Agreement”) with Abbott Vascular, Inc., a subsidiary of Abbott Laboratories (“Abbott”). Under the terms of the Agreement, Abbott will have exclusive worldwide commercialization rights for Surmodics’ SurVeil® drug-coated balloon to treat the superficial femoral artery (the “Product”), which product is currently being evaluated in a U.S. pivotal clinical trial. Abbott also received options to negotiate agreements for Surmodics’ below-the-knee and arteriovenous (AV) fistula drug-coated balloon products, which products are currently in pre-clinical development.

Pursuant to the terms of the Agreement, Surmodics will receive a \$25 million upfront payment and may earn an additional \$67 million for various product development milestones (each, a “milestone”). The payment associated with each milestone is subject to a step-down in the event that the applicable milestone event is not achieved by an agreed upon target date. Surmodics will be responsible for the manufacture and supply of clinical and commercial quantities (upon regulatory approval) of the Product and will realize revenue based on initial product sales to Abbott as well as a share of profits resulting from Abbott’s third-party sales. Abbott will have the right to manufacture the Product in the event of a supply disruption (as defined in the Agreement) or upon the occurrence of certain other specified conditions or events. Abbott will have the right, upon the occurrence of certain specified conditions or events, to request and receive a technology transfer, including the transfer of materials and know-how, that would enable Abbott to manufacture the Product.

Unless earlier terminated, the Agreement will remain in effect until December 31, 2032, or if Abbott elects by prior written notice, until December 31, 2035. The Agreement may be terminated by either Surmodics or Abbott based upon an uncured material breach, provided that certain conditions related to such breach and its remedy have not been satisfied. The Agreement may also be terminated by Abbott (a) for convenience upon one year’s prior written notice, or (b) for cause based upon (i) product-related concerns, provided that the applicable dispute resolution procedures specified in the Agreement relating to such concerns have been followed, or (ii) failure by Surmodics to achieve any of the milestones within a certain time period following the agreed upon target date applicable to each such milestone. In the event that the Agreement is terminated for convenience, Abbott will be required to pay all milestone payments for any milestones that were not achieved or paid prior to the effective date of such termination. The Agreement also contains customary representations, warranties, and covenants concerning intellectual property, confidentiality, and indemnification.

Other than the Agreement, Surmodics is party to other license agreements with Abbott or its affiliates pursuant to which Surmodics has licensed certain of its surface modification technologies for use with specified medical device product applications.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement. A copy of the Agreement, with the exception of certain information contained therein that may be excluded pursuant to a request for confidential treatment to be made to the Securities and Exchange Commission, will be filed as an exhibit to Surmodics’ Quarterly Report on Form 10-Q for the quarter ended March 31, 2018.

Item 7.01 Regulation FD Disclosure.

On February 27, 2018, Surmodics and Abbott issued a joint press release announcing they had entered into the Agreement. The press release is furnished as Exhibit 99.1 hereto. The information contained in Exhibit 99.1 is being furnished pursuant to Item 7.01 of this Current Report on Form 8-K, and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to liabilities under Section 18. Furthermore, the information contained in Exhibit 99.1 shall not be deemed to be incorporated by reference into the filings of the Company under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

**Exhibit
Number**

Description

99.1

[Joint Press Release of Abbott Vascular, Inc., a subsidiary of Abbott Laboratories, and Surmodics, Inc. dated February 27, 2018](#)

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.

SURMODICS, INC.

Date: March 2, 2018

/s/ Bryan K. Phillips

Bryan K. Phillips

Sr. Vice President, General Counsel and Secretary

Abbott and Surmodics Announce Agreement for Next-Generation Drug-Coated Balloon

- **COMPANIES TO COLLABORATE ON PRODUCT DEVELOPMENT, CLINICAL TRIALS AND REGULATORY ACTIVITIES TO OBTAIN APPROVAL IN U.S. AND E.U.**
 - **AGREEMENT COMPLEMENTS AND EXTENDS ABBOTT'S BROAD LINE OF VASCULAR CARE PRODUCTS AND DEMONSTRATES VALUE OF SURMODICS' PROPRIETARY DRUG-DELIVERY AND WHOLE-PRODUCT SOLUTIONS STRATEGY**
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ABBOTT PARK, Ill., and EDEN PRAIRIE, Minn., (Feb. 27, 2018) – Abbott (NYSE: ABT) and Surmodics (NASDAQ: SRDX) today announced that the companies have entered into an agreement whereby Abbott will have exclusive worldwide commercialization rights for Surmodics' SurVeil® drug-coated balloon to treat the superficial femoral artery, which is currently being evaluated in a U.S. pivotal clinical trial. Separately, Abbott also received options to negotiate agreements for Surmodics' below-the-knee and arteriovenous (AV) fistula drug-coated balloon products, which are currently in pre-clinical development.

As part of the agreement, Surmodics, a leading provider of medical device and in vitro diagnostic technologies to the healthcare industry, will supply the SurVeil drug-coated balloon to Abbott. The two companies will collaborate on product development, clinical trials and regulatory activities to obtain marketing approval in the U.S. and Europe. The SurVeil drug-coated balloon will complement and extend Abbott's broad line of vascular devices for treating peripheral artery disease (PAD), including stents and vessel closure devices. In addition to its devices for PAD, Abbott has one of the broadest portfolios of medical devices serving the \$30 billion-dollar global cardiovascular market, with leadership positions in several large and fast-growing areas, including cardiac rhythm management, electrophysiology, structural heart and heart failure.

PAD is a serious and often underdiagnosed circulatory condition that can lead to other serious vascular conditions. Drug-coated balloons have emerged as an important treatment option in



treating PAD, which affects an estimated 200 million people worldwide. The SurVeil drug-coated balloon includes a proprietary drug-excipient formulation for a durable balloon coating and is manufactured using an innovative process to improve coating uniformity. Pre-clinical data have shown a three- to five-times higher target tissue drug concentration, a more evenly distributed and durable drug effect, and lower incidence of downstream drug particles compared to the control drug-coated balloon.¹ The design of the SurVeil drug-coated balloon reflects Surmodics' industry leadership in the development of surface technology for vascular medical devices.

"Abbott is committed to providing leading treatments for people with peripheral artery disease, and the SurVeil drug-coated balloon is a next-generation device that utilizes best-in-class technology," said Chuck Brynelsen, senior vice president of Abbott's vascular business. "This agreement enhances our fast-growing endovascular portfolio, and we look forward to offering this solution to physicians to give them more and better options to help their patients live their fullest lives."

"The SurVeil drug-coated balloon is the first device developed by Surmodics that combines our proprietary drug-delivery and surface technologies with our exceptional design, development and manufacturing capabilities," said Gary Maharaj, Surmodics' president and chief executive officer. "We are excited to enter this partnership with Abbott given its deep expertise in vascular care products and its worldwide strength in the market. We look forward to working together with Abbott to realize the full potential of our SurVeil drug-coated balloon to help people with peripheral artery disease."

Surmodics' SurVeil drug-coated balloon is currently being evaluated in the TRANSCEND pivotal clinical trial and is being compared with the current market-leading drug-coated balloon in treating PAD in the legs. The SurVeil drug-coated balloon is currently for investigational use only.

Pursuant to the terms of the agreement, Surmodics will receive a \$25 million upfront payment and may earn an additional \$67 million for various product development milestones. Upon the regulatory approval of the device, Surmodics will be responsible for the manufacture and supply of clinical and commercial quantities of the product and will realize revenue based on initial product sales to Abbott as well as a share of profits resulting from third-party sales.

About Peripheral Artery Disease

Worldwide, over 200 million people have PAD,² a serious and underdiagnosed circulatory condition caused by build-up of arterial plaque, most commonly in the legs. Between 12-20 percent of Americans over 60 years old have PAD.³ PAD increases risk of coronary artery disease, heart attack and stroke, and can impair the ability to walk. If left untreated, PAD can lead to gangrene and limb amputation.⁴

About Abbott

Abbott is a global healthcare company devoted to improving life through the development of products and technologies that span the breadth of healthcare. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 99,000 people.

Visit Abbott at www.abbott.com and connect with us on Twitter at @AbbottNews.

About Surmodics, Inc.

Surmodics is the global leader in surface modification technologies for intravascular medical devices and a leading provider of chemical components for in vitro diagnostic (IVD) immunoassay tests and microarrays. Surmodics is pursuing highly differentiated whole-product solutions that are designed to address unmet clinical needs for its medical device customers and engineered to the most demanding requirements. This key growth strategy leverages the combination of the Company's expertise in proprietary surface technologies, along with enhanced device design, development and manufacturing capabilities. The Company mission remains to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota. For more information, visit www.surmodics.com. The content of Surmodics' website is not part of this press release or part of any filings that the company makes with the SEC.

— Private Securities Litigation Reform Act of 1995 — A Caution Concerning Forward-Looking Statements

Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. Abbott cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Economic, competitive, governmental, technological and other factors that may affect Abbott's operations are discussed in Item 1A, "Risk Factors" to our Annual Report on Securities and Exchange Commission Form 10-K for the year ended Dec. 31, 2017, and are incorporated by reference. Abbott undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

Surmodics, Inc. Safe Harbor for Forward-Looking Statements

This press release contains forward-looking statements. Statements that are not historical or current facts, including statements about beliefs and expectations regarding Surmodics' strategy to transform to a provider of whole-product vascular solutions. Forward-looking statements involve inherent risks and uncertainties, and important factors could cause actual results to differ materially from those anticipated, including (1) Surmodics' ability to successfully develop and obtain regulatory approval for the SurVeil drug-coated balloon; (2) Surmodics' ability to realize the full potential benefits of its agreement with Abbott; and (3) the factors identified under "Risk Factors" in Part I, Item 1A of Surmodics' Annual Report on Form 10-K for the fiscal year ended Sept. 30, 2017, and updated in its subsequent reports

filed with the SEC. These reports are available in the Investors section of Surmodics' website at www.surmodics.com and at the SEC website at www.sec.gov. Forward-looking statements speak only as of the date they are made, and Surmodics undertakes no obligation to update them in light of new information or future events.

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1 Surmodics data on file

2 Fowkes FGR, et al. *Lancet* 2013, 382(9901):1329-1340.

3 Centers for Disease Control and Prevention. Peripheral Arterial Disease (PAD) Fact Sheet. n.d. Web.

4 National Institutes of Health. What is Peripheral Artery Disease? n.d. Web.