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 (Date of earliest event reported): June 20, 2023

Surmodics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Minnesota	**0-23837**	**41-1356149**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

9924 West 74th Street **Eden Prairie, Minnesota**	**55344**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 952 500-7000

(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:

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.05 par value	SRDX	Nasdaq Global Select Market

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 June 20, 2023, Surmodics, Inc. (the "Company") issued a press release (the "Press Release") announcing that the Company had received premarket approval of the SurVeil™ drug-coated balloon from the U.S. Food and Drug Administration. A copy of the full text of the Press Release is furnished as Exhibit 99.1 to this report.

The information in this Item 7.01, including Exhibit 99.1, 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, nor shall such information be deemed incorporated by reference into any 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	Press Release dated June 20, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: June 20, 2023

By: /s/ Timothy J. Arens

Timothy J. Arens
Senior Vice President of Finance and Chief Financial Officer

Exhibit 99.1

Surmodics Receives FDA Approval for the SurVeil™ Drug-Coated Balloon

Surmodics to receive $27 million milestone payment from Abbott

June 20, 2023 06:30 a.m. Eastern Daylight Time

EDEN PRAIRIE, Minn.—(BUSINESS WIRE)—Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced the receipt of U.S. Food and Drug Administration (FDA) approval for the SurVeil™ drug-coated balloon (DCB).

The SurVeil DCB may now be marketed and sold in the U.S. to physicians for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo or restenotic lesions (≤ 180 mm in length) in femoral and popliteal arteries having reference vessel diameters of 4 mm to 7 mm. The SurVeil DCB received CE Mark Certification in the European Union in June 2020.

“Obtaining FDA approval for our SurVeil DCB is one of the most important achievements in Surmodics’ history,” said Gary Maharaj, President and CEO of Surmodics. “It represents a major milestone in our efforts to develop next-generation products to help millions of people affected by peripheral artery disease and the physicians that treat them. I would like to thank our internal SurVeil DCB team and our external advisors, investigators and partners for their multi-year efforts to make this achievement possible.”

Abbott has exclusive worldwide commercialization rights for the SurVeil DCB. Surmodics will manufacture and supply the product and realize revenue from product sales to Abbott and a share of profits from Abbott’s third-party sales. Surmodics will also receive a $27 million milestone payment from Abbott. The company expects to recognize approximately $24.0 to $24.5 million of revenue related to the milestone payment in the third quarter of its fiscal year 2023.

Mr. Maharaj continued, “Building on our recent progress, Surmodics remains focused on supporting Abbott and its exclusive worldwide commercialization rights for the SurVeil DCB. We’ll discuss details on the developments and update our fiscal year 2023 financial guidance during our third quarter earnings call.”

“I am excited that the Surveil DCB will be available to treat patients in the US,” said Kenneth Rosenfield, M.D., co-principal investigator of the TRANSCEND clinical trial. “The Surveil DCB is the next generation DCB as established by results from the TRANSCEND trial which is the only head-to-head pivotal study that has been conducted vs the market-leading DCB. The Surveil DCB successfully demonstrated non-inferior safety and effectiveness at two years post-treatment with a substantially lower drug dose.”

SurVeil DCB TRANSCEND Trial Results Summary

24-month clinical trial results demonstrated the sustained durability of SurVeil DCB safety and efficacy outcomes.[1] SurVeil DCB remained non-inferior to market-leading IN.PACT® Admiral® DCB at a substantially lower drug dose. At 24 months:

- 81.8% of subjects treated with the SurVeil DCB met the secondary safety endpoint, a composite of freedom from device- and procedure-related death through 30 days post-index procedure and freedom from major target limb amputation (above the ankle) and clinically driven target vessel revascularization (CD-TVR) vs. 83.2% of subjects treated with the IN.PACT Admiral DCB.
- Less than 15% of patients in both arms of the trial required repeat revascularization procedures. One patient in the IN.PACT group required major leg amputation.
- Primary patency rate for SurVeil DCB subjects was 70.8% vs. 70.4% for IN.PACT Admiral.

Both the SurVeil and IN.PACT Admiral DCBs utilize paclitaxel drug coatings. However, the IN.PACT Admiral DCB has a 75% higher drug load of paclitaxel (3.5 µg/mm²) than the SurVeil DCB, which has a 2.0 µg/mm² drug load. The design of the SurVeil DCB is intended to provide more uniform drug distribution, better efficiency of drug transfer, and fewer downstream particulates and downstream emboli.

About the SurVeil DCB

The SurVeil DCB, a next-generation device that utilizes best-in-class technology in the treatment of peripheral artery disease (PAD), includes a proprietary drug-excipient formulation for a durable balloon coating and is manufactured using an innovative process to improve coating uniformity.

About Surmodics, Inc.

Surmodics is a leading provider of performance coating technologies for intravascular medical devices and chemical and biological components for in vitro diagnostic immunoassay tests and microarrays. Surmodics also develops and commercializes highly differentiated vascular intervention medical devices that are designed to address unmet clinical needs and engineered to the most demanding requirements. This key growth strategy leverages the combination of the company's expertise in proprietary surface modification and drug-delivery coating technologies, along with its device design, development and manufacturing capabilities. The company's mission is 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.

Safe Harbor for Forward-Looking Statements

This press release contains forward-looking statements. Statements that are not historical or current facts, including statements about Surmodics' manufacture and supply of SurVeil DCB products and the potential product revenue the company may realize, the milestone payment the company expects to receive from Abbott and the amount and timing of revenue recognition related to the milestone payment, and the company's growth strategy, are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties, and important factors could cause actual results to differ materially from those anticipated, including the actions of Abbott, the availability of components to manufacture SurVeil DCB products, the stability of SurVeil DCB manufacturing and sterilization processes at commercial scale, future accounting estimates related to the recognition of revenue from milestone payments, and the factors identified under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2022, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at https://surmodics.gcs-web.com and at the SEC website at www.sec.gov. Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update them in light of new information or future events.

1. Rosenfield K. Intermediate-Term (24-Month) Results of the TRANSCEND Study Comparing a Next-Generation Paclitaxel Drug-Coated Balloon (SurVeil DCB) to IN.PACT DCB in the Treatment of Femoropopliteal Artery Disease. Presented at the 20th Annual VIVA (Vascular InterVentional Advances) conference; November 1, 2022; Las Vegas, Nevada.

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