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

January 19, 2023
Date of report (Date of earliest event reported)

Surmodics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Minnesota	**0-23837**	**41-1356149**
(State of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

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

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	The 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 January 19, 2023, Surmodics, Inc. (the "Company") issued a press release (the "Press Release") disclosing communications that the Company received from the U.S. Food and Drug Administration related to the Company's application for premarket approval of the SurVeil™ drug-coated balloon. 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 January 19, 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: January 19, 2023

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

Surmodics Provides Regulatory Update Related to its FDA Premarket Approval Application for the SurVeil™ Drug-Coated Balloon

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--January 19, 2023--Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced it has received a letter from the U.S. Food and Drug Administration (FDA; the Agency) related to its premarket approval (PMA) application for the SurVeil™ drug-coated balloon (DCB).

In the letter, the FDA indicated that the application is not currently approvable, while providing specific guidance as to a path forward. The letter stated that certain information within two general categories—biocompatibility and labeling—must be added by an amendment to the company's PMA application to place it in approvable form. Although the information identified by the Agency to put the PMA application in approvable form would require additional testing and analysis, the letter did not question the human clinical data submitted nor request any further human clinical data.

"We are disappointed by the FDA's response to our PMA application and continue to have confidence in our SurVeil DCB including its compelling performance in the TRANSCEND clinical study," said Gary Maharaj, Chief Executive Officer of Surmodics, Inc. "We are evaluating the issues raised in the FDA's letter and plan to meet with Agency representatives regarding its contents. Based on our discussion with the Agency, our team and external advisors will determine the appropriate path forward. Concurrently, we will be evaluating options to reduce our use of cash given this development. We expect to address these topics further in connection with our upcoming first quarter fiscal 2023 earnings call."

About the SurVeil DCB and the TRANSCEND Clinical Study

The SurVeil DCB, a next-generation device for the treatment of peripheral artery disease (PAD), includes a proprietary drug-excipient formulation using an innovative process to improve coating uniformity. A presentation on the Intermediate-Term (24-month) Results of the TRANSCEND Study, presented by Kenneth Rosenfield, MD, MHCDS, is available on the Events & Presentation page of the Investors section of our website at https://surmodics.gcs-web.com. In the United States, the SurVeil DCB is an investigational device, limited by Federal law to investigational use.

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 the company meeting with the Agency, determining the appropriate path forward on the PMA application for the SurVeil DCB product, the company's intent to evaluate options to reduce its use of cash, 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 availability of FDA personnel, Surmodics' personnel, and Surmodics' consultants to address the FDA letter, limitations on Surmodics' ability to reduce its use of cash due to financial obligations of the company, 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.

Contacts

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