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

March 28, 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	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 March 28, 2023, Surmodics, Inc. (the "Company") issued a press release (the "Press Release") disclosing feedback that the Company received from the U.S. Food and Drug Administration related to the Company's planned amendment to its 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 March 28, 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: March 28, 2023

/s/ Timothy J. Arens

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

Exhibit 99.1

Surmodics Provides Regulatory Update on its Strategy to Submit an Amended Premarket Approval Application for the SurVeil™ Drug-Coated Balloon

- ***Announces Receipt of Positive Formal FDA Feedback via the Q-Submission Program***
- ***Substantially reduces the anticipated time and cost needed to receive a PMA***

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--March 28, 2023--Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced that it has received formal feedback from the Food and Drug Administration (FDA; the Agency) related to its proposed approach to submit an amended premarket approval (PMA) application for the SurVeil™ drug-coated balloon (DCB).

Following the receipt of the FDA letter announced in the company's press release on January 19th, Surmodics has been focused on obtaining additional clarification and feedback from the Agency on the pathway and requirements to submit an amended PMA application for the SurVeil DCB in an approvable form. To this end, Surmodics prepared and submitted a Submission Issue Request (SIR), under the FDA's Q-Submission Program, to obtain the Agency's formal feedback on its proposed approach for addressing the FDA letter. The company has received written feedback from the FDA in response to its Submission Issue Request and completed a Submission Issue Meeting with the Agency to discuss the request and this written feedback.

In its verbal and written feedback, the FDA requested additional clarification related to already completed biocompatibility studies and revisions to the company's proposed labeling to amend the PMA application to put it into an approvable form. The FDA noted that the feedback it provided was based on the level of information included in the company's Submission Issue Request, and that the actual determination for the acceptability of the company's responses will depend on the information provided in company's formal amended PMA application to be filed with the FDA.

"We are delighted with our progress towards achieving a PMA for the SurVeil DCB," said Gary Maharaj, Chief Executive Officer of Surmodics, Inc. "The feedback from the FDA provides the necessary clarity on the process and content required to successfully amend our PMA application. Importantly, we do not anticipate the need for additional biocompatibility studies, which will significantly reduce our initial assumptions of the time and cost to amend our PMA application. With this alignment and clarity, we are preparing our amended PMA application for submission in the third quarter of our fiscal 2023 with a target of receiving premarket approval in the fourth quarter of our fiscal 2023."

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 the company's 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: regarding placing the amended PMA application for the SurVeil DCB in an approvable form, regarding the anticipated time and cost to receive a PMA for the SurVeil DCB, related to successfully amending the company's PMA application, about the company's anticipation of not needing additional biocompatibility studies, regarding the expected timing for submission of an amended PMA application for the SurVeil DCB and the target for receipt of premarket approval for the SurVeil DCB, and about 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 Surmodics' personnel, and Surmodics' consultants to prepare and amended PMA application, the ability of the company and the FDA to reach a consensus on the appropriate labeling for the SurVeil DCB, the availability of FDA personnel to review an amended PMA, any further comments the FDA may have on an amended PMA, 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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