SURMODICS INC
Form 8-K
March 18, 2019

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 15, 2019

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))
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 March 15, 2019, the United States Food and Drug Administration (FDA) issued a communication to healthcare providers about the potential for increased long-term mortality after use of paclitaxel-coated balloons and paclitaxel-eluting stents (collectively paclitaxel-coated products) to treat peripheral arterial disease (PAD) in the femoropopliteal artery. The communication updates a previous notification from the FDA on the same topic, which was in response to meta-analysis of randomized trials published in the Journal of the American Heart Association in December 2018. The FDA communication can be accessed on the FDA s website at: https://www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm633614.htm.

In the communication, the FDA provides certain recommendations regarding the treatment of patients with PAD and the use of paclitaxel-coated products. The communication does not provide any recommendations regarding the conduct of ongoing clinical trials involving paclitaxel-coated products. The Company is working with the FDA to obtain clarification regarding the recommendations contained in the communication and their impact on the Company s TRANSCEND clinical trial, which is a randomized trial intended to evaluate the safety and effectiveness of the Company s SurVeil® drug-coated balloon (the *SurVeil* DCB) for the treatment of subjects with symptomatic PAD. The TRANSCEND clinical trial will enroll up to 446 subjects at up to 60 sites in the U.S. and 18 outside the U.S. In the communication, the FDA indicated that it plans to convene an advisory committee meeting of the Circulatory System Devices Panel to, among other things, continue its discussion and analysis of the presence and magnitude of a long-term mortality signal, consider modifications to ongoing and future US clinical trials evaluating paclitaxel-coated products, including the TRANSCEND clinical trial. These potential modifications include added surveillance, updated informed consent, and enhanced adjudication for drug-related adverse events and deaths.

The Company is currently assessing the impact of the FDA communication on the TRANSCEND clinical trial, its expectations regarding the timing of completion of patient enrollment in the TRANSCEND clinical trial and related regulatory approvals for the *SurVeil* DCB, and any corresponding effect on its fiscal 2019 financial guidance.

The information in this Item 8.01 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.

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 18, 2019

/s/ Bryan K. Phillips
Bryan K. Phillips
Sr. Vice President, Legal and Human Resources,
General Counsel and Secretary