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

April 17, 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 April 17, 2019, Surmodics, Inc. issued a press release providing an update regarding the TRANSCEND clinical trial. A copy of a press release announcing the foregoing is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit Number	Description
99.1	Press Release dated April 17, 2019.

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: April 17, 2019

/s/ Bryan K. Phillips

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated April 17, 2019.

Exhibit 99.1

Surmodics Provides Update Regarding TRANSCEND Clinical Trial

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--April 17, 2019--Surmodics, Inc. (NASDAQ: SRDX), a leading provider of medical device and in vitro diagnostic technologies to the healthcare industry, has resumed patient enrollment into its TRANSCEND clinical trial and is nearly 75 percent of the way to its goal of 446 randomized patients.

Patient enrollment in TRANSCEND, the pivotal clinical trial for the SurVeil™ drug-coated balloon (DCB), was temporarily paused following the March 15 publication of a Food & Drug Administration (FDA) letter to physicians. The letter included an update on the Agency's preliminary analysis of a potentially concerning signal of increased long-term mortality with paclitaxel-coated devices and recommended that physicians consider alternative treatment methods until additional analysis has been performed.

"Immediately following publication of the March 15 FDA communication, we reached out to the Agency seeking guidance on the recommendations and the impact on TRANSCEND," said Gary Maharaj, Surmodics President and CEO. "Following multiple conversations, we've taken several actions in response to the Agency's recommendations, including updates to investigator communications, patient Informed Consent Forms (ICF), and data safety review and patient follow-up procedures. A number of our trial sites have already secured IRB or Ethics Committee approval of the updated ICF and are actively enrolling and randomizing patients."

FDA Recommendations:	Surmodics Action:
Follow device recommendations from March 15 letter	Communicated FDA recommendations to trial investigators
Update patient informed consent form (ICF)	Initiated process to update ICF at sites worldwide
Include ongoing independent Data Safety Monitoring Board (DSMB) review	Ongoing Clinical Events Committee (CEC) and DSMB reviews were initiated at trial onset
Take measures to increase follow-up with patients	Establishing an aggressive patient follow-up program for both new patient randomizations and those already treated

The TRANSCEND randomized trial will evaluate the *SurVeil* DCB for treatment of peripheral artery disease (PAD) in the upper leg compared to a commercially available DCB treatment. The results of the trial will also include long-term, patient-level data out to 5 years. The Company continues to assess the impact of the March 15 FDA communication on its expectations regarding the timing of completion of patient enrollment in the TRANSCEND clinical trial and related regulatory approvals for the *SurVeil* DCB.

"Patient safety is the top priority in every study, so pausing trial enrollment while implementing the recommendations from the FDA was in the best interest of both our patients and this trial," said William Gray, MD, the national Co-Principal Investigator of the TRANSCEND study. "We're pleased to see many sites enthusiastically resuming enrollments. The TRANSCEND trial comes at a critical time in the endovascular field and will provide important safety and efficacy data for the next generation *SurVeil* DCB as it compares to the Medtronic IN.Pact® DCB and will ultimately be useful for physicians and the patients that they treat."

Worldwide, over 200 million people have PAD, a serious and underdiagnosed circulatory condition caused by build-up of arterial plaque, most commonly in the legs. Twelve to 20 percent of Americans over 60 years old have PAD. 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.

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 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.

Safe Harbor for Forward-Looking Statements

This press release contains forward-looking statements. Statements that are not historical or current facts are forward-looking statements, including statements and beliefs about the TRANSCEND clinical trial and the *SurVeil* DCB. Forward-looking statements involve inherent risks and uncertainties, and important factors could cause actual results to differ materially from those anticipated, including 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, 2018, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our 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 we undertake no obligation to update them in light of new information or future events.

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