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

July 26, 2017
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))

Item 8.01 Other Events.

On July 26, 2017, Surmodics, Inc. announced receipt of an investigational device exemption from the U.S. Food and Drug Administration to initiate a pivotal clinical trial of the SurVeil™ drug-coated balloon. 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

99.1 Press Release dated July 26, 2017

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: July 26, 2017

/s/ Bryan K. Phillips

Bryan K. Phillips

Sr. Vice President, General Counsel and Secretary

EXHIBIT INDEX

Exhibit Number	Description	Manner of Filing
99.1	Press Release dated July 26, 2017	Filed Electronically

Exhibit 99.1

Surmodics Receives IDE Approval to Initiate Pivotal Trial of the SurVeil™ Drug-Coated Balloon

- **Study compares SurVeil™ DCB to Medtronic IN.PACT® Admiral® DCB**
- ***SurVeil* DCB design includes new proprietary coating for interventional treatment of PAD**

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--July 26, 2017--Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies, today announced it has received an investigational device exemption (IDE) from the U.S. Food and Drug Administration (FDA) to initiate a pivotal clinical trial of the SurVeil™ drug-coated balloon (DCB). The randomized trial will evaluate the *SurVeil* DCB for treatment for peripheral artery disease (PAD) in the upper leg compared to the Medtronic IN.PACT® Admiral® DCB.

The *SurVeil* DCB pivotal trial will be among the first trials in the U.S. to compare a next-generation DCB with a commercially-available DCB.

“By providing a head-to-head comparison with today’s market-leading DCB, the TRANSCEND trial will answer clinically important questions about the relative performance of DCBs,” said Gary Ansel, MD, system medical chief of the Vascular Program at OhioHealth. “DCB therapy for patients with lower extremity PAD is growing rapidly, and while results have been encouraging there is significant room for improvement.”

The design of the *SurVeil* DCB reflects Surmodics’ long-standing industry leadership in the development of surface technology for vascular medical devices. The device includes a proprietary drug-excipient formulation for the balloon coating and is manufactured using a proprietary process to improve coating uniformity. Pre-clinical data have shown a three to five times higher target tissue drug concentration, a more evenly distributed and durable drug effect, and lower incidence of downstream drug concentrations compared to control DCBs.[1]

“Surmodics’ expertise and capabilities in surface technology are evident in the design and pre-clinical performance of the *SurVeil* DCB,” said Kenneth Rosenfield, MD, Section head, Vascular Medicine and Intervention at Massachusetts General Hospital and chair of the Surmodics clinical advisory board. “We’re excited about Surmodics’ capability to improve on the performance of existing DCBs.”

The *SurVeil* DCB early feasibility study (EFS), conducted in the U.S., met its primary endpoint by demonstrating peak paclitaxel plasma concentrations post-index procedure. Consistent with pre-clinical data, systemic levels were low and cleared rapidly. No safety issues attributed to the product have been reported.

“Surmodics’ decision to pursue the EFS in the U.S. demonstrated our confidence in the device and we are excited to be moving this into the pivotal trial,” said Gary Maharaj, president and CEO of Surmodics. “The next-generation technology in the *SurVeil* DCB aims to improve drug transfer and effect on the arterial wall with a lower drug dose and a reduction in the amount of drug reaching tissue outside the area of treatment. We have been extremely satisfied with our pre-clinical and EFS results and look forward to working with our investigators in this trial to further evaluate the safety and efficacy compared to standard-of-care DCB therapy.”

The development of the *SurVeil* DCB is a major step forward in Surmodics’ strategy to transform from a surface modification technology company to a provider of whole-product solutions for its medical device customers. In 2015, the company acquired Creagh Medical, an innovative developer and manufacturer of balloon catheters located in Ireland, and U.S.-based NorMedix, a manufacturer of differentiated specialty catheter and device delivery systems. Surmodics now has complete capabilities for design, development and high-volume manufacturing of a wide variety of highly differentiated balloon catheter solutions that utilize the company’s advanced surface technology.

About the *SurVeil* DCB Pivotal Trial

The objective of the *SurVeil* DCB pivotal trial, TRANSCEND, is to evaluate the safety and effectiveness of the device for treatment of subjects with symptomatic PAD due to stenosis of the femoral and/or popliteal arteries. The clinical study will be used to support regulatory approvals (U.S. and Europe) and reimbursement.

The trial will enroll up to 446 subjects at approximately 60 sites in the U.S. and 18 outside the U.S. Study participants will be randomized to receive either treatment with *SurVeil* DCB or IN.PACT Admiral DCB. The primary efficacy endpoint of the trial is primary patency, defined as a composite of freedom from restenosis and clinically-driven target lesion revascularization (TLR) through 12 months post-index procedure. All randomized subjects will be followed through 36 months post-index procedure. Surmodics expects to initiate enrollment in the TRANSCEND clinical trial in the fourth quarter of calendar 2017.

The trial will be led by national co-principal investigators Kenneth Rosenfield, MD, Section Head, Vascular Medicine and Intervention at Massachusetts General Hospital, and Gary Ansel, MD, System Medical Chief of the Vascular Program at OhioHealth. Marianne Brodmann, MD, Substitute Head of the Division of Angiology, Department of Internal Medicine, Medical University of Graz, Graz, Austria, is the European principal investigator.

The *SurVeil* DCB is not available for sale in the U.S. and is for investigational use only.

About Peripheral Artery Disease

Worldwide, over 200 million people have PAD,[2] 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.[3] 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.[4]

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 (IVD) tests and microarrays. Following two recent acquisitions of Creagh Medical and NorMedix, the Company is executing a key growth strategy for its medical device business by expanding to offer total intravascular product solutions to its medical device customers. The combination of proprietary surface technologies, along with enhanced device design, development and manufacturing capabilities, enables Surmodics to significantly increase the value it offers with highly differentiated intravascular solutions designed and engineered to meet the most demanding requirements. With this focus on offering total solutions, Surmodics' mission remains to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota. For more information about the company, 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 beliefs and expectations regarding the company's strategy to transform to a provider of whole-product solutions, and the timing, impact and success of the clinical evaluation of the *SurVeil* DCB, 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 (1) our ability to successfully develop, obtain regulatory approval for, and commercialize our *SurVeil* DCB, and other proprietary products; (2) our ability to achieve expected benefits from our acquisitions; (3) possible adverse market conditions and possible adverse impacts on our cash flows, and (4) 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, 2016, 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.

[1] Surmodics data on file
[2] Fowkes FGR, et al. *Lancet* 2013, 382(9901):1329-1340.
[3] Centers for Disease Control and Prevention. Peripheral Arterial Disease (PAD) Fact Sheet. n.d. Web.
[4] National Institutes of Health. What is Peripheral Artery Disease? n.d. Web.

CONTACT:
Surmodics, Inc.
Andy LaFrence, 952-500-7000
ir@surmodics.com