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

October 5, 2015
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 October 5, 2015, SurModics, Inc. (the "Company") announced that it has received U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) approval to move forward in pursuing its first-in-human early feasibility study using the SurModics SurVeil™ drug-coated balloon (DCB). This approval allows the Company to take the steps required to start an early feasibility clinical trial. The Company has identified its clinical investigators and is developing plans for up to three clinical sites in the U.S. and expects to enroll the first patient in the second quarter of fiscal 2016.

The foregoing disclosure contains forward-looking statements, including those relating to the timing to start an early feasibility clinical trial involving the SurModics 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 Company's ability to successfully receive the required institutional approvals at the clinical sites and satisfy other conditions required to initiate the 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 October 5, 2015

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: October 8, 2015

/s/ Bryan K. Phillips

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated October 5, 2015

Exhibit 99.1

SurModics Receives FDA IDE Approval for Early Feasibility Study of the SurVeil™ Drug-Coated Balloon

- Important milestone in moving toward DCB clinical trials in the U.S.
- SurVeil™ DCB design includes new, proprietary coating for interventional treatment of PAD
- Advances SurModics' strategic transformation to a whole-product solutions provider

EDEN PRAIRIE, Minn. – Oct. 5, 2015 – SurModics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies, today announced that it has received U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) approval to move forward in pursuing its first-in-human early feasibility study using the SurModics SurVeil™ drug-coated balloon (DCB).

The development of the SurVeil DCB is a major step forward in the company's strategy to transform from a surface modification technology company to a provider of whole-product solutions to the medical device industry. This approval allows the company to take the steps required to start an early feasibility clinical trial. The company has identified its clinical investigators and is developing plans for up to three clinical sites in the U.S. and expects to enroll the first patient in the second quarter of fiscal 2016.

"We are excited to have reached this milestone for the SurVeil DCB. Our decision to conduct the early feasibility study in the U.S. reflects our confidence in the advanced drug delivery capability of the device that has been demonstrated in promising pre-clinical research," said Gary Maharaj, president and CEO of SurModics. "We are proud to use the early feasibility study pathway established by the FDA and have been very satisfied with the interactions and responsiveness of the Agency. This IDE approval allows us to start the process of working with U.S. clinical sites and investigators."

"While the utilization of DCB therapy is growing rapidly and the clinical results for patients with lower extremity PAD are very encouraging, there are real opportunities to improve upon the early generation DCB technologies that are currently available," said Kenneth Rosenfield, M.D., section head, Vascular Medicine and Intervention at Massachusetts General Hospital, and chair of the SurModics Clinical Advisory Board. "We are excited about SurModics' technology, and their efforts to improve upon the performance of existing DCBs in the interest of further enhancing patient outcomes."

Though SurModics has long provided surface modification and drug delivery solutions to medical device companies, the SurVeil DCB will be the first complete vascular medical device developed and tested clinically by SurModics.

U.S. medical device companies commonly conduct clinical trials abroad to expedite time to market. To encourage medical device innovation in the U.S., in 2013 the FDA introduced new guidelines under the early feasibility study program to facilitate the early clinical evaluation of medical devices in small numbers of human subjects. The guidelines allow companies to collect data on product efficacy and safety before finalization of product design while still adhering to exacting human subject protections.

“Some may see SurModics’ decision to initiate human trials on their drug-coated balloon in the U.S. as a bold move,” said Renu Virmani, M.D., president and medical director of CVPath Institute. CVPath has performed the histopathological assessment of all pre-clinical studies involving the SurVeil DCB since the inception of the program. “Those of us who have followed the development of this product are confident in its potential given its performance in pre-clinical studies.”

About Drug-Coated Balloons

Clinical trials have demonstrated the efficacy of DCBs in treating PAD. The collective results of these trials have demonstrated that DCBs lead to decreased late lumen loss (LLL) – or increased lumen diameter – six months post intervention as compared to non-drug-coated balloons. In some cases, DCBs have also led to decreased need for recurrent intervention.[1-6]

DCBs often deliver paclitaxel, an antiproliferative drug, to arterial walls to limit restenosis which may reduce blood flow. The drug is usually combined with an excipient, which facilitates its transfer into the arterial wall.

Medical device manufacturers face significant challenges in optimizing DCB design. The aim of a DCB is to deliver the correct dosage of antiproliferative drug at the site of a lesion, and apply the drug uniformly to the arterial wall. To do this, the DCB must minimize unintended release of the drug into the blood stream during the procedure. Factors that may affect DCB performance include the ability of the excipient to preserve and release the drug at the appropriate time during the procedure, uniformity of the coating application on the balloon, and consistency of the paclitaxel drug on the balloon.

About the SurVeil Drug-Coated Balloon

The SurVeil DCB design incorporates SurModics’ decades of experience as a leading supplier of surface modification technologies to the medical device industry. It includes a SurModics-proprietary drug-excipient formulation for the balloon coating, and a new and proprietary manufacturing process for the coating applications. It also includes the SurModics Serene™ low-friction, low-particulate hydrophilic coating on the catheter shaft. The SurVeil DCB is not available for sale in the US and is for investigational use only.

About SurModics, Inc.

SurModics partners with the world’s leading and emerging medical device, diagnostic and life sciences companies to develop and commercialize innovative products designed to improve lives by enabling the detection and treatment of disease. Our mission is to be a trusted partner to our customers by providing the most advanced surface modification technologies and *in vitro* diagnostic chemical components that help enhance the well-being of patients. The company’s

core offerings include surface modification coating technologies that impart lubricity, prohealing and biocompatibility characteristics and components for *in vitro* diagnostic test kits and microarrays. SurModics' strategy is to build on the product and technical leadership within these fields, and expand the core offerings to generate opportunities for longer term sustained growth. 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 clinical development (including future regulatory milestones) of the SurModics 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 Drug-Coated Balloon product; (2) our ability to successfully receive the required institutional approvals and satisfy other conditions required to initiate the clinical trial; (3) the possibility of unfavorable or delayed clinical trial results, whether the FDA and other relevant agencies will be satisfied with those results, even if favorable, and the impact on further trials and studies that will be required; and (4) other factors, including those identified under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2014, 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.

CONTACT:
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1 Fanelli F, Cannavale A, Boatta E, Corona M, Lucatelli P, Wlderk A, Cirelli C and Salvatori FM. Lower limb multilevel treatment with drug-eluting balloons: 6-month results from the DEBELLUM randomized trial. *J Endovasc Ther*. 2012;5:571-580.

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3 Tepe G, Zeller T, Albrecht T, Heller S, Schwarzwalder U, Beregi JP, Claussen CD, Oldenburg A, Scheller B and Speck U. Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. *N Engl J Med*. 2008;358:689-99.

4 Werk M, Langner S, Reinkensmeier B, Boettcher HF, Tepe G, Dietz U, Hosten N, Hamm B, Speck U and Ricke J. Inhibition of restenosis in femoropopliteal arteries: paclitaxel-coated versus uncoated balloon: femoral paclitaxel randomized pilot trial. *Circulation*. 2008;118:1358-65.

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6 Rosenfield K, Jaff M, White C, Rocha-Singh C, Mena-Hurtado C, Metzger C, Brodmann M, Pilger E, Zeller T, Krishnan P, Gammon R, Müller-Hülsbeck S, Nehler M, Benenati J, Scheinert D. Trial of a Paclitaxel-Coated Balloon for Femoropopliteal Artery Disease. *N Engl J Med*. 2015; 373:145-153.