

SURMODICS INC
Form 8-K
October 08, 2015

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
(State of Incorporation)

0-23837
(Commission File Number)

41-1356149
(I.R.S. Employer Identification
No.)

9924 West 74th Street

Eden Prairie, Minnesota
(Address of Principal Executive Offices)

(952) 500-7000

55344
(Zip Code)

(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