SURMODICS INC
Form 8-K
August 15, 2017

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

August 11, 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))

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 August 11, 2017, Surmodics, Inc. (the "Company") entered into a clinical trial services agreement (the "Agreement") with Baim Institute for Clinical Research, Inc. ("Baim") pursuant to which Baim will serve as the Company's clinical research organization to assist the Company with the administration of the TRANSCEND™ clinical trial for the SurVeil® drug-coated balloon ("DCB"). The TRANSCEND trial is a randomized clinical trial intended to evaluate the SurVeil DCB for the treatment of peripheral artery disease in the upper leg compared to the Medtronic IN.PACT® Admiral® DCB. The trial will enroll up to 446 subjects at approximately 60 sites in the U.S. and 18 outside the U.S. Pursuant to the Agreement, the Company will make payments to Baim for services rendered, costs incurred, and upon the completion of certain specified milestones. If all services and the milestones under the Agreement are completed and the estimated pass-through costs are incurred (including with respect to the expected number of clinical sites), the estimated total payments by the Company under the Agreement will be in the range of approximately $26.0 million to $33.0 million, which payments are likely to be concentrated during the first two to three years of the study. In addition, any changes to budget parameters identified in the Agreement may result in additional expenses. We estimate that the total cost of the TRANSCEND clinical trial will range between $32 million to $40 million over the next several years. There can be no assurance that Baim will complete its performance under the Agreement, and to the extent that such performance is completed, the clinical results for the SurVeil DCB will be satisfactory.

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: August 15, 2017 /s/ Bryan K. Phillips
Bryan K. Phillips
Sr. Vice President, General Counsel and Secretary