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

November 6, 2018
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 7.01 Regulation FD Disclosure.

On November 6, 2018, Surmodics, Inc. (the "Company") issued a press release regarding the 12-month data from the PREVEIL early feasibility study ("EFS") of the Company's SurVeilâ drug-coated balloon. The data were presented at the Vascular Interventional Advances (VIVA) 2018 conference in Las Vegas. A copy of the press release is furnished as Exhibit 99.1 to this Current Report. Additionally, a copy of the presentation is furnished as Exhibit 99.2 to this Current Report.

The information contained in Exhibit 99.1 is being furnished pursuant to Item 7.01 of this Current Report on Form 8-K, and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liabilities under Section 18. Furthermore, the information contained in Exhibits 99.1 and 99.2 shall not be deemed to be incorporated by reference into the filings of the Company under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit Number	**Description**
99.1	Press Release dated November 6, 2018.
99.2	Presentation entitled, "PREVEIL DCB Feasibility Study, A Prospective, Multi-Center, Single-Arm Trial to Assess the Safety and Feasibility of the Surmodics SurVeil Drug-Coated Balloon in the Treatment of Subjects with De Novo Lesions of the Femoropopliteal Artery"

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: November 6, 2018

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

EXHIBIT INDEX

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Exhibit 99.1

12-Month Data from Surmodics SurVeil® Drug-Coated Balloon Early Feasibility Study Presented at VIVA 2018

- **Study met primary endpoint and all 12-month secondary safety endpoints including 100 percent freedom from CD-TLR or TVR**
- **Results demonstrated continued clinically significant improvement in ABI, walking distance, walking speed and stair-climbing scores at 12 months**

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--November 6, 2018--Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies, today announced that data from the PREVEIL early feasibility study (EFS) of the company's SurVeil® drug-coated balloon (DCB) was shared in a late-breaking clinical trial presentation at the Vascular Interventional Advances (VIVA) 2018 conference in Las Vegas. PREVEIL is a prospective, U.S., multi-center, single-arm trial designed to assess the safety and feasibility of the *SurVeil* DCB in the treatment of subjects with symptomatic peripheral artery disease (PAD) due to *de novo* lesions of the femoral and popliteal arteries.

Twelve-month data from the study show that acute success measures of safety were achieved in 100 percent of subjects. No subjects required re-intervention of either the target lesion or the target vessel at 12 months (100 percent freedom from clinically driven target lesion revascularization and target vessel revascularization (CD-TLR or CD-TVR)). The results also demonstrate continued significant improvement in Rutherford classification, resting ankle brachial index (ABI), and walking impairment questionnaire (WIQ) including walking distance, walking speed and stair-climbing scores at 12 months. As was presented with the six-month results, median paclitaxel plasma concentration peaked immediately post-procedure (C_{max} 1.07 ng/mL) and was undetectable at 30 days. Secondary technical, device, and procedure success criteria were achieved. The *SurVeil* DCB is not yet approved for sale in the United States.

"The ongoing positive results from this study demonstrate that the SurVeil DCB has the potential to be a next-generation DCB with improved efficacy of drug transfer," said Kenneth Rosenfield, M.D., Section Head, Vascular Medicine and Intervention at Massachusetts General Hospital, and U.S. co-principal investigator for the TRANSCEND trial. "These 12-month data continue to support the functionality and safety of the device."

"Our goal all along with the *SurVeil* DCB has been to advance the technology to improve drug transfer and distribution effect on the arterial wall offering the opportunity to use a lower drug dose," said Gary Maharaj, president and CEO of Surmodics. "We are pleased with the ongoing results from the EFS and look forward to the opportunity to continue to demonstrate the potential for this technology with outcomes from our pivotal TRANSCEND clinical trial that is currently underway."

Data presented include 12-month results from 13 patients (Rutherford class 2 to 4) at three clinical sites who were treated with the SurVeil DCB. Average lesion length was 56 mm. Clinical assessments for the study include primary patency and late lumen loss through six months, plasma paclitaxel levels, and changes in Rutherford classification, ABI/TBI, 6-minute walk test, and WIQ at 1, 6, 12, 24 and 36 months. Key secondary safety endpoints included freedom from major vascular complications, evidence of paclitaxel toxicity, or thrombolysis in myocardial infarction (TIMI).

About the Surmodics SurVeil DCB

In July 2017, Surmodics received an investigational device exemption (IDE) from the U.S. Food and Drug Administration (FDA) to initiate a pivotal clinical trial of the *SurVeil* DCB, and the first patient was enrolled in October 2017. The randomized trial, TRANSCEND, is designed to evaluate the *SurVeil* DCB for treatment for PAD in the upper leg compared to the Medtronic IN.PACT® Admiral® DCB.

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]

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) 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, including statements about beliefs and expectations regarding the company's strategy to transform to a provider of whole-product solutions, and the *SurVeil* DCB and TRANSCEND clinical trial, 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) Surmodics' ability to successfully develop and obtain regulatory approval for the *SurVeil* drug-coated balloon; (2) Surmodics' ability to realize the full potential benefits of its agreement with Abbott; and (3) the factors identified under "Risk Factors" in Part I, Item 1A of Surmodics' Annual Report on Form 10-K for the fiscal year ended September 30, 2017, and updated in its subsequent reports filed with the SEC. These reports are available in the Investors section of Surmodics' 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 Surmodics undertakes no obligation to update them in light of new information or future events.

[1] Surmodics data on file

CONTACT:
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PREVEIL DCB Feasibility Study

A Prospective, Multi-Center, Single-Arm Trial to Assess the Safety and Feasibility of the Surmodics SurVeil Drug-Coated Balloon in the Treatment of Subjects with *De Novo* Lesions of the Femoropopliteal Artery

D. Christopher Metzger, MD

Wellmont CVA Heart Institute

Kingsport, Tennessee

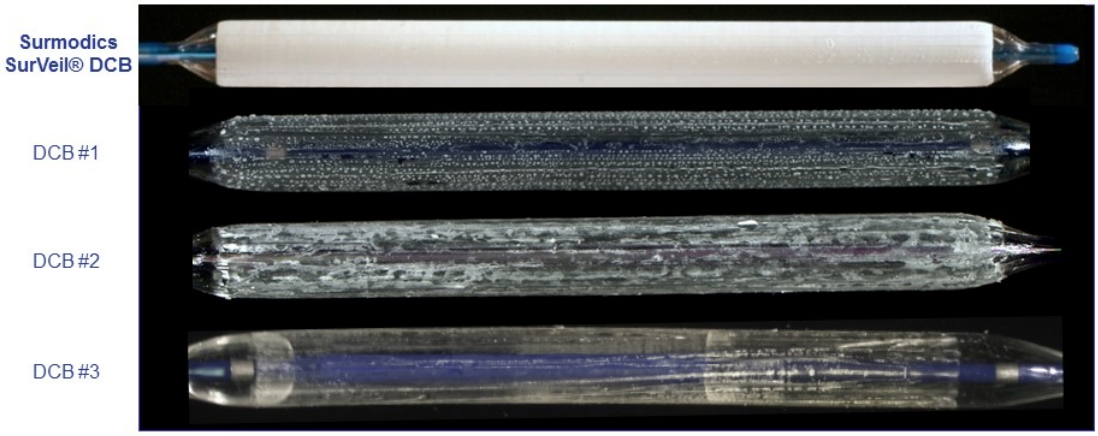
VIVA 18

PREVEIL DCB Feasibility Study

Study design	Prospective, U.S., multi-center, single-arm, safety and feasibility
Objective	To assess the safety and functionality of the Surmodics SurVeil drug coated balloon in the treatment of symptomatic PAD due to *de novo* stenoses of the femoral and popliteal arteries.
Patients / sites	13 subjects at 3 clinical sites • Dr. Gary Ansel; OhioHealth (OH) • Dr. Ravish Sachar; Rex Hospital (NC) • Dr. D. Christopher Metzger; Wellmont CVA Heart Institute (TN)
Primary endpoint	Peak paclitaxel plasma concentrations through 30 days post-index DCB procedure
Key secondary performance endpoints	Primary patency and late lumen loss at 6 months
Key secondary safety endpoints	Freedom from evidence of paclitaxel toxicity, major vascular complications, or thrombolysis in Myocardial Infarction (TIMI)-defined major and minor bleeding
Follow-up	Immediate, 1, 2, 4, 12 hours post-procedure; 1, 6, 12, 24, 36 month visits Follow up included angiogram at 6 months and duplex ultrasound (DUS) at 1, 6, 12, 24, 36 month visits
Status	First subject: April 5, 2016 Enrollment completion: December 9, 2016

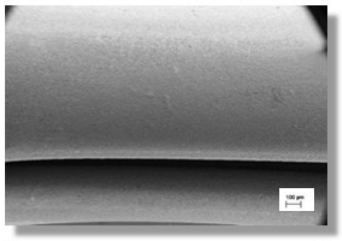
Comparison to Benchmark DCBs

Balloons dry expanded to nominal pressure

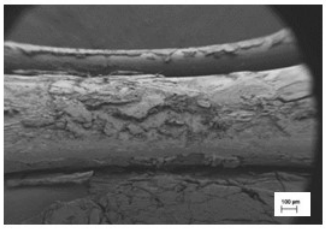


DCB Comparison: SEM 50X

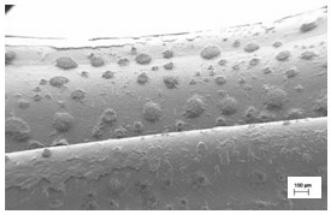
Surmodics SurVeil® DCB



DCB #2



DCB #1



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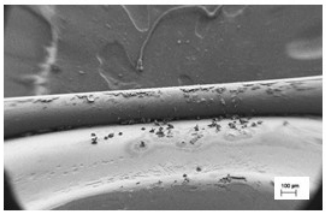

Key Inclusion Criteria

PREVEIL DCB Feasibility Study

Clinical	• ≥18 years old • Rutherford-Becker class 2-4
Angiographic	• *De novo* target lesion in femoral and popliteal arteries • Target lesion ≥ 50% stenosis • Target lesion length ≤ 90 mm • Target vessel RVD 4-6 mm • After pre-dilation, target lesion ≤ 70% residual stenosis • Patent inflow artery free from significant stenosis • At least one patent native outflow artery to ankle or foot, free from significant stenosis

Key Exclusion Criteria

PREVEIL DCB Feasibility Study

Clinical	• Acute limb ischemia • Previous lower-extremity PTA with DCB within 3 months • Prior vascular intervention within 2 weeks or planned vascular intervention within 30 days post-procedure
Angiographic	• Previous intervention at lesion site • Previous treatment of target vessel • Severe concentric calcification of target lesion • Target lesion involved or adjacent to aneurysm

Demographics

PREVEIL DCB Feasibility Study

	(n=13)
Mean age	67.8
Male (%)	69.2%
Current smoking (%)	53.9%
Diabetes mellitus (%)	46.2%
Hypertension (%)	84.6%
Hypercholesterolemia (%)	100%
Family history of PAD (%)	0%
Family history of CAD (%)	81.8%
Ischemic heart disease (%)	23.1%

Lesion Characteristics

PREVEIL DCB Feasibility Study

	(n=13)
Mean Lesion Length (mm)	56.4
Mean Treatment Area (mm)	81.5
Mean Pre-Procedure Diameter Stenosis (%)	87.2
Mean RVD (mm)	5.0
Mean Post-Procedure Diameter Stenosis (%)	14.2

Secondary Safety Endpoints

PREVEIL DCB Feasibility Study

	Discharge (n=13)	30 Days (n=13)	6 Months (n=13)	12 Months (n = 13)
Evidence of Paclitaxel Toxicity	0%	0%	0%	0%
Major Vascular Complications	0%	0%	0%	0%
TIMI-Defined Bleeding	0%	0%	0%	0%

	30 Days (n=13)	6 Months (n=13)	12 Months (n = 13)
Target Lesion Revascularization	0%	0%	0%
Target Vessel Revascularization	0%	0%	0%
Arterial Thrombosis	0%	0%	0%
Embolic Events	0%	0%	0%

Primary Endpoint

PREVEIL DCB Feasibility Study

Peak Paclitaxel Plasma Concentration	Cmax (ng/mL) (N=13)
Mean ± SD (N)	2.25 ± 2.5 (10)
Median (25%tile, 75%tile)	1.22 (0.472, 3.10)
Range (min, max)	(0.235, 8.24)

Group Mean Plasma Paclitaxel Concentration (ng/mL) Versus Nominal Time

	Baseline	Post Procedure	1 Hour	2 Hours	4 Hours	12 Hours/ (Or Upon Discharge)	30 Days
Mean	0.00	1.92	0.348	0.301	0.326	0.255	BLQ
Min	0.00	0.175	BLQ	BLQ	BLQ	BLQ	BLQ
Median	0.00	1.07	0.249	0.235	0.231	0.222	BLQ
Max	0.00	8.24	0.962	0.736	0.986	0.723	BLQ

Primary Endpoint

PREVEIL DCB Feasibility Study

Peak Plasma Paclitaxel Concentrations Comparison

Device	Patients	Paclitaxel Dose (mg)	T_{max}	C_{max} (ng/mL)	$AUC_{0\text{-last}}$ (hr*ng/mL)
Surmodics SurVeil DCB EFS[1]	13	1.3 – 3.8	Immediately post-procedure	2.25 ± 2.5	3.74 ± 3.2
Bard Lutonix[2]	22	1.3 – 5.0	Immediately post-procedure	5.10±3.21	8.39±4.00
Medtronic IN.PACT Admiral[3]	24	2.8 – 16.8	0.17 hr	7.9±7.70	29.4±22.06

[1]Three subjects had insufficient data to complete the analysis and are excluded from descriptive statistics

[2]Levant 2 Subset (serum); data from PMA P130024 SSED

[3]IN.PACT SFA Trial Sub-Study (plasma); data from PMA P140010 SSED

Secondary Performance Endpoints

PREVEIL DCB Feasibility Study

Patency at 6 Months		
	N=13	95% CI
Primary Patency	100% (13/13)	[75.3%,100.0%]
No restenosis* at 6 months	100% (13/13)	[75.3%,100.0%]
Freedom from TLR at 6 months	100% (13/13)	[75.3%,100.0%]
Late Lumen Loss (mm)		
Mean±SD (N)	0.27±0.54 (13)	[-0.06,0.59]
Median (Q1, Q3)	0.19 (0.04,0.62)	
Range (min,max)	(-0.91,1.05)	

*Primary patency, freedom from binary restenosis by US or TLR

Secondary Performance Endpoints

PREVEIL DCB Feasibility Study

Rutherford-Becker Classification			
Clinical Improvement Compared With Baseline	**30 Days (n=13)**	**6 Months (n=13)**	**12 Months (n=13)**
Grade + 3 Markedly Improved	46.2%	69.2%	**61.5%**
Grade + 2 Moderately Improved	23.1%	30.8%	**23.1%**
Grade +1 Mildly Improved	7.7%	0.0%	**7.7%**
Grade 0 No Change	23.1%	0.0%	**7.7%**
Grade -1 Mildly Worsening	0.0%	0.0%	**0.0%**
Grade -2 Moderately Worsening	0.0%	0.0%	**0.0%**
Grade -3 Markedly Worsening	0.0%	0.0%	**0.0%**

Secondary Performance Endpoints

PREVEIL DCB Feasibility Study

Ankle Brachial Index/Toe Brachial Index (ABI/TBI)

Measurements	Difference 30 Days-Baseline	Difference 6 Months-Baseline	Difference 12 Months-Baseline
Resting ABI			
Mean±SD (N)	0.29±0.26 (13)	0.28±0.24 (11)	0.19±0.31 (13)
Median (Q1, Q3)	0.25 (0.17, 0.49)	0.16 (0.12, 0.48)	0.13 (0.07, 0.34)
P Value from Signed Rank Test	0.001	<0.001	**0.046**

6-Minute Walk Test

6-Minute Walk Test	Difference 30 Days-Baseline	Difference 6 Months-Baseline	Difference 12 Months-Baseline
Change from Baseline (m)			
Mean±SD (N)	62.02±74.65 (11)	90.37±119.87 (11)	75.97 ± 113.10 (11)
Median (Q1, Q3)	30.76 (10.00, 129.62)	115.00 (10.00,178.70)	30.76 (-26.00, 198.12)
P Value from Signed Rank Test	0.014	0.032	**0.102**

Speaker Name

Secondary Performance Endpoints

PREVEIL DCB Feasibility Study

Walking Impairment Questionnaire (WIQ)			
WIQ Measurements	**Difference 30 Days-Baseline**	**Difference 6 Months-Baseline**	**Difference 12 Months-Baseline**
Walking Distance Score			
Mean±SD (N)	31.70±44.73 (13)	41.77±33.15 (13)	50.72±45.57 (13)
Median (Q1, Q3)	37.57 (-0.14, 65.48)	53.27 (24.86, 68.68)	65.48 (21.02, 89.99)
P Value[1]	0.040	0.003	**0.003**
Walking Speed Score			
Mean±SD (N)	19.48±35.82 (13)	23.24±42.10 (13)	28.09±43.52 (13)
Median (Q1, Q3)	20.65 (-4.35, 42.39)	21.74 (4.35, 43.48)	32.61 (1.09, 64.13)
P Value[1]	0.081	0.089	**0.045**
Stair Climbing Score			
Mean±SD (N)	38.78±41.99 (13)	27.56±39.25 (13)	36.22±41.02 (13)
Median (Q1, Q3)	54.17 (0.00, 66.67)	25.00 (8.33, 50.00)	50.00 (12.50, 62.50)
P Value[1]	0.007	0.032	**0.008**

[1]P Value from Signed Rank Test

Summary

PREVEIL DCB Feasibility Study

- Device met secondary performance criteria
  - Technical, device, and procedure success criteria achieved
- 30 day results demonstrated:
  - Systemic paclitaxel levels were low and cleared rapidly
  - Acute success achieved in 100% of subjects
- 6 month results demonstrated:
  - Primary patency rate of 100%
  - Late lumen loss data encouraging
- 12 month results demonstrated:
  - Improvement in Rutherford classification (92.3%)
    - Statistically significant improvements in ABI, walking distance, walking speed and stair-climbing
  - 100% freedom from TLR through 12 months