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

January 28, 2021
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))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, $0.05 par value	SRDX	Nasdaq Global Select Market

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 January 28, 2021, Surmodics, Inc. ("Surmodics") will post to its website at www.surmodics.com the information attached to this report as Exhibit 99.1 regarding 12-month results of the TRANSCEND pivotal trial of the Surmodics SurVeil™ drug-coated balloon.

The information in this Item 7.01, including Exhibit 99.1, 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, nor shall such information be deemed incorporated by reference into any 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	TRANSCEND Pivotal Trial 12-Month Results
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: January 28, 2021

/s/ Gordon S. Weber

Gordon S. Weber
Senior Vice President of Legal, General Counsel and Secretary

EXHIBIT INDEX

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99.1	TRANSCEND Pivotal Trial 12-Month Results
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Surmodics SurVeil™ Drug-Coated Balloon

TRANSCEND Pivotal Trial

12-Month Results

The Randomized And Controlled Noninferiority Trial to Evaluate Safety and Clinical Efficacy of the SurVeil™ Drug-Coated Balloon iN the Treatment of Subjects with Stenotic Lesions of the Femoropopliteal Artery Compared to the Medtronic IN.PACT® Admiral® Drug-Coated Balloon

Presented at LINC 2021: Late Breaking Clinical Trial
January 25, 2021
Dr.Kenneth Rosenfield on behalf of TRANSCEND Steering Committee and Investigators

TRANSCEND Pivotal Trial 12-month Results

SURVEIL™ DCB: THIRD-GENERATION

GOALS for 3rd generation device (SURMODICS)

- **CLINICAL -** Similar therapeutic outcome with lower dose
  - Lower potential for complications
  - Wider therapeutic window

- **TECHNOLOGICAL** – Reduce Paclitaxel dose to 2.0 µg/mm²; improve uniformity of drug delivery/distribution
  - Better efficiency of drug transfer
  - Reduction in downstream embolization

THESIS: similar outcome with **lower dose** of cytotoxic drug
- **advance the state of the art**
- **provide better therapeutic choice**

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CAUTION: SurVeil™ Drug-Coated Balloon is an investigational device. Limited by Federal (or United States) law to investigational use.

TRANSCEND TRIAL JOURNEY

- First U.S. head-to-head DCB trial comparing novel device to control device that has 75% more drug load
- Paclitaxel debate
  → Enrollment pause slows study completion
- COVID 19
  → Subject follow-up more challenging

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TRANSCEND Pivotal Trial 12-month Results

TRIAL OVERVIEW

- Prospective, multicenter, international, randomized, single-blind trial of Surveil DCB versus IN.PACT Admiral DCB (1:1)
- 446 subjects randomized
  - 52 US sites (N=290) and 13 OUS sites (N=156)
  - Surveil (N=222) and IN.PACT ADMIRAL (N=224)
  - 60-month follow-up
- Independent and blinded: DUS Core Lab, Angiographic Core Lab, Clinical Events Committee; unblinded Data Monitoring Committee
- Hypotheses test - Non inferiority (15% NI margin for efficacy; 10% for safety)

PRINCIPAL INVESTIGATORS
Marianne Brodmann, MD
William Gray, MD
Kenneth Rosenfield, MD

TRIAL DESIGN, BIOSTATISTICS, DSMB, CEC
Baim Institute

TRIAL OPERATIONS
Medpass (OUS); Clinlogix (US)

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TRANSCEND Pivotal Trial 12-month Results

KEY INCLUSION CRITERIA

CLINICAL	ANGIOGRAPHIC
• **Subject ≥ 18 years** • **Target limb Rutherford Class 2, 3, or 4**	• De Novo or non-stented restenotic lesion > 90 days after POBA angioplasty or > 180 days post prior DCB treatment • Target lesion length ≤ 180 mm • Target lesion starts ≥ 10mm below common femoral bifurcation and terminates at or above end of P1 segment of popliteal artery • Target vessel diameter ≥ 4mm and ≤ 7mm • Target lesion must have ≥ 70% stenosis by visual estimate • Target lesion residual stenosis ≤ 70% after pre-dilatation

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TRANSCEND Pivotal Trial 12-month Results

BASELINE PATIENT AND LESION CHARACTERISTICS

	SURVEIL N = 222 subjects	IN.PACT N = 224 Subjects	P-value
Age (yrs)	**68.7 ± 9.4** (222)	**67.4 ± 9.3** (224)	0.136
Male	**62.6%** (139/222)	**63.4%** (142/224)	0.922
Rutherford Class			
2	**21.6%** (48/222)	**34.4%** (77/224)	
3	**75.7%** (168/222)	**61.2%** (137/224)	0.022 (*)
4	**2.7%** (6/222)	**4.5%** (10/224)	
Lesion length (mm)[1]	**72.5 ± 48.4** (221)	**70.0 ± 50.5** (223)	0.597
Minimum Lumen Diameter (mm)[1]	**1.4 ± 1.1** (221)	**1.3 ± 1.0** (223)	0.106
Reference Vessel Diameter (mm)[1]	**5.3 ± 0.9** (221)	**5.3 ± 0.7** (223)	0.842
% Diameter stenosis[1]	**72.9 ± 18.8** (221)	**75.8 ± 18.1** (223)	0.102

[1] Core Lab reported data
Data reported as Mean±SD (N) or % (n/N)
(*) t-test for equality of means

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TRANSCEND Pivotal Trial 12-month Results

PRIMARY ENDPOINTS

Safety (composite)	• Freedom from device- and procedure-related death through 30 days • Freedom from major amputation (above ankle) • Freedom from clinically-driven target vessel revascularization (CD-TVR) through 12 months

Efficacy	• *Primary patency* through 12 months, defined as a composite of
	  ○ Freedom from clinically-driven target lesion revascularization (CD-TLR)
	  ○ Freedom from binary restenosis (peak systolic velocity ratio [PSVR] ≥2.4 or ≥50% stenosis)[1]

[1]Assessed by independent DUS and angiographic core labs. In cases when there is a discrepancy between angiographic and DUS assessment of patency, angiographic assessment takes precedence.

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TRANSCEND Pivotal Trial 12-month Results

PROCEDURAL CHARACTERISTICS

	SURVEIL N = 222 subjects	IN.PACT N = 224 Subjects	P-value
Stenosis (%)			
After Pre-Dilatation[1]	**29.5 ± 15.2** (212)	**31.2 ± 16.0** (218)	0.280
After DCB deployment[2]	**20.3±10.4** (215)	**19.9±10.1** (220)	0.728
Final[2]	**18.7 ± 9.6** (217)	**18.9 ± 9.3** (223)	0.875
Max Inflation Pressure (atm)[3,4]	**8.3 ± 2.4** (290)	**9.2 ± 2.4** (266)	<0.001
Inflation Duration (sec)[3]	**183.3 ± 64.4** (290)	**185.5 ± 63.6** (267)	0.686
Final MLD (mm)[2]	**4.3 ± 0.8** (221)	**4.3 ± 0.7** (223)	0.604
Dissection (>/= Grade C) (Post Procedure)[2]	**21.7%** (47/217)	**15.7%** (35/223)	0.108
% of subjects requiring Post dilatation	**18.0%** (40/222)	**17.4%** (39/224)	0.902
% of subjects with Bailout stenting	**8.1%** (18/222)	**6.7%** (15/224)	0.592

Data reported as Mean±SD (N) or % (n/N)

[1] Site Data
[2] Core Lab data
[3] Information based on number of devices used
[4] Nominal pressure for IN.PACT 8atm and 5atm (200mm and 250mm), 6atm for SurVeil.

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TRANSCEND Pivotal Trial 12-month Results

12-MONTH SAFETY RESULTS (ITT)

ENDPOINT MET	SURVEIL ARM	IN.PACT ARM	DIFFERENCE (2-sided 95% CL)	P-VALUE for Non-Inferiority (NI=10%)
Primary safety[1]	**91.7%**	**89.6%**	**2.1** (-4.0%, 8.2%)	**<0.001**
Freedom from all cause death at 30 days[2,3]	**99.5%** (217/218)	**100.0%** (223/223)		
Freedom from target limb amputation[2,5]	**100.0%** (196/196)	**100.0%** (215/215)		
Freedom from CD-TVR[2,4]	**92.4%** (183/198)	**89.9%** (195/217)		

[1]Multiple Imputation
[2]Complete case analysis
[3] Denominators include subjects with at least 28 days of follow-up or subjects experiencing device- or procedure-related death through 30 days.
[4] Denominators include subjects with at least 335 days of follow-up or subjects experiencing clinically-driven TVR through 365 days.
[5] Denominators include subjects with at least 335 days of follow-up or subjects experiencing target limb amputation through 365 days.

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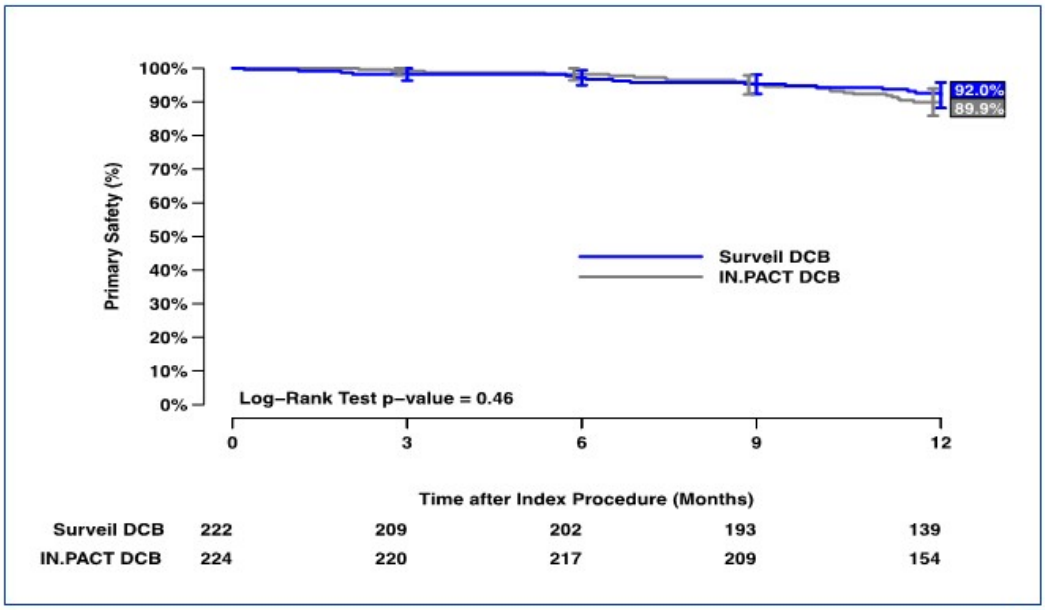
TRANSCEND PIVOTAL TRIAL 12-MONTH RESULTS

KAPLAN-MEIER FOR PRIMARY SAFETY ENDPOINT (ITT)



Surveil DCB	222	209	202	193	139
IN.PACT DCB	224	220	217	209	154

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TRANSCEND Pivotal Trial 12-month Results

12-MONTH PRIMARY EFFICACY RESULTS (ITT)

ENDPOINT MET	SURVEIL ARM	IN.PACT ARM	Difference (2-sided lower 95% CL)	P-Value for Non-Inferiority (NI = 15%)
Primary effectiveness[1]	**81.7%**	**85.9%**	**-4.2%** (-12.0%, 3.6%)	**0.003**
Freedom from CD-TLR (12 months)[2,3]	**91.9%** (182/198)	**94.4%** (203/215)		
Freedom from Binary restenosis (PSVR ≥2.4 or ≥50% stenosis)[2,4]	**88.0%** (139/158)	**91.2%** (165/181)		

[1]Multiple Imputation
[2]Complete Case Analysis
[3]Denominators include subjects with at least 335 days of follow-up or subjects experiencing clinically-driven TLR through 395 days.
[4]Denominators include subjects with evaluable 12-month DUS (within or outside the visit window of 365±30 days) or subjects whose stenosis status could have been imputed from later assessments.

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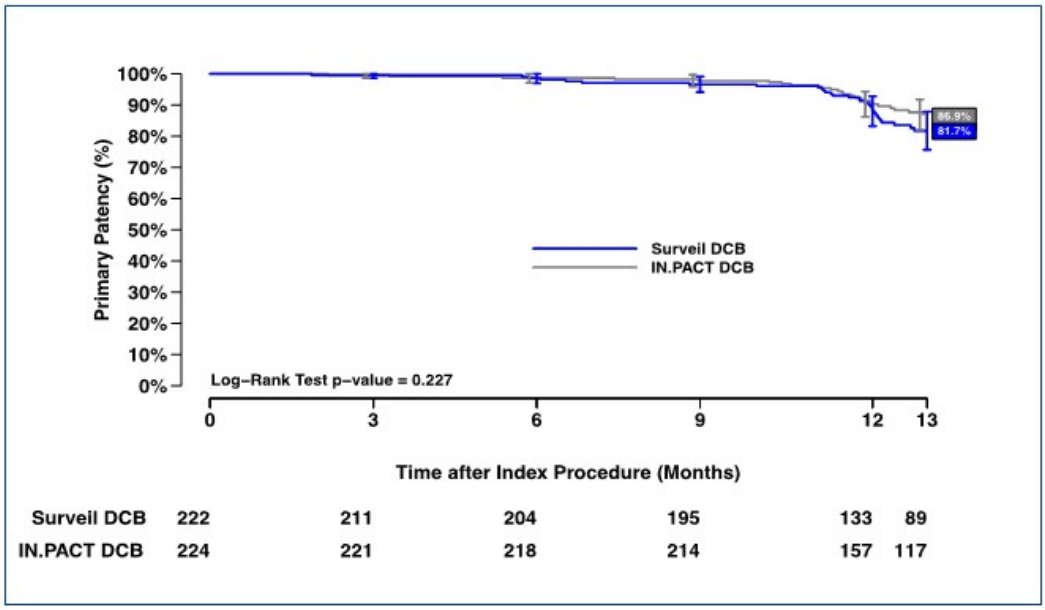
TRANSCEND PIVOTAL TRIAL 12-MONTH RESULTS

KAPLAN MEIER FOR PRIMARY EFFICACY ENDPOINT (ITT)



Surveil DCB	222	211	204	195	133	89
IN.PACT DCB	224	221	218	214	157	117

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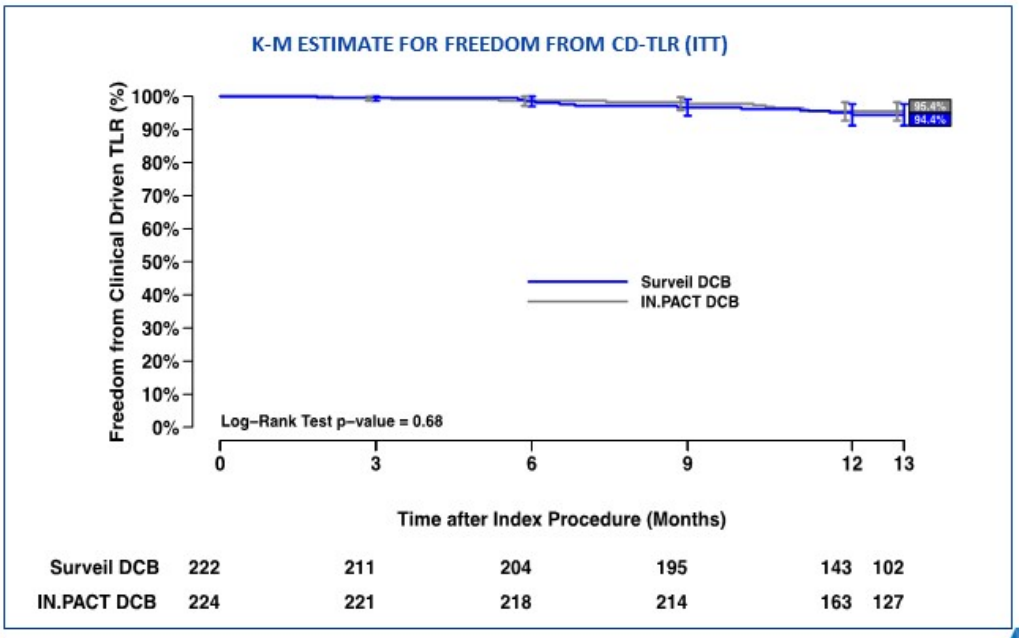
TRANSCEND Pivotal Trial 12-month Results

KAPLAN MEIER FOR FREEDOM FROM CD-TLR (ITT)



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CONCLUSIONS

TRANSCEND

SURVEIL® DRUG-COATED BALLOON TRIAL

- First head-to-head RCT of next generation low-dose DCB vs high-dose DCB
- Safety and Efficacy endpoints were achieved in a pivotal RCT
- SurVeil DCB non-inferior to market leading IN.PACT DCB with respect to Composite Patency, including CD-TLR and Binary restenosis
- Comparable effectiveness achieved at a substantially lower dose of drug

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