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

April 9, 2019
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.

Surmodics, Inc. (the "Company") will make a presentation at the 18th Annual Needham Healthcare Conference on Wednesday, April 10, 2019. A copy of the presentation materials to be used in conjunction with the conference is attached to this report as Exhibit 99.1. A complete copy of the presentation materials will be made available in the investor section of the Company's website at www.surmodics.com.

The information in this Item 7.01 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	Investor Presentation Materials.

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: April 9, 2019

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Investor Presentation Materials.

Gary Maharaj
President and CEO

Tim Arens
Vice President of Finance and CFO

APRIL 2019

SURMODICS

SAFE HARBOR

Some of the statements made during this presentation may be considered forward-looking statements. Statements that are not historical or current facts, including statements about beliefs and expectations regarding our performance in the near- and long-term, including our revenue and earnings expectations for fiscal 2019, and our SurVeil® drug-coated balloon and other proprietary products, including the timing, impact and success of the 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) our ability to successfully develop, obtain regulatory approval for, and commercialize our *SurVeil* DCB product (including realization of the full potential benefits of our agreement with Abbott) and other proprietary products; (2) our reliance on third parties (including our customers and licensees) and their failure to successfully develop, obtain regulatory approval for, market and sell products incorporating our technologies; (3) possible adverse market conditions and possible adverse impacts on our cash flows, and (4) the factors identified under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2018, 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.

SURMODICS

FOCUSED ON PRODUCT INNOVATION

IMPACT TO PATIENTS

Growing incidence of peripheral artery disease (PAD)

VISION

3 of the Top 10 Innovations
Focused on PAD and designed to be:
safe, clinically effective & improve healthcare economics

IMPACT TO INVESTORS

Investing to build long-term sustainable growth and profitability

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VISION

Well-stocked R&D pipeline with multiple new product launches planned over next 5 years

3 of the top10 INNOVATIONS in vascular medicine by 2020

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IMPACT TO PATIENTS

Growing Incidence of
Peripheral Artery Disease

PATIENTS

202 million patients worldwide living with Peripheral Artery Disease (PAD)

DESIRED OUTCOMES

Goal of improving clinical outcomes while reducing healthcare costs

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IMPACT TO PATIENTS

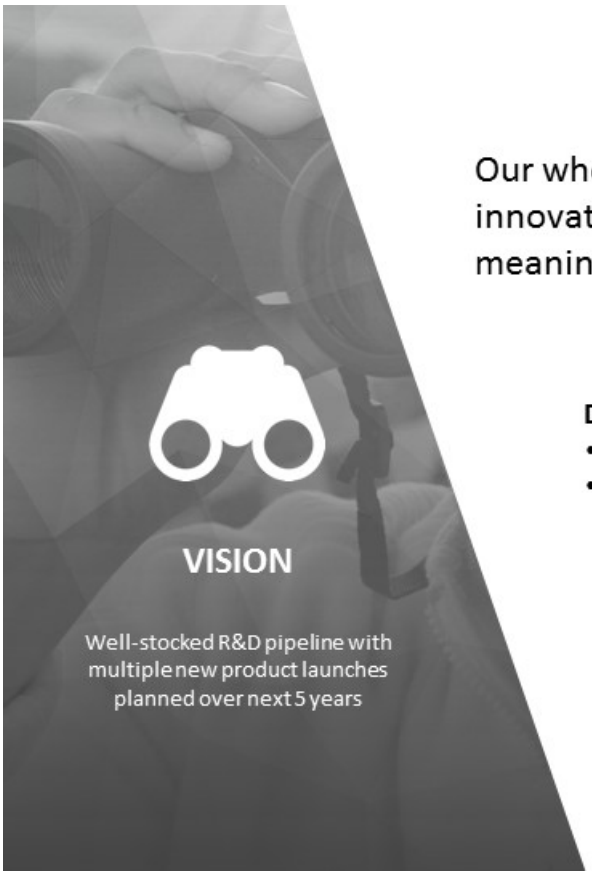
Product innovations aimed at making significant improvements in patient outcomes and quality of life (QOL)

PATIENTS	DESIRED OUTCOMES

• **Superficial Femoral Artery (SFA)**
  • **> 500K procedures** annually
  • Pain on ambulation – reduced QOL
	• Reduction in reintervention rates
	• Improved QOL by reduction in pain and increase in mobility

• **Below-the-knee disease (BTK)**
  • More than **3.5 million patients** with critical limb ischemia (CLI) by 2020
  • 33% amputation; 20% die in 1 year
	• Reduction in reintervention rates
	• Improved QOL as a result

• **AV access for End Stage Renal Disease (AV for ESRD)**
  • More than **5 million patients** with ESRD WW
  • AV access 1% of procedures but 7% of Medicare Costs
  • Impacts QOL for ESRD patients
	• Healthcare economic benefits across the board in all indications above



VISION

Well-stocked R&D pipeline with multiple new product launches planned over next 5 years

Our whole product solutions strategy is focused on creating innovative, differentiated product platforms that solve clinically meaningful problems in treating peripheral vascular disease

Desired Outcomes
- Improve Clinical Outcomes
- Reduce Healthcare Costs

Initial Platforms
- Drug Coated Balloons
  - SurVeil® DCB
  - Avess™ DCB
    Sundance™ DCB
- Thrombectomy
- Radial Access

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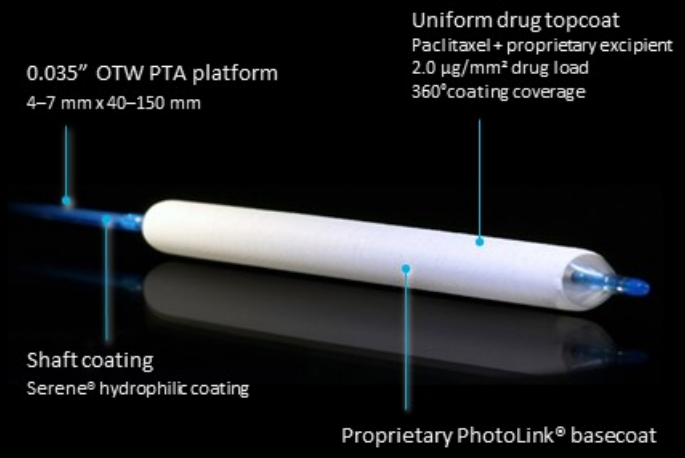
SURVEIL® DCB 12-MONTH DATA



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

PREVEIL 12-Month Study Results:

- First-in-human trial conducted in the U.S. (13 patients / 3 sites)
- 12 month data results:
  - Acute success measures of safety achieved in 100% of subjects
  - 100% freedom from CD-TLR and CD-TVR
  - 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
  - Median paclitaxel plasma concentration peaked immediately post-procedure (C_{max} 1.07 ng/mL) and was undetectable at 30 days (reported in six-month results)
- Device met secondary performance criteria
  - Key secondary safety endpoints included freedom from major vascular complications, evidence of paclitaxel toxicity, or thrombolysis in myocardial infarction (TIMI)

"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. These 12-month data continue to support the functionality and safety of the device."

— Kenneth Rosenfield, MD, Nov. 2018

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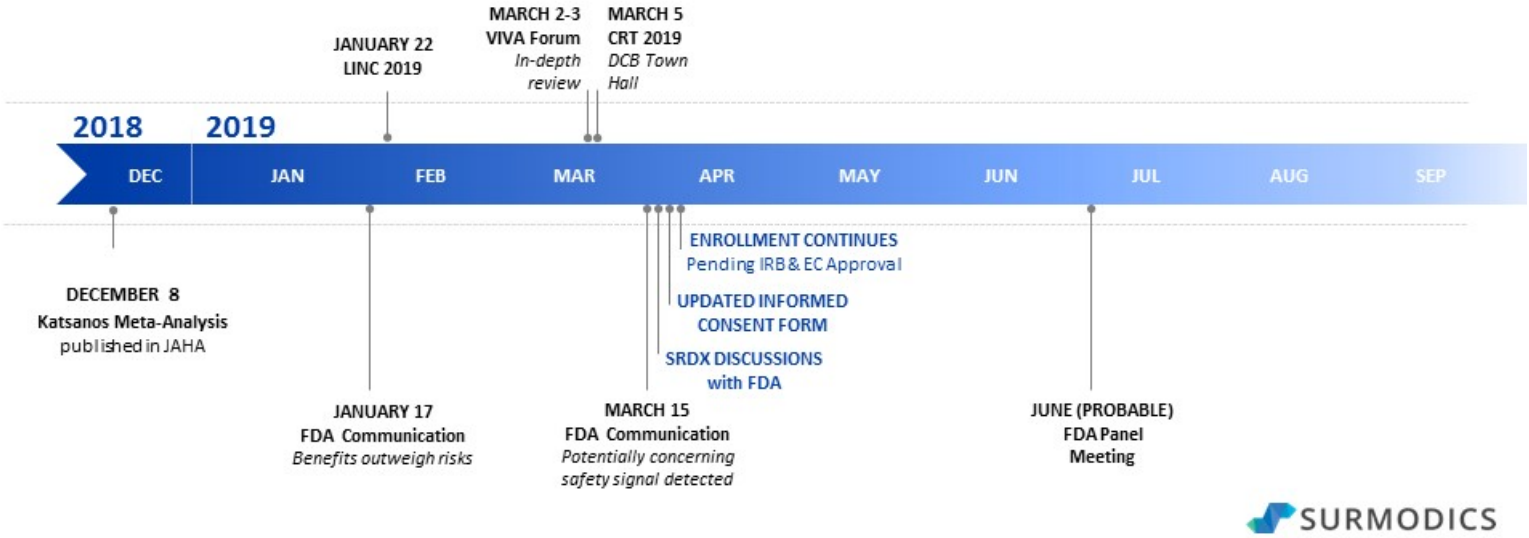
CURRENT DEBATE ON PACLITAXEL-COATED DEVICES TO TREAT PAD

RECAP OF RECENTS EVENTS



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DECEMBER 8: KATSANOS META-ANALYSIS

Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

Meta-Analysis Limitations:

- No access to patient-level data
- No plausible mechanism of action noted
- Questions regarding statistical model used
- Selection bias due to lack of complete follow up
- Lost to follow up and withdrawals are not accurately or completely accounted
- PTA group is likely not paclitaxel-naïve for entirety of analysis (prior disease in contralateral limb and potential post-treatment follow-up with paclitaxel-coated device)

Katsanos, Konstantinos & Spiliopoulos, Stavros & Kitrou, Panagiota & Krokidis, Miltiadis & Karnabatidis, Dimitrios. (2018). Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Journal of the American Heart Association. 7. 10.1161/JAHA.118.011245.

Information represents a recap of key points and takeaways captured during the VNA Leadership Forum meeting, March 1-2, 2018 in Washington DC.
https://vasculamows.com/ivo-updates-vascular-leaders-forum-drug-eluting-devices

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MARCH 15: FDA COMMUNICATION TO HEALTH CARE PROVIDERS

- FDA conducted a preliminary pooled analysis of long-term follow-up data (up to 5 years) of the pivotal premarket RCTs for paclitaxel-coated products and has identified a *potentially* concerning signal of increased long-term mortality (analysis is ongoing)
- Acknowledged that the data should be interpreted with caution
  - Large variability in risk estimate due to limited long-term data
  - Uncertainty surrounding data that was not intended to be pooled
  - The specific cause and mechanism of increased mortality is not known
- FDA will convene an Advisory Committee meeting to sort this out

This Advisory Committee *may* not convene for several months

https://www.fda.gov/MedicalDevices/Safety/LettertoHealthCareProviders/ucm633614.htm

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FDA RECOMMENDATIONS TO US HEALTH CARE PROVIDERS (MARCH 15 LETTER)

- Continue diligent monitoring of patients
- Evaluate and inform of potential risks
  - Consider there may be an increased rate of long-term mortality with paclitaxel-coated devices when recommending treatment or consenting patients
  - Discuss the risks and benefits of all available PAD treatment options with patients
    - For most patients, alternative treatment options should generally be used until additional analysis of the safety signal has been performed
- For some patients at particularly high risk for restenosis, clinicians may determine the benefits may outweigh the risks
- Ensure patients receive optimal medical therapy and guidance for healthy lifestyle

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WHAT IS A "SIGNAL"

- From the FDA: A Signal represents new information which:
  - May arise from one or several sources
  - May suggest a new potentially causal association between a marketed medical device and an event or set of related events
  - May justify or require further evaluation and/or action by the Agency
- Important to note, the "Signal" that has been identified:
  - Exists when clinical trial data from multiple devices and device types are pooled
  - Has not been observed in individual devices
  - Has not been observed in large CMS data sets
  - Does not necessarily implicate Paclitaxel
  - There are competing hypotheses of what may be causing it
- Correlation ≠ Causality
- The future discussion will center on this issue and what is causality

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FDA'S COMMUNICATION WITH SURMODICS

Multiple conversations with the Agency to seek clarification:

FDA RECOMMENDATION FOR TRANSCEND:

- Follow the device recommendations outlined in March 15 letter
- Update patient informed consent form (ICF)
- Have ongoing independent Data Safety Monitoring Board (DSMB) review
- Take measures to increase follow-up of patients

SURMODICS IMPLEMENTATION:

- Communicated FDA recommendations to Investigators
- Initiated process to update ICF at worldwide sites
- Ongoing Clinical Events Committee (CEC) and DSMB reviews already in place
- Implementing measures to increase follow-up of patients already treated under the TRANSCEND trial

We continue to assess the impact of the FDA communication on the TRANSCEND clinical trial and our expectations related to the timing of completion of patient enrollment

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TRANSCEND: SURVEIL® DCB PIVOTAL TRIAL

Received IDE approval from the U.S. FDA to begin pivotal trial for *SurVeil* DCB

STUDY DESIGN

Summary
Randomized control pivotal trial evaluates *SurVeil* drug-coated balloon for treatment of peripheral artery disease in the upper leg compared to the Medtronic IN.PACT® Admiral® drug-coated balloon.

Number of Subjects and Sites
Up to 446 subjects
Up to 60 sites in U.S. and 18 outside U.S.

Study Duration
60 months post procedure

TRANSCEND
SURVEIL® DRUG-COATED BALLOON TRIAL

10/20/17
FPI

PRIMARY ENDPOINTS

Effectiveness
Primary patency, defined as a composite of freedom from clinically-driven target lesion revascularization (TLR) and binary restenosis (restenosis defined as duplex ultrasound [DUS] peak systolic velocity ratio [PSVR] ≥2.4 or >50% stenosis as assessed by independent angiographic and DUS core labs) through 12 months post-index procedure.

Safety
Composite of freedom from device- and procedure-related death through 30 days post-index procedure and freedom from major target limb amputation (above the ankle) and clinically-driven target vessel revascularization (TVR) through 12 months post-index procedure.

* We continue to assess the impact of the FDA communication on SurVeil DCB milestones

PRINCIPAL INVESTIGATORS

William (Bill) Gray, MD, FACC, FSCAI
Clinical Advisor — Main Line Health, Inc., Wynnewood, PA

Kenneth Rosenfield, MD
Chair Advisory Board — Interventional Cardiology, Mass. General Hospital

Marianne Brodmann MD, PhD
Clinical Advisor— Interventional Cardiology, Division of Angiology Medical University, Graz

TRANSCEND ENROLLMENT PROGRESS*
Currently anticipate study enrollment completion by September 2019

CE MARK PROGRESS*
Currently anticipate obtaining CE mark by December 2019

SURMODICS

STRATEGIC AGREEMENT WITH ABBOTT

February 27, 2018 – Abbott and Surmodics Announce Agreement for Next-Generation Drug-Coated Balloon Development and Commercialization

- Demonstrates value of whole-product solutions strategy
- Leverages Surmodics' leadership in drug-delivery technologies, design, development capabilities, and manufacturing capacity
- Combines with Abbott's deep experience in vascular care products and worldwide strength in the market

Abbott

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

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TERMS OF AGREEMENT

Abbott

- Exclusive worldwide commercialization rights for SurVeil® drug-coated balloon (DCB) for superficial femoral artery (SFA)
- $25 million upfront payment
- $67 million for milestones associated with product development
- All milestones are pre-commercialization
- Options to negotiate agreements for Sundance™ below-the-knee (BTK) and Avess™ arteriovenous (AV) fistula drug-coated balloon products (currently in pre-clinical development)
- Revenue realized from product sales to Abbott
- Share of profits resulting from Abbott sales

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

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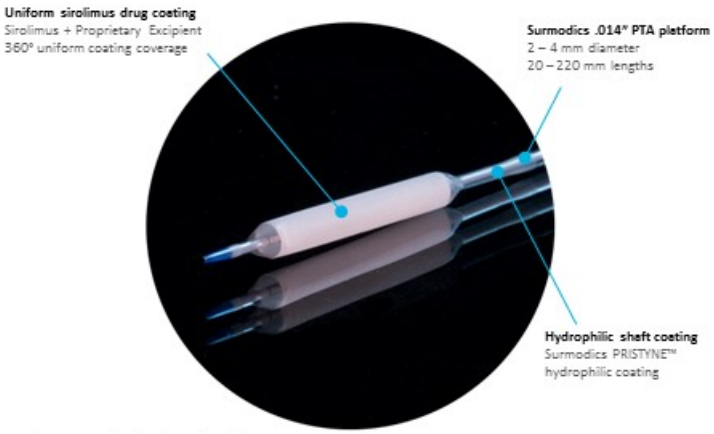
DCB PLATFORM EXTENSION

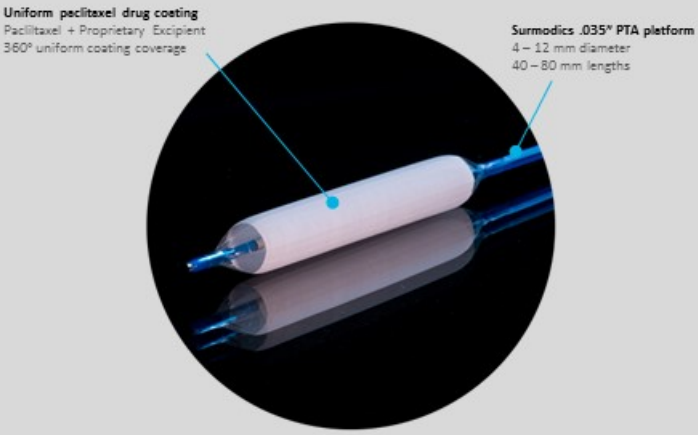
Sundance™ Below-The-Knee DCB



- In preclinical evaluation
- Initiate FIH process in FY 2019

CAUTION: Sundance™ and Avess™ Drug-Coated Balloons are investigational devices. Limited by Federal (or United States) law to investigational use.

Avess™ AV Fistula DCB*



- Treated initial patient in FIH study Q1 FY 2019
- Initiate and anticipate completing FIH in FY 2019

*FDA evaluating paclitaxel-coated devices for use in AV fistula

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WE ARE MAKING PROGRESS ON OUR WHOLE-PRODUCT SOLUTIONS STRATEGY

Drug-Coated Balloons (DCB)

JULY — IDE Approval to Initiate Pivotal Trial for SurVeil® DCB

OCTOBER — First Patient Enrolled in TRANSCEND Clinical Trial for SurVeil® DCB

FEBRUARY — Abbott & Surmodics Announce Agreement for SurVeil® DCB

DECEMBER — Initial patient treated in First-in-Human Study for Avess™ AV Access DCB

Q1 Q2 **2017** Q3 Q4 Q1 Q2 **2018** Q3 Q4 Q1

510 (K) / CE Mark

SEPTEMBER — Global Clearance of .014" Low-Profile PTA Balloon Catheter

JANUARY — 510 (K) Clearance for Telemark™ Coronary / Peripheral Support Catheter

APRIL — FDA Clearance for .018" Low-Profile PTA Balloon Dilation Catheter

MAY — Surmodics Announces Acquisition of Embolitech Thrombectomy Technology & IP

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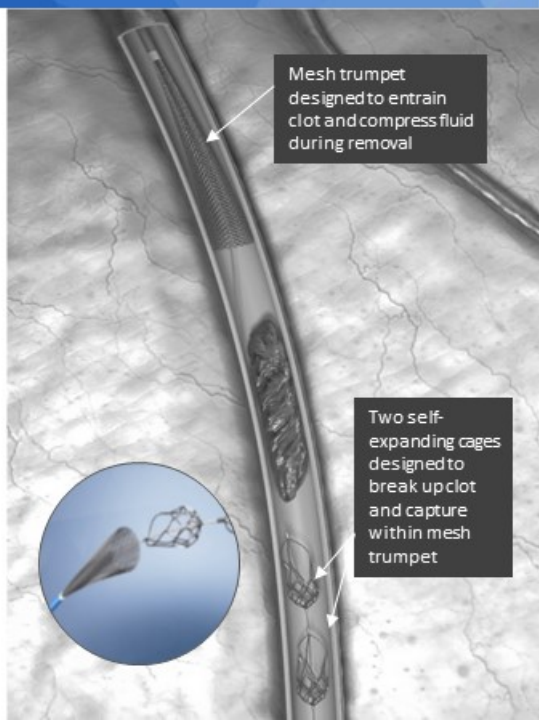
THROMBECTOMY PLATFORM TECHNOLOGY

Acquired innovative thrombectomy platform technology and IP from Embolitech

- Game-changing technology designed for removal of organized thrombi and emboli, in an approximately $400M growing global market
- Simple stand-alone intervention, eliminates need for capital equipment and may reduce the need for thrombolytics and complex procedures
- Development is on schedule with successful early pre-clinical results and positive hands-on physician feedback



RADIAL ACCESS PLATFORM TECHNOLOGY

- Radial artery access offers many benefits relative to femoral artery access including reduced bleeding complications, early ambulation, reduced length of stay and costs
- Radial access is widely adopted in coronary procedures where devices have been developed to accommodate the need
- Surmodics Xtreme™ braided technology offers the ability to treat peripheral procedures, including below-the-knee applications
- Initial radial-based products in development include:
  - **Access Devices from Radial Artery to Legs:**
    - .018 & .035 Peripheral Radial Guide Sheath
  - **Therapeutic Devices to Treat Lesions:**
    - .014 Radial BTK PTA Balloon Catheter

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PRODUCT MILESTONES*

CY 2019 GOALS

- Enroll the TRANSCEND trial as fast as reasonable: complete enrollment by Q4 FY19
- Attain CE marking for SurVeil® by December 2019
- Initiate and complete first-in-human trial for AV DCB and initiate first-in-human trial for BTK DCB
- Submit for 510(k) regulatory clearance on three to four devices
- Complete design freeze for initial thrombectomy device by end of fiscal 2019
- Secure commercialization agreements for approved devices

FY 2019 – FY 2021 GOALS

- Secure PMA of SurVeil® DCB
- Complete pivotal trial of Avess™ AV DCB
- Initiate pivotal trial for Sundance™ BTK DCB
- Obtain regulatory clearance on the initial device for vascular thrombosis and on at least seven other new-to-the-world vascular devices in areas of unmet clinical needs

*We continue to assess the impact of the FDA communication on certain product milestones

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IMPACT TO INVESTORS

Investing to build long-term sustainable growth and profitability

PIPELINE PRODUCTS

- SurVeil® DCB
- Sundance™ Below-the-knee DCB
- Avess™ AV DCB
- Multiple 510(k)'s

Achieving SurVeil® DCB milestone successes (positive clinical results and regulatory approvals) enables the business to reach the financial performance targets

FINANCIAL PERFORMANCE TARGETS

- >10% revenue growth (achieved fiscal 2018)
- >30% EBITDA margin by 2021

- The agreement with Abbott has a meaningful positive impact on our commitment to deliver the returns described above within the targeted time frame given the potential for pre-commercialization revenue within the next 5 years
- In addition, successful US and OUS commercialization of the Surveil DCB contributes in a meaningful way to the long-term consistency of revenue and EBITDA growth at the targeted levels
- We continue to assess the impact of the FDA communication and any effect on our fiscal 2019 financial and long-term guidance

SURMODICS

MANAGEMENT TEAM

Gary R. Maharaj
President and Chief Executive Officer
(2010)

Timothy J. Arens
Vice President of Finance and
Chief Financial Officer
(2007)

Thomas Greaney
Chief Operating Officer of Medical Devices
(2015)

Bryan K. Phillips
Senior Vice President of Legal and Human
Resources, General Counsel and Secretary
(2005)

Teryl L.W. Sides
Senior Vice President and
Chief Marketing Officer
(2018)

Joseph J. Stich
Vice President and General Manager of
In Vitro Diagnostics
(2010)

Gregg S. Sutton
Vice President of Research and
Development
(2016)

SURMODICS

CLINICAL & SCIENTIFIC ADVISORS

Ken Rosenfield, MD
Chair Advisory Board — Interventional Cardiology
Massachusetts General Hospital

Marianne Brodmann MD, PhD
Clinical Advisor— Interventional Cardiology
Division of Angiology Medical University Graz

Gary Ansel, MD, FACC
Clinical Advisor — Interventional Cardiology
Ohio Health Research

Mike Dake, MD
Clinical Advisor — Interventional Radiology
Stanford Health Care

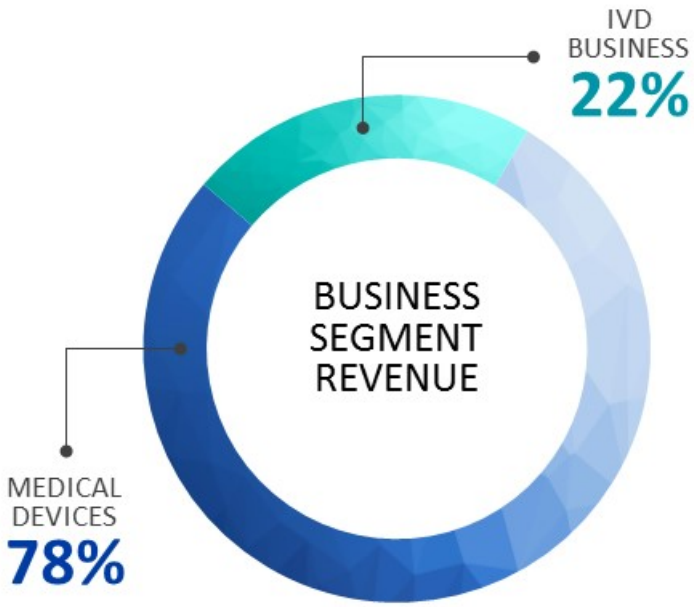
SURMODICS

Peter Schneider, MD
Clinical Advisor — Vascular Surgery
University California San Francisco

Michael Jaff, DO
Clinical Advisor — Vascular Medicine
Newton Wellesley Hospital

Renu Virmani, MD, FACC
Clinical Research Advisor — Cardiovascular Pathologist
CVPath

SURMODICS BUSINESS SEGMENTS

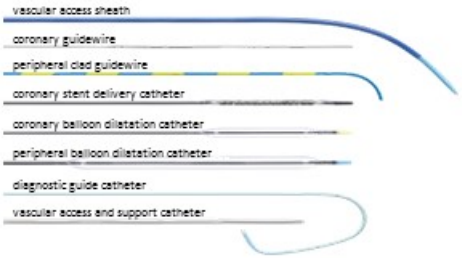


For the three months ended December 31, 2018

SURMODICS

SURMODICS CORE BUSINESS

MEDICAL DEVICE COATINGS



Leveraging science and expertise to offer world-class coatings and drug delivery

IN VITRO DIAGNOSTICS

Providing critical components for in vitro diagnostic tests and microarrays

Creating sustainable margins for long-term growth and profitability

- Technology
- Design capability
- Agility of a start-up

+

- Operational excellence
- Manufacturing
- Process Engineering

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FINANCIAL PERFORMANCE

QUARTERLY REVENUE (MILLIONS)

ANNUAL REVENUE (MILLIONS)

*We continue to assess the impact of the FDA communication on our fiscal 2019 financial and long-term guidance

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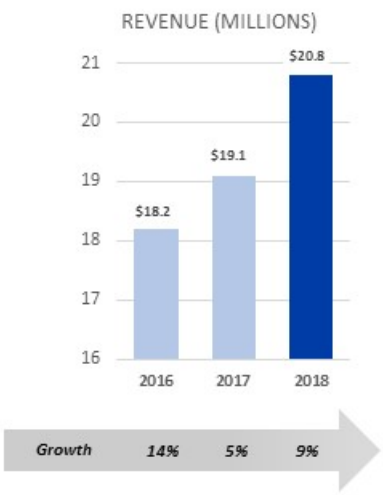
FINANCIALS BY SEGMENT

MEDICAL DEVICE

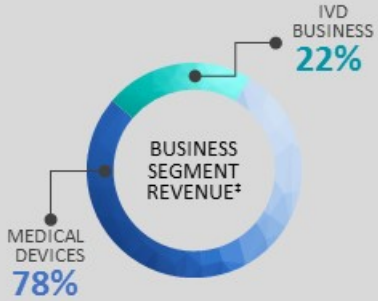
IN VITRO DIAGNOSTICS



MISSION: To improve the treatment and detection of disease

Strong balance sheet and attractive cash flows to fund growth strategy

- $45.9 million of cash/investments as of December 31, 2018
- Operating cash flow of **$34.1 million** and adjusted EBITDA of **$7.3 million** in fiscal 2018



‡For the three months ended December 31, 2018

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2019 GUIDANCE[1]

2019 Financial Guidance

Total Revenue: $94 million to $97 million (includes $14-$15 million of SurVeil DCB revenue)[2]

GAAP Loss per Share[3]: $(0.22) to $(0.02)

Non-GAAP Earnings per Share[3]: $0.02 to $0.22

Long Term Objectives

Continue consistent double digit top line revenue growth and generate EBITDA margins at or above 30% by 2021

(1) Reflects guidance issued by the Company as of January 30, 2019. The Company is assessing the impact of the March 15, 2019 FDA communication on our fiscal 2019 financial and long-term guidance and, as a result, nothing herein should be interpreted as reaffirming its earlier guidance.

(2) Our fiscal 2019 SurVeil DCB revenue is driven by the recognition of (a) a portion of the $25 million up front license fee received following the execution of the distribution agreement in late February 2018 and (b) a portion of a $10 million milestone payment which may be received upon the successful completion of enrollment in the TRANSCEND clinical study.

(3) GAAP loss per share is the estimated fiscal 2019 diluted loss per share as determined by U.S. generally accepted accounting principles. Non-GAAP (loss) earnings per share adjusts GAAP loss per share for estimated fiscal 2019 contingent consideration adjustment, acquired intangible amortization, and foreign exchange gain on contingent consideration of $0.08, $0.17 and $(0.01) per share, respectively.

SURMODICS

INVESTOR RELATIONS

For additional inquiries, please contact:
Tim Arens • 952-500-7056

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