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 12, 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 8.01 Other Events.

On August 12, 2019, Surmodics, Inc. (the "Company") updated its investor presentation, which is available under the "Investors" section of the Company's website at www.surmodics.com. Representatives of the Company will use the updated presentation in various meetings with analysts and investors from time to time. A copy of the presentation is attached to this report as Exhibit 99.1.

The information in this Item 8.01 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: August 12, 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.

SURMODICS

Gary Maharaj
President and CEO

Tim Arens
Vice President of Finance and CFO

AUGUST 2019

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, our SurVeil™ drug-coated balloon (DCB) and other proprietary products, and 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, timely complete clinical trials for, obtain regulatory approval for and, if approved, 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.

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

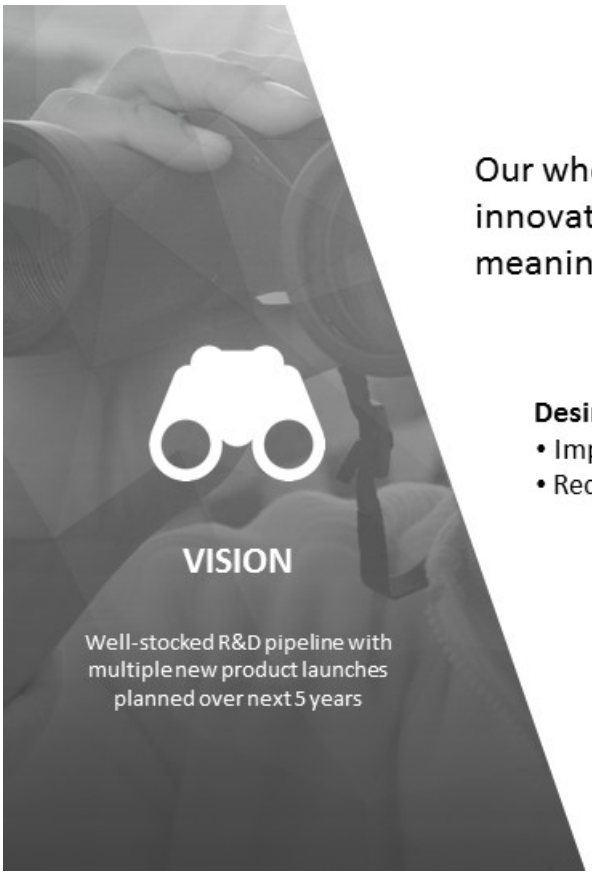
Product innovations aimed at making significant improvements in patient outcomes and quality of life (QOL)

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
  - Pounce™ mechanical thrombectomy
- Sublime™ Radial Access Platform
  - Guide sheath
  - .014" PTA balloon catheter

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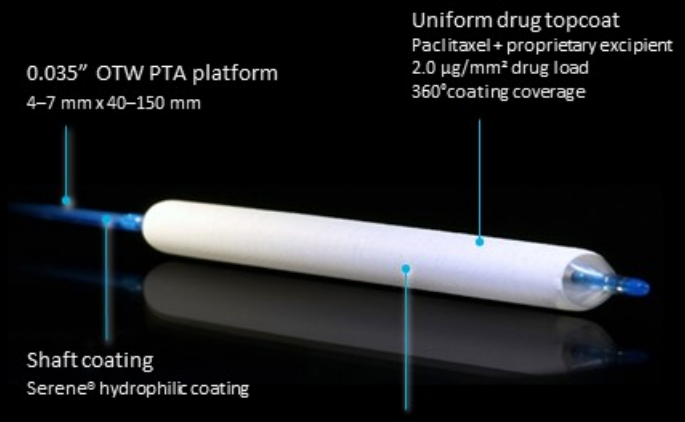
VISION

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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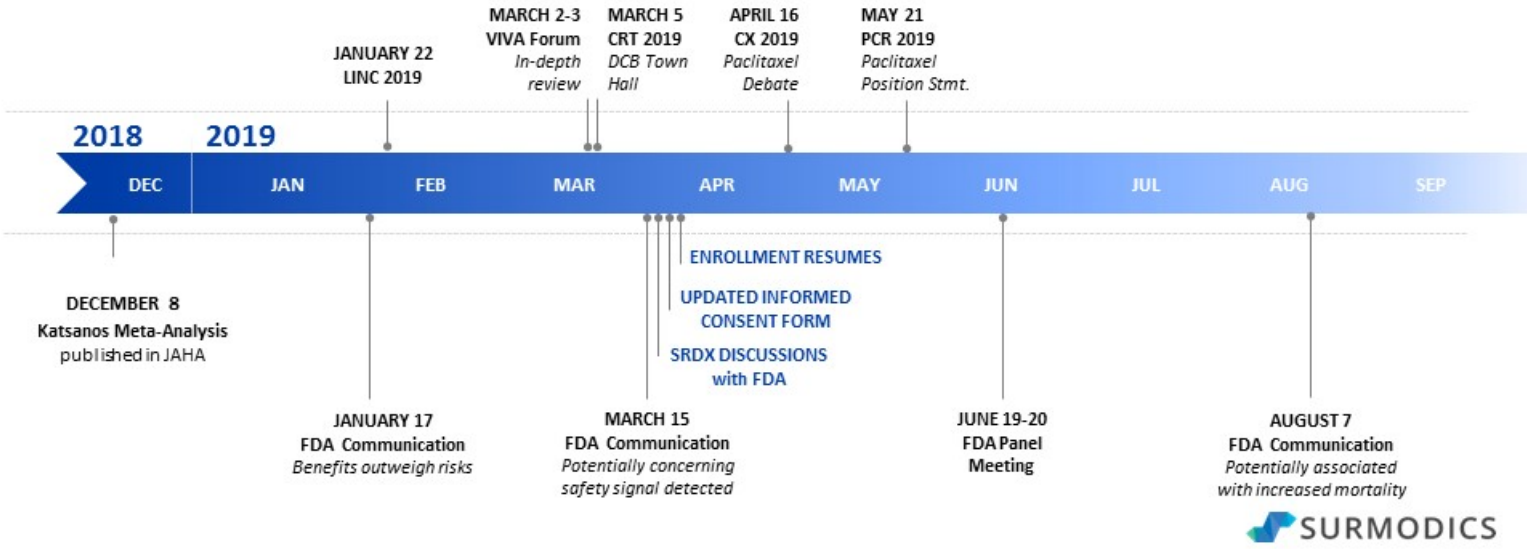
CURRENT DEBATE ON PACLITAXEL-COATED DEVICES TO TREAT PAD

RECAP OF RECENTS EVENTS



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FDA PANEL ADVISORY COMMITTEE MEETING

MEETING HIGHLIGHTS – JUNE 19-20, 2019

- **Signal present from meta-analysis**, no plausible cause identified
- **Totality of data should include large well-constructed observational studies** where no signal has been found
- **Benefits of paclitaxel-coated devices are significant**, must be considered when balancing risk/benefit ratio
- Patient advocates stressed **need to give patients ability to choose paclitaxel treatment; Quality of life is as important as quantity of life**
- Panel supports **continued use and marketing of paclitaxel-coated devices**
- Broad support for the **continuation of existing paclitaxel device trials**
- Increased emphasis on **high quality data and adherence to follow-up through 5 years**

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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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AUGUST 7 – UPDATE: FDA COMMUNICATION TO HEALTH CARE PROVIDERS

- Update to January 17 and March 15 FDA notifications
- FDA is taking additional steps to address the safety signal, including working with manufacturers on updates to device labeling and clinical trial informed consent documents
- FDA is also continuing to actively work with the manufacturers and investigators on additional clinical evidence development for assessment of the long-term safety of paclitaxel-coated devices
- FDA believes clinical studies of these devices may continue and should collect long-term safety (including mortality) and effectiveness data
  - Studies require appropriate informed consent and close safety monitoring to protect enrolled patients

https://www.fda.gov/medical-devices/letters-health-care-providers/august-7-2019-update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel

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FDA RECOMMENDATIONS TO US HEALTH CARE PROVIDERS (MARCH 15 AND AUGUST 7 LETTERS)

March 15, 2019 Letter	August 7, 2019 Letter
• Continue diligent monitoring of patients	• Continue diligent monitoring of patients
• Evaluate and inform of potential risks	• 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	• 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	• Discuss the risks and benefits of all available PAD treatment options with patients • For **many** patients, alternative treatment options to paclitaxel-coated balloons and paclitaxel-eluting stents **provide a more favorable benefit-risk profile based on currently available information**
	• **In discussing treatment options, physicians should explore their patients' expectations, concerns and treatment preferences**
• For some patients at particularly high risk for restenosis, clinicians may determine the benefits may outweigh the risks	• For individual patients **judged to be** at particularly high risk for restenosis **and repeat femoropopliteal interventions**, clinicians may determine the benefits may outweigh the risk **of late mortality**
• Ensure patients receive optimal medical therapy and guidance for healthy lifestyle	• Ensure patients receive optimal medical therapy and guidance for healthy lifestyle
• Report any adverse events or suspected adverse events experienced with the use of paclitaxel-coated balloons and paclitaxel-eluting stents	• Report any adverse events or suspected adverse events experienced with the use of paclitaxel-coated balloons and paclitaxel-eluting stents

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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.

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 >90% enrollment

CE MARK PROGRESS
Currently anticipate obtaining CE mark by December 2019

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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
- 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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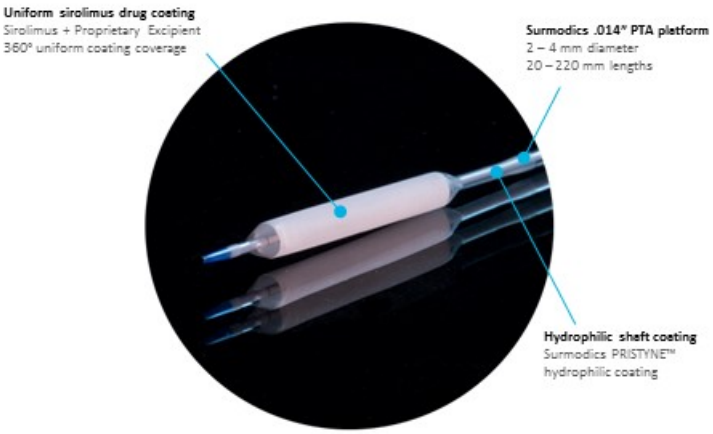
DCB PLATFORM EXTENSION

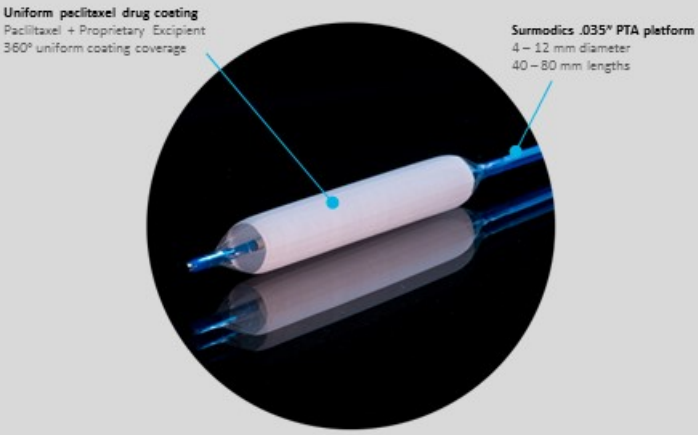
Sundance™ Below-The-Knee DCB



- Successfully completed preclinical studies
- Completed selection of drug dose and coating formulation
- Initiate FIH filing 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
- Target completion of FIH in FY 2019

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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

FY2017 Q1 Q2 Q3 Q4 | **FY2018** Q1 Q2 Q3 Q4 | **FY2019** Q1 Q2 Q3 Q4

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
- **APRIL** — 510 (K) Clearance for Sublime™ Guide Sheath
- **JULY** — Commercialization agreement signed for Telemark™ Coronary Support Catheter

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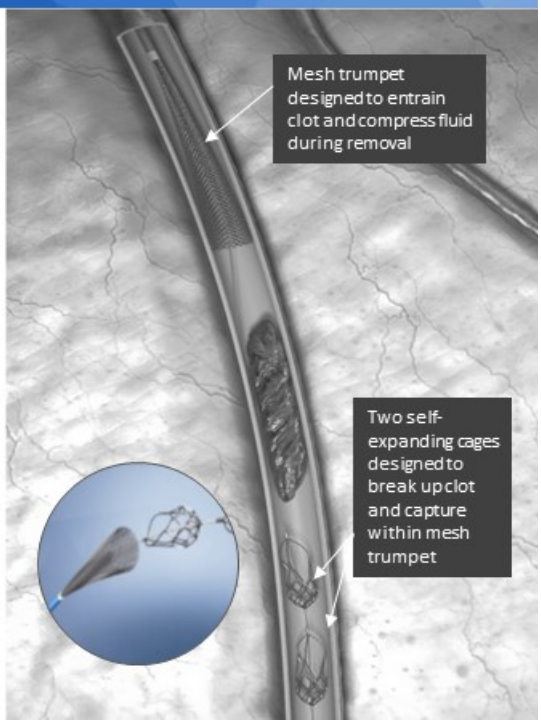
POUNCE™ THROMBECTOMY PLATFORM TECHNOLOGY

- 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
- Expect to submit for our first regulatory clearance in Q1 FY 2020



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
  - Widely adopted in coronary procedures where devices exist
- Initial radial-based products in development include:
  - **Sublime™ Guide Sheath (FDA Cleared):**
    - Surmodics Xtreme™ braided technology offers the ability to treat peripheral procedures, including below-the-knee applications
    - Full-length hydrophilic coating for Guide Sheaths
    - 5 Fr and 6 Fr:
      - 120 cm and 150 cm working lengths
      - .018" and .035" Guidewire compatible
  - **Therapeutic Devices to Treat Lesions:**
    - .014" Radial BTK PTA Balloon Catheter
      - Q4 FY 2019 submission for 510 (K) clearance
    - 2 mm - 4 mm, up to 220 mm long
    - 150 cm working length

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PRODUCT MILESTONES

CY 2019 GOALS

- Enroll the TRANSCEND trial as fast as reasonable: complete enrollment by Q4 FY 2019
- 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

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

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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 – on track for fiscal 2019)
- >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 regulatory actions and any effect on our fiscal 2019 financial and long-term guidance

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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)

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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

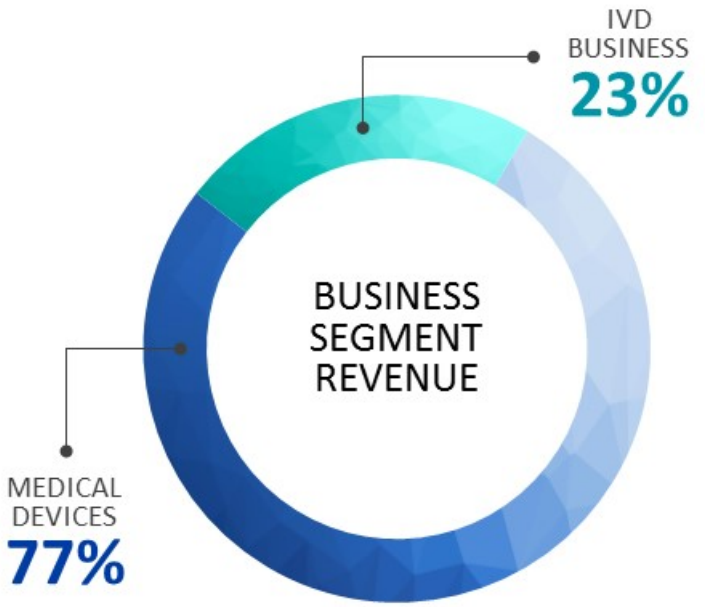
Michael Jaff, DO
Clinical Advisor — Vascular Medicine
Newton Wellesley Hospital

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

Prof. Ramon Varcoe
Clinical Research Advisor — Vascular Surgeon
Prince of Wales Hospital

SURMODICS BUSINESS SEGMENTS

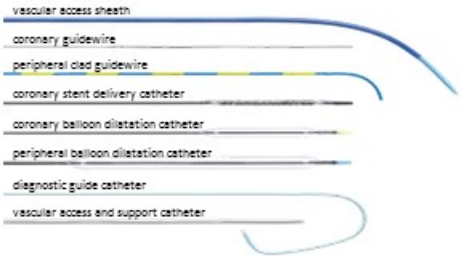
For the nine months ended June 30, 2019



SURMODICS

SURMODICS CORE OFFERINGS

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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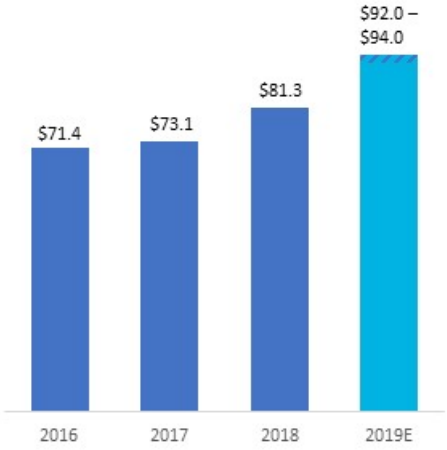
FINANCIAL PERFORMANCE

QUARTERLY REVENUE (MILLIONS)

ANNUAL REVENUE (MILLIONS)



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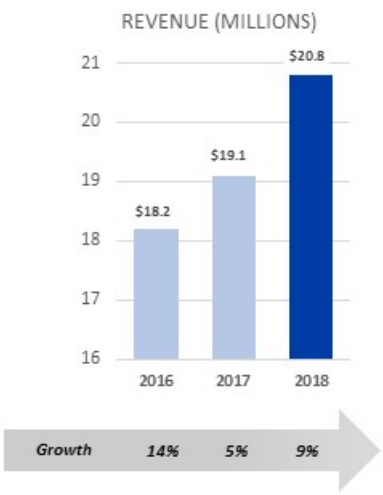
FINANCIALS BY SEGMENT

MEDICAL DEVICE

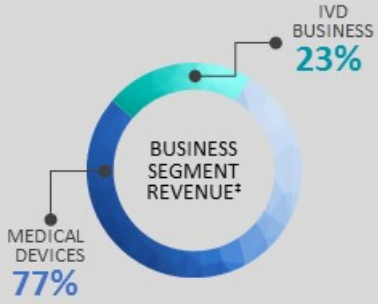
IN VITRO DIAGNOSTICS



MISSION: To improve the treatment and detection of disease

Strong balance sheet and attractive cash flows to fund growth strategy

- $45.0 million of cash/investments as of June 30, 2019
- Operating cash flow of **$34.1 million** and adjusted EBITDA of **$7.3 million** in fiscal 2018



‡For the nine months ended June 30, 2019

SURMODICS

2019 GUIDANCE

2019 Financial Guidance

Total Revenue: $92.0 million to $94.0 million (includes $7.5 million to $8.0 million of SurVeil™ DCB revenue)[1]

GAAP Earnings per Share[2]: $0.24 to $0.32

Non-GAAP Earnings per Share[2]: $0.41 to $0.49

Long Term Objectives

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

(1) Our fiscal 2019 *SurVeil* DCB revenue is driven by the recognition of a portion of the $25 million up front license fee received following the execution of the distribution agreement in late February 2018.

(2) GAAP earnings per share is the estimated fiscal 2019 diluted earnings per share as determined by U.S. generally accepted accounting principles. Non-GAAP earnings per share adjusts GAAP earnings per share for estimated fiscal 2019 contingent consideration adjustment, acquired intangible amortization, foreign exchange gain on contingent consideration, claim settlement and acquired in-process research and development of $0.01, $0.16, $(0.01), $(0.04) and $0.03 per share, respectively.

SURMODICS

INVESTOR RELATIONS

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

SURMODICS