

**Gary Maharaj**  
President and CEO

**Tim Arens**  
Senior Vice President of Finance, IT and CFO

MAY 2021



**SURMODICS**

# SAFE HARBOR

Some of the statements made during this presentation may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements that are not historical or current facts, including statements about our vision and its impact to investors; our fiscal 2021 strategic objectives and future goals; statements about current or future clinical trials; statements about desired outcomes or potential for product innovations or product platforms; statements about future potential revenue from our Development and Commercialization Agreement with Abbott Vascular, Inc.; estimates of future revenues related to the TRANSCEND study; expectations regarding regulatory submissions, clearances and approvals; statements about planned product development and product launches; statements about our future capital allocation; 2021 financial guidance; and statements about future growth rates and EBITDA margins 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 and commercialize our SurVeil™ DCB (including realization of the full potential benefits of our agreement with Abbott), A vess™ DCB, Sundance™ DCB 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 impacts, duration and severity of the global COVID-19 pandemic and the effects of responses to it on healthcare systems, the general economy, our business partners, and our operations; and (5) 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, 2020, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at <https://surmodics.gcs-web.com> and at the SEC website at [www.sec.gov](http://www.sec.gov). Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update them in light of new information or future events

# PRODUCT PIPELINE: FOCUSED ON PRODUCT INNOVATION



## IMPACT TO PATIENTS

Growing incidence of  
peripheral artery disease (PAD)

## VISION

**3 of the Top 10 Innovations  
in Vascular Medicine**  
Focused on PAD

## IMPACT TO INVESTORS

Investing to build long-term  
sustainable growth and  
profitability



## VISION

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

### Fiscal 2021 Strategic Objectives:

- **SurVeil™ Drug-Coated Balloon**
  - Complete PMA submission to the FDA
- **Product Pipeline**
  - Sundance™ DCB – complete enrollment in SWING first in-human trial
  - Sublime™ radial access devices – achieve clearances and obtain clinical experience necessary for commercialization
  - Pounce™ thrombectomy – complete manufacturing validations and commence limited product evaluations for arterial indication; commence development for treatment of additional indication(s)
- **Optimize cash flow and revenue performance from legacy product offerings**

# IMPACT TO PATIENTS

**Product innovations aimed at making significant improvements in patient outcomes and quality of life (QOL), while reducing healthcare costs**

## PATIENTS

### • Superficial Femoral Artery (SFA)

- > 500K Above-the-knee interventional procedures performed annually in the U.S. <sup>(1)</sup>
- Pain on ambulation – reduced QOL

### • Below-the-knee disease (BTK)

- Nearly **1 million Medicare patients** with Critical Limb Ischemia (CLI) annually, with annual cost > \$3B <sup>(2)</sup>
- 33% amputation; 20% die in 1 year <sup>(3)</sup>

### • AV access for End Stage Renal Disease (AV for ESRD)

- Approximately 750K Medicare patients with ESRD <sup>(4)</sup>
- AV access 1% of procedures but 7% of Medicare Costs <sup>(5)</sup>
- Impacts QOL for ESRD patients

## DESIRED OUTCOMES

- Reduction in reintervention rates
- Improved QOL by reduction in pain and increase in mobility

- Reduction in reintervention rates
- Improved QOL as a result

- Healthcare economic benefits across the board in all indications above



**Significant Need**  
202 million patients worldwide  
living with Peripheral Artery  
Disease (PAD) <sup>(6)</sup>

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(1) Annual procedures in the U.S. according to iData and Company estimates

(2) 1. Jihad A. Mustapha MD, et. al. Determinants of Long-Term Outcomes and Costs in the Management of Critical Limb Ischemia: A Population-Based Cohort Study. J Am Heart Assoc. 2018;7:e009724. DOI: 10.1161/JAHA.118.009724.

(3) Westin GG, Armstrong EJ, Bang H, Yeo KK, Anderson D, Dawson DL, Pevcec WC, Amsterdam EA, Laird JR. Association between statin medications and mortality, major adverse cardiovascular event, and amputation-free survival in patients with critical limb ischemia. J Am Coll Cardiol. 2014;63(7):682–690.

(4) United States Renal Data System – 2017 USRDS Annual Data Report

(5) Domenick Sridharan N, et. al. The associations of hemodialysis access type and access satisfaction with health-related quality of life. J Vasc Surg. 2018 Jan;67(1):229-235

(6) Fowkes FGR, Rudan D, Rudan I, Aboyans V, Denenberg JO, McDermott MM, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. Lancet, Lond Engl. 2013 Oct 19;382(9901):1329–40



## VISION

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

## Three highly differentiated platform technologies with potential for disruption in large and growing addressable markets

### 1. Drug-Coated Balloons: SurVeil™ DCB, Sundance™ DCB, & Avess™ DCB

Next-generation drug-delivery technology designed to improve patient safety without sacrificing efficacy

### 2. Thrombus Management: Pounce™ Thrombectomy

Uniquely designed to provide single session treatment for removal of difficult clots with no capital equipment and reduced need for lytic drugs

### 3. Radial Access: Sublime™ Radial Access Portfolio

Designed to enable lower extremity interventions via radial (wrist) access, reducing potential for patient complications

## Desired Outcomes:



Improve Clinical Outcomes



Reduce Healthcare Costs



# TRANSCEND Pivotal Trial 12-month Results

## SURVEIL™ DCB: THIRD-GENERATION DESIGN

### 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/mm<sup>2</sup>; 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**





# TRANSCEND: SURVEIL™ DCB PIVOTAL TRIAL

## 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 randomized  
52 US sites (N=290) and 13 OUS sites (N=156)  
SurVeil (N=222) and IN.PACT ADMIRAL (N=224)

### Study Duration

60 months post procedure

## 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]  $\geq 2.4$  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.

**TRANSCEND**  
SURVEIL™ DRUG-COATED BALLOON TRIAL

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



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## 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

## PMA PROGRESS

TRANSCEND 12-month data presented at Leipzig Interventional Course (LINC) 2021 virtual event on Jan. 25, 2021

First, second and third modules for PMA submitted in FY20

**PMA APPROVAL: EXPECTED BY DECEMBER 2021**

**CE MARK: RECEIVED – JUNE 2020**

## 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: SURVEIL™ DCB PIVOTAL TRIAL

## TRANSCEND Trial Fast Facts

**1<sup>st</sup>** head-to-head RCT of next generation low-dose DCB vs high-dose DCB

**446** Subjects randomized 1:1 to SurVeil™ DCB or IN.PACT® Admiral® DCB

**65** Global Sites: 52 US sites N=290 and 13 OUS sites, N = 156

**75%** higher paclitaxel drug load in IN.PACT® Admiral® DCB (3.5 µg/mm<sup>2</sup>) vs. SurVeil DCB (2.0 µg/mm<sup>2</sup>)

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

## PRIMARY SAFETY

**91.7%**

of subjects in the SurVeil arm achieved primary safety endpoint vs. 89.6% of subjects treated with the IN.PACT® Admiral® DCB.

## PRIMARY EFFICACY

**81.7%**

of SurVeil DCB subjects met the efficacy endpoint of primary patency vs. 85.9% of the IN.PACT® Admiral® DCB arm.

## CONCLUSIONS

- ✓ SurVeil™ DCB achieved both Safety and Efficacy endpoints in pivotal RCT
- ✓ SurVeil DCB is non-inferior to the market-leading IN.PACT® Admiral® DCB with respect to Composite Patency, including CD-TLR and Binary Restenosis
- ✓ SurVeil DCB achieved comparable effectiveness to IN.PACT® Admiral DCB at a substantially lower drug dose

For complete TRANSCEND study data presented at the 2021 LINC conference, see presentation posted on our website at <https://surmodics.gcs-web.com/>

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# STRATEGIC AGREEMENT WITH ABBOTT



**Abbott**



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

- Exclusive worldwide commercialization rights for SurVeil™ drug-coated balloon (DCB) for superficial femoral artery (SFA)
- \$15 million related to the successful completion of the clinical study report of the TRANSCEND pivotal trial demonstrating safety and clinical non-inferiority with the control device – February 2021
- We have received \$60.8 million in total milestones from Abbott
- Final milestone of up to \$30 million due upon receipt of PMA approval from the FDA
- Option to negotiate agreement for Sundance™ below-the-knee (BTK) DCB
- Revenue to be realized from product sales to Abbott, including a base transfer price plus a share of profits from Abbott sales of the device

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

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# SURVEIL™ DCB - IMPACT TO FINANCIALS

**\$61M of the potential \$91M** of SurVeil™ DCB upfront and milestone **payments** have been achieved through Q2 FY2021

Payment	Amount	Date
Upfront License Fee	\$25M	Feb 2018
TRANSCEND Enrollment Milestone	\$10M	Aug 2019
CE Mark Milestone	\$10.8M	June 2020
Clinical Report Milestone	\$15M	Feb 2021

**~75% of the estimated total \$35M – \$40M TRANSCEND Clinical Study costs** were incurred through Q2 2021

Upfront and milestone revenue is recognized based upon the % of the TRANSCEND study costs incurred\*

For example, FY'19 revenue was recognized as follows:

- Upfront license fee - \$25M x (~51% - ~18%) = \$8.4M
- TRANSCEND completion milestone - \$10M x ~51% = \$5.1M

\*TRANSCEND costs incurred following the execution of the SurVeil™ DCB development and distribution agreement with Abbott Vascular

## TRANSCEND Study Cost Schedule<sup>(1)</sup>

	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
<b>Value Creating Event</b>	Abbott Agreement Signed	TRANSCEND Enrollment Complete	CE Mark Received	Final Clinical Report Delivered	U.S. PMA Approval Expected			5-year Follow-Up Complete
<b>Estimated % of TRANSCEND Study Costs Incurred *</b>	~18%	~ 51%	~ 65%	~ 76%	~ 82%			~ 100%

## Revenue Recognition Schedule Through Fiscal 2020

Revenue (\$ in millions)	FY 2018A	FY 2019A	FY 2020A	FY 2021E
Upfront License Fee	\$4.4	\$8.4	\$3.5	\$2.7 - \$3.1
TRANSCEND Completion Milestone	-	5.1	1.4	1.1 - 1.3
CE Mark Milestone	-	-	7.0	1.2 - 1.3
Clinical Report Milestone	-	-	-	11.5 - 11.8
<b>Total SurVeil Upfront &amp; Milestone Revenue</b>	<b>\$4.4</b>	<b>\$13.5</b>	<b>\$12.0</b>	<b>\$16.5-\$17.5</b>
Cumulative Revenue	\$4.4	\$17.9	\$29.9	\$46.4 - \$47.4
<b>% recognized *</b>	<b>~18%</b>	<b>~ 51%</b>	<b>~ 65%</b>	<b>~ 77%</b>

(1) Based on the costs incurred and expected to be incurred from the execution of the Abbott agreement and not the actual cost from study inception

We expect to recognize the entire \$60.8 million associated with the license fee and achieved milestones over the period ending fiscal 2025; revenue from the \$30 million of outstanding milestones (if any) will be recognized over the same time period, beginning in the period of achievement

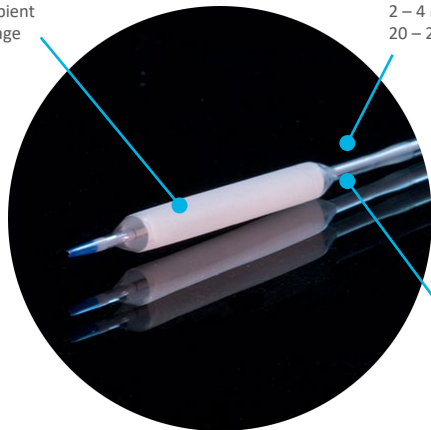


# DCB PLATFORM EXTENSIONS

## Sundance™ Below-The-Knee DCB

**Uniform sirolimus drug coating**  
Sirolimus + Proprietary Excipient  
360° uniform coating coverage

**Surmodics .014" PTA platform**  
2 – 4 mm diameter  
20 – 220 mm lengths



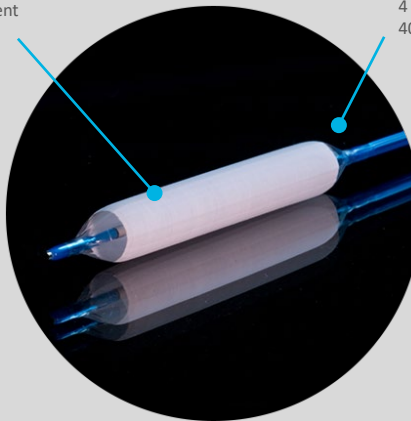
**Hydrophilic shaft coating**  
Surmodics Serene™  
hydrophilic coating

- Initiated FIH study enrollment in June 2020
- Completed enrollment in the January 2021
- Expect 6-month endpoint data by end of calendar 2021

## A vess™ AV Fistula DCB

**Uniform paclitaxel drug coating**  
Paclitaxel + Proprietary Excipient  
360° uniform coating coverage

**Surmodics .035" PTA platform**  
4 – 12 mm diameter  
40 – 80 mm lengths



- Completed FIH study enrollment Q4 FY 2019
- FIH study results were presented at the November 2020 VIVA conference by Dr. Andrew Holden, MBChB.
- Freedom from revascularization at six months was greater than 90% for the 12 subjects (one re-intervention) with no AVF's thrombosed. Safety endpoints met.



# POUNCE™ THROMBECTOMY SYSTEM TECHNOLOGY

## Pounce advantages align with Surmodics vision

- Simple, stand-alone intervention, eliminates need for capital equipment
- Designed to be a single session therapy which may reduce the need for thrombolytics and complex procedures
- Off-the-shelf design simplifies setup, limited learning curve

## Pounce technology has potential to be advantageously differentiated from existing devices

- Designed to be efficient and effective in removing *organized* clot, while minimizing blood loss

**FDA 510(k) Clearance Received Sept. 2020**



### Device Specs

- Basket Delivery Catheter: 5 Fr, 140 cm
- Basket Wire Assembly: 300 cm
- Trumpet Assembly: 120 cm
- Trumpet: 6.5 cm length; 7 mm unconstrained diameter



# SUBLIME™ 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
- Barriers to adoption for peripheral procedures include the lack of available devices

## 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
- Successfully completed initial clinical cases in 2021
- Full-length hydrophilic coating
- 5 Fr and 6 Fr sizes:
  - 120 cm and 150 cm working lengths
  - .018" and .035" Guidewire compatible

- **Therapeutic Devices to Treat Lesions:**

- .014" Radial BTK PTA Balloon Catheter – successfully completed initial clinical cases in 2021
- .018" Radial PTA Balloon Catheter – submitted for 510(k) clearance in April 2021
- Balloon Diameter: 2.0 mm – 4.0 mm
- Balloon Length: Up to 220 mm long
- 250 cm working length



Guide Sheath  
Coiled 5 Fr Hoop

Braided Peripheral  
Radial Guide Sheath

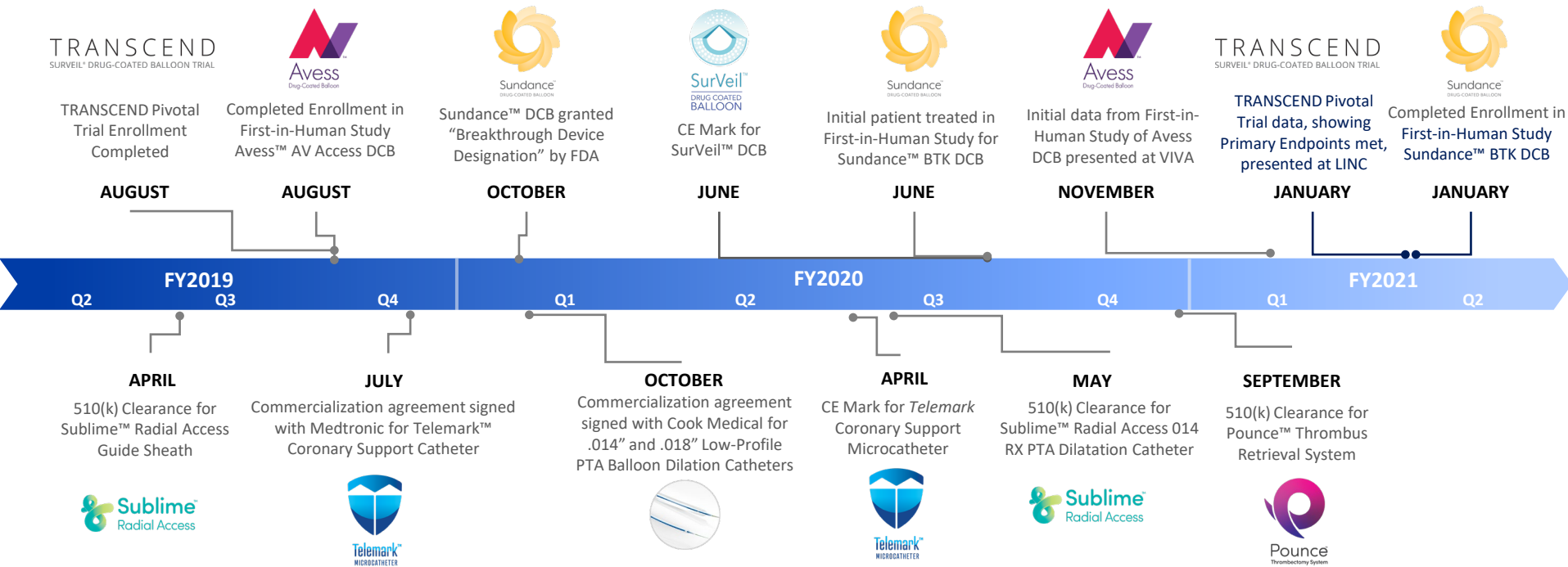


.014 Radial BTK PTA  
Balloon Catheter



# WE ARE MAKING PROGRESS ON OUR WHOLE-PRODUCT SOLUTIONS STRATEGY

## Drug-Coated Balloons (DCB)



## 510(k) / CE Mark Products

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

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# PRODUCT MILESTONES

FY 2021 GOALS	Timeline
• Complete primary endpoint clinical study report for TRANSCEND trial	✓
• Complete PMA submission of our SurVeil™ DCB to the FDA	Q4 FY21
• Complete enrollment in the first-in-human trial for our Sundance™ sirolimus BTK DCB	✓
• Evaluate FIH data for our A vess™ AV Access DCB and relevant data from TRANSCEND to determine next steps	Q4 FY21
• Initiate clinical evaluations for our recently cleared Pounce™ Thrombectomy device	Q4 FY21
• Conduct product evaluations for our cleared Sublime™ Radial Access devices	Q3 FY21
• Receive 510(k) regulatory clearance for Sublime radial 018 PTA balloon catheter	Q4 FY21
FY 2022 – FY 2023 GOALS	
• Secure PMA of SurVeil™ DCB	FY22
• Support SurVeil™ commercialization in the U.S. and other geographies with our partner Abbott	FY22
• Initiate pivotal trial for Sundance™ BTK DCB	FY22
• Commercialize our cleared Pounce™ Thrombectomy and Sublime™ Radial Access devices	FY22
• Obtain regulatory clearance for devices that support our Sublime™ Radial Access and Pounce™ Thrombectomy platforms	FY22 – FY23



# MANAGEMENT TEAM



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



**Timothy J. Arens**  
Senior Vice President of Finance and  
Information Technology and  
Chief Financial Officer  
(2007)



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



**Teryl L.W. Sides**  
Senior Vice President of  
Product Development and  
Chief Marketing Officer  
(2018)



**Charles W. Olson**  
Senior Vice President of  
Commercial and Business  
Development, Medical Devices  
(2001)



**Gordon S. Weber**  
Senior Vice President of Legal,  
General Counsel & Secretary  
(2020)



**Nusrath Sultana, M.D.**  
Vice President of Clinical Affairs  
(2020)

# SCIENTIFIC ADVISORY BOARD



**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



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



**Constantino Peña, MD**  
**Clinical Advisor** — Vascular and Interventional Radiology  
Miami Cardiac & Vascular Institute



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

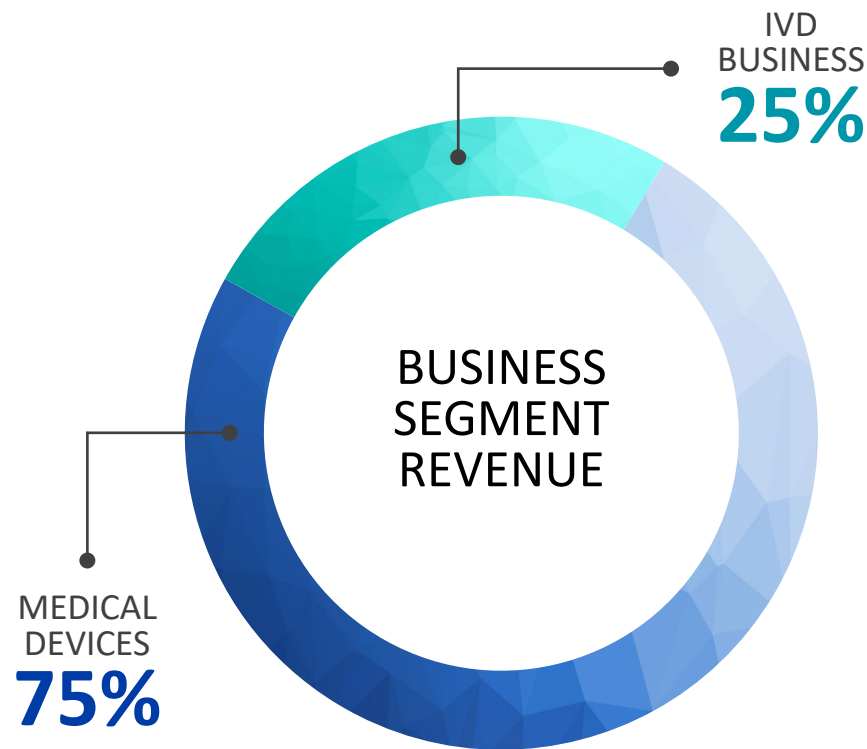


**Renu Virmani, MD, FACC**  
**Clinical Advisor** — Cardiovascular Pathologist  
CVPPath



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

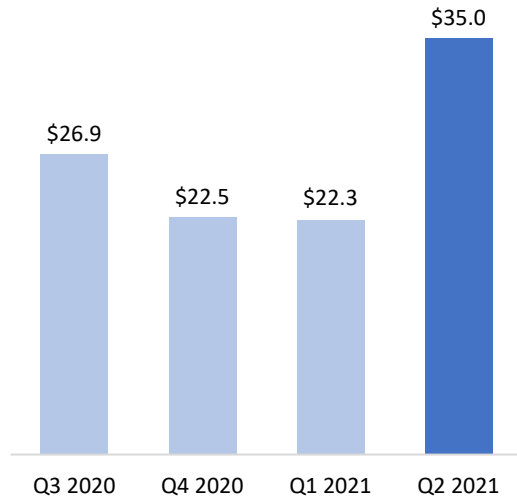
# SURMODICS BUSINESS SEGMENTS



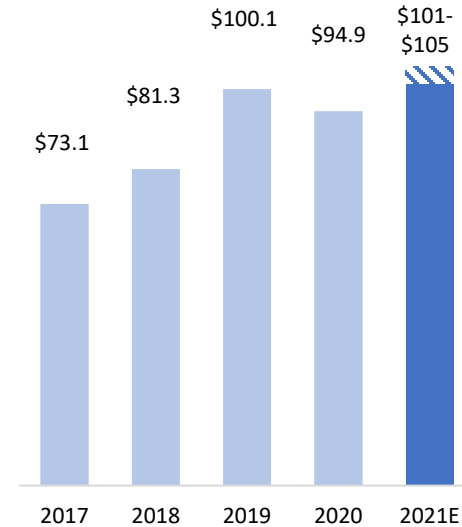
For the fiscal year ended September 30, 2020

# FINANCIAL PERFORMANCE

**QUARTERLY REVENUE (MILLIONS)**



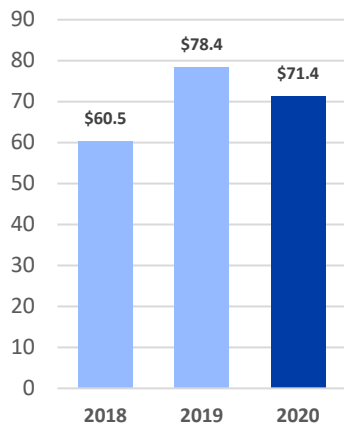
**ANNUAL REVENUE (MILLIONS)**



# FINANCIALS BY SEGMENT

## MEDICAL DEVICE

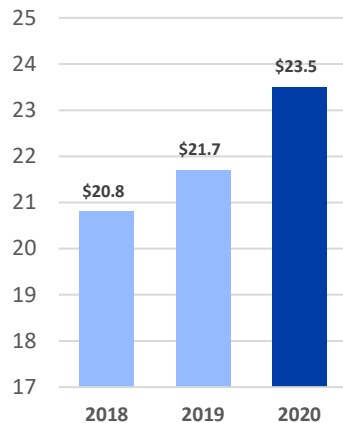
REVENUE (MILLIONS)



Growth 12% 30% (9)%

## IN VITRO DIAGNOSTICS

REVENUE (MILLIONS)

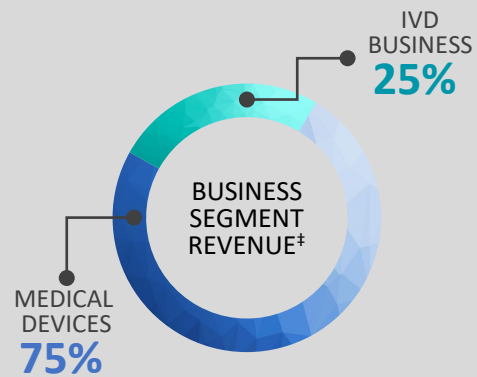


Growth 9% 4% 8%

**MISSION:** To improve the treatment and detection of disease

Strong balance sheet and attractive cash flows to fund growth strategy

- \$70.0 million of cash/investments as of March 31, 2021
- Operating cash flow of **\$14.0 million** and adjusted EBITDA of **\$5.8 million** for fiscal 2020



\*For the twelve months ended September 30, 2020

# 2021 GUIDANCE



## 2021 Financial Guidance

Total Revenue: \$101.0 million to \$105.0 million (includes \$16.5 million to \$17.5 million of SurVeil™ DCB revenue)<sup>(1)</sup>

GAAP (Loss)/Earnings per Share<sup>(2)</sup>: \$(0.05) to \$0.20

Non-GAAP Earnings per Share<sup>(2)</sup>: \$0.10 to \$0.35



## Long Term Objectives

Consistent double-digit revenue growth and EBITDA margins above 25% beginning 2022

(1) Our fiscal 2021 *SurVeil* DCB revenue is driven by the recognition of the upfront and milestone payments totaling \$61.8 million that have been received, pursuant to our distribution and development agreement with Abbott.

(2) GAAP earnings per share is the estimated fiscal 2021 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 2021 acquired intangible amortization totaling \$0.15 per share, net of tax.

# CAPITAL ALLOCATION PRIORITIES

Our long-term capital allocation priorities remain unchanged.

We continue to support long-term value creation through investment in our innovative product platforms.

Available Capital (\$'s in Millions)	March 31, 2021
Cash	\$48.2
Short-term Investments	\$17.8
Long-term Investments	\$4.0
Revolving Line-of-Credit	\$25.0
<b>Total</b>	<b>\$95.0</b>

Available Capital



Protect Liquidity & Balance Sheet



Invest in Long-term Value Creation

## **Support the Core Businesses**

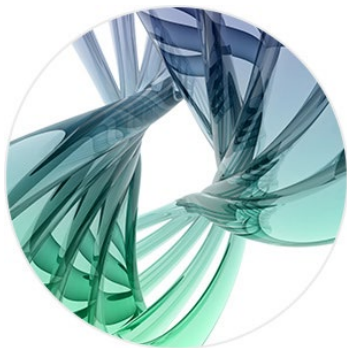
Optimize revenue and cash flow performance

## **Invest in Innovation**

- Drug-coated balloons
- Thrombectomy system
- Radial access platform

# SURMODICS CORE OFFERINGS

## MEDICAL DEVICE COATINGS



Leveraging science and expertise to offer world-class coatings and drug delivery, revenue from our Coatings product offerings is expected to grow in the mid-single digits annually, beginning in fiscal 2022

## IN VITRO DIAGNOSTICS



Providing critical components for in vitro diagnostic tests and microarrays, our IVD product offerings expected to continue to deliver mid-to-high single digit revenue growth, annually.

## Creating sustainable margins for long-term growth and profitability

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



- Operational excellence
- Manufacturing
- Process Engineering



## INVESTOR RELATIONS

For additional inquiries, please contact:

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