

**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 11, 2022

Date of report (Date of earliest event reported)

**Surmodics, Inc.**

(Exact Name of Registrant as Specified in its Charter)

Minnesota

(State of Incorporation)

0-23837

(Commission File Number)

41-1356149

(I.R.S. Employer  
Identification No.)

9924 West 74th Street  
Eden Prairie, Minnesota

(Address of Principal Executive Offices)

55344

(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:**

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, \$0.05 par value	SRDX	The 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.

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**Item 7.01 Regulation FD Disclosure.**

On January 11, 2022, Surmodics, Inc. (“Surmodics”) will post to its website at [www.surmodics.com](http://www.surmodics.com) the investor information attached to this report as Exhibit 99.1.

The information in this Item 7.01, including Exhibit 99.1 and the information accessed by links through QR codes appearing in 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**

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[99.1](#) [Surmodics Investor Information January 2022](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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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 11, 2022

/s/Timothy J. Arens

Timothy J. Arens  
Senior Vice President of Finance and Chief Financial Officer

**Gary Maharaj**  
President and CEO

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



**January 2022**

# 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 growth opportunities, expected revenue growth and annual growth rates, our fiscal 2022 strategic objectives, statements about the commercialization potential of the SurVeil™ drug coated balloon (“DCB”), statements about the premarket approval and commercial launch of the SurVeil DCB, the expected timing of market evaluations of our products, statements about future potential revenue from our Development and Commercialization Agreement with Abbott Vascular, Inc., expectations regarding completion of the 5-year follow-up in the TRANSCEND study, fiscal 2022 financial guidance, and estimates of future revenues related to the TRANSCEND study, 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), Avest™ 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; (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; (5) whether anticipated increases in our operating expenses are effective in generating profitable revenues; and (6) 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, 2021, 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/investors](#) and at the SEC website at [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.

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

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## Simply Better.

Because technology innovation is only as good as the confidence and adoption of its users.

We believe simpler and better is the way to go to enable greater access to care by giving physicians the freedom to treat, anytime, anywhere.

### Simply **Better.**

Simply Surmodics

Simply Driven

Simply DCB

Simply Pounce

Simply Radial

Simply Solid

Simply Strong

# Simply Surmodics.

## Growth Opportunity:

High-growth, underpenetrated market opportunities serving current trends and future market needs

**Core Business:** Strong source of operating cash fuels growth initiatives and commercial operations

- Strong and growing businesses
- High ROIC

**Who are we?**  
Learn more about us.



### Performance Coatings

- Hemocompatible Coatings
- Drug-Delivery Coatings
- Hydrophilic Coatings
- Combination Coatings

### Vascular Device Platforms

- Sublime™ Radial Access Platform
- Pounce™ Arterial Thrombectomy
- Pounce™ Venous Thrombectomy
- Drug-Coated Balloons

### In Vitro Diagnostics (IVD)

- Stopping Solutions & Support Reagents
- Protein Stabilizers & ELISA Substrates
- Antigens & Antibodies (Direct™)
- Microarray Slides & Surfaces



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# Our Sights Are On Something Bigger

Our journey has prepared us.  
**This is just the beginning.**



### Global Leader

*The global leader in medical device coatings and in vitro diagnostics specialty reagents.*



### Secret Sauce

*We've been the secret sauce but received a fraction of the value – and couldn't control our destiny.*



### Born to Innovate

*We are innovators. We owe it to our shareholders to command the return that fully reflects the value of our innovations.*



### We Can Help

*Vascular disease is pushing healthcare to the brink. We can make a difference.*



### Driven to do More

*The problems we address and the markets we serve are growing. We are directly relevant.*

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# What Matters Most



**It's personal.**  
We are on a mission.



## Patients

No one should suffer from lifelong disability when the right treatment at the right time could have prevented it.

## Customers

Life-changing technology must move quickly into the hands of physicians everywhere. And it needs to happen fast.

## Employees

Surmodics employees are personally invested to drive this change. That's why we work here.

## Shareholders

We recognize the investment made to support our mission. We are driven to quickly maximize shareholder return.

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# Simply Better Solutions

**We Innovate**

Learn more about our product portfolios



## Vascular Device Platforms

### RADIAL ACCESS



**Sublime**  
Radial System

### THROMBO-EMBOLECTOMY



**Pounce**  
ARTERIAL  
Thrombectomy



**Pounce**  
VENOUS  
Thrombectomy

### DRUG-COATED BALLOONS



**SurVeil**  
DRUG COATED  
BALLOON



**Sundance**  
DRUG COATED BALLOON



**Aves**  
Drug Coated Balloon

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# It's Not Enough To Be Different



## DIFFERENT



- First 5F radial sheath
- Longest length balloon catheters
- Broke the trade-off between length & performance



- Stand-alone arterial mechanical device designed to clear chronic thrombo-embolic obstructions
- Grab and go, on-table resolution



- First dual-action technology
- Grab and go, on-table resolution
- Device and procedure simplicity



- First worldwide head-to-head RCT of next generation low-dose DCB vs high-dose DCB

## DIFFERENCE

*You can't treat what you can't reach. Get wherever you need to go — quickly and confidently — from any access site*

*An arterial clot can quickly cost a limb — or a life. Strike fast with a simple, surefire device that captures and removes hard clots*

*Clots adhere to veins and damage them on contact. We believe in moving fast: just grab and go.*

*Comparable effectiveness achieved at a substantially lower dose of drug*

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# Big Opportunities: We are Driven to Achieve

## Large, Underpenetrated Markets Addressable By Our Innovations



**PAD**  
Peripheral Artery Disease

0.8 M  
patients/year

\$0.4 B  
TAM

<10%  
Penetrated



**PAO/DVT**  
Peripheral Arterial Occlusion and Venous Thrombo-embolism

0.4 M  
patients/year

\$2.2 B  
TAM Market

~15%  
Penetrated



**PAD ATK**  
Peripheral Artery Disease Above the knee

0.5 M  
patients/year

\$1.0 B  
TAM Market

~20%  
Penetrated

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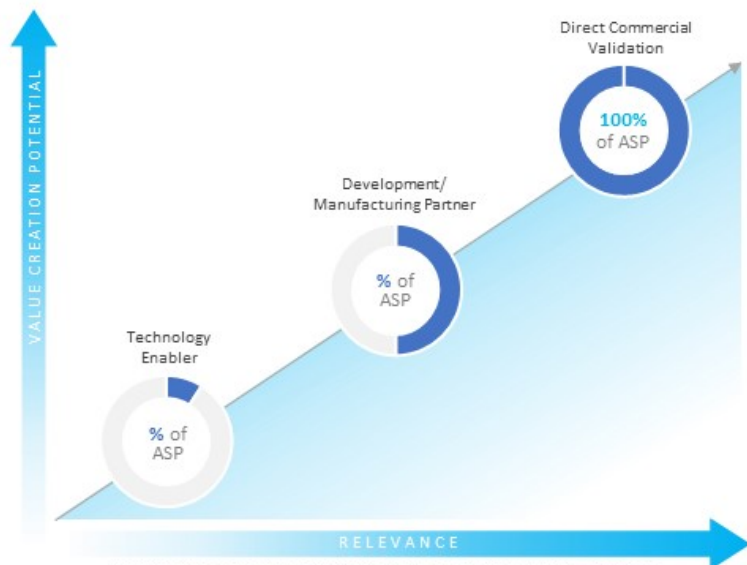
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† Patient figures and ASP ranges based on Management Estimates as well as Public Health and Industry Data

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# Our Commercialization Strategies Enable Us To Maximize Our Opportunities In Significant And Growing Markets



For illustration only. No representation is made or implied regarding the actual revenue Surmodics realizes relative to the ASP of any medical device or product.



## Direct Commercial Validation

- Focused commitment from sales and marketing
- Product development initiatives to expand portfolio
- Ability to expand and grow markets
- Enhanced customer insights to inform product development initiatives

## Development/Mfg. Partnership

- SurVeil™ Drug-Coated Balloon
- Telemark™ Microcatheter
- Cook Advance Serenity™ PTA Balloons

## B2B Technology Enabler

- Medical Coatings and IVD

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# We Are Committed To Driving Long-term Revenue Growth And Value Creation For Our Shareholders

- **Innovative product pipeline aimed at significant growth opportunities**

- Seeking FDA approval for SurVeil™ DCB, which will address a \$1.5B worldwide market opportunity through our commercial partner, Abbott<sup>(1)</sup>
- U.S. FDA clearances on five unique and differentiated thrombectomy and radial access products to address market opportunities totaling up to \$2.6 billion<sup>(1)</sup>

- **Direct commercialization of our thrombectomy and radial access products in FY2022**

- Current team of 12 experienced sales professionals (avg. experience 21 years) will build on success with initial clinical evaluations

- **Technology-enabling Medical Device Coatings and In Vitro Diagnostics offerings**

- Generate \$80+ million of revenue annually
- Expected to grow annually in the mid single digits
- Provide consistent and reliable cash flow



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(1) Patient figures based on Management Estimates as well as Public Health and Industry Data

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# Our Fiscal 2022 Objectives Support Our Mission.

# 1

## SurVeil™ Drug-Coated Balloon

- Achieve FDA PMA Approval
- Support the commercialization efforts of our partner, Abbott Vascular

# 2

## Pounce™ Thrombectomy Platform and Sublime™ Radial Access platforms

- Validate commercial opportunity
- Capitalize on physician preference by establishing solid customer base with repeat business

# 3

## Medical Device Coatings and In Vitro Diagnostics offerings

- Drive top-line revenue growth and optimize cash flow

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# SurVeil™ DCB: Third-Generation Design

## GOALS for 3<sup>rd</sup> generation device are focused on addressing important clinical problems

- **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
  - Market-leading device has 75% higher dose

## THESIS: similar outcome with lower dose of cytotoxic drug

- Advance the state of the art
- Provide better therapeutic choice

SurVeil™ DCB



Check here for  
product specs  
and TRANSCEND  
12-month data



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SurVeil™ DRUG-COATED BALLOON

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# Commercialization Of Our SurVeil™ DCB Has The Potential To Be A Significant Growth Catalyst

Above-the-knee Balloon Angioplasty Market – U.S.<sup>(1)</sup>



(1) Patient figures based on Management Estimates as well as Public Health and Industry Data

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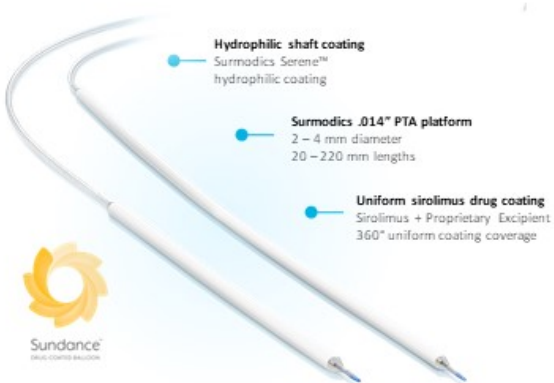
Our commercial partnership with Abbott is expected to lead to a significant and growing revenue stream upon commercialization



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# DCB Platform Extensions

## Sundance™ Below-The-Knee DCB



- First in human study 6-month follow-ups complete and preliminary analysis underway

## Aves™ AV Fistula DCB



- First in human study results presented at 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.

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# Poised, Positioned and Ready to Pounce



## Poised, Positioned and Ready to **Pounce**.

**Poised:** Two stand-alone, easy-to-use, highly effective mechanical thrombectomy devices; one for arterial use, the other for venous cases

**Positioned:** Simple, effective designs make these devices ideal first-line treatments in their respective spaces

**Pounce** into action with intuitive, off-the-shelf devices that empowers physicians to rapidly respond, remove clot, and restore blood flow when time is of the essence

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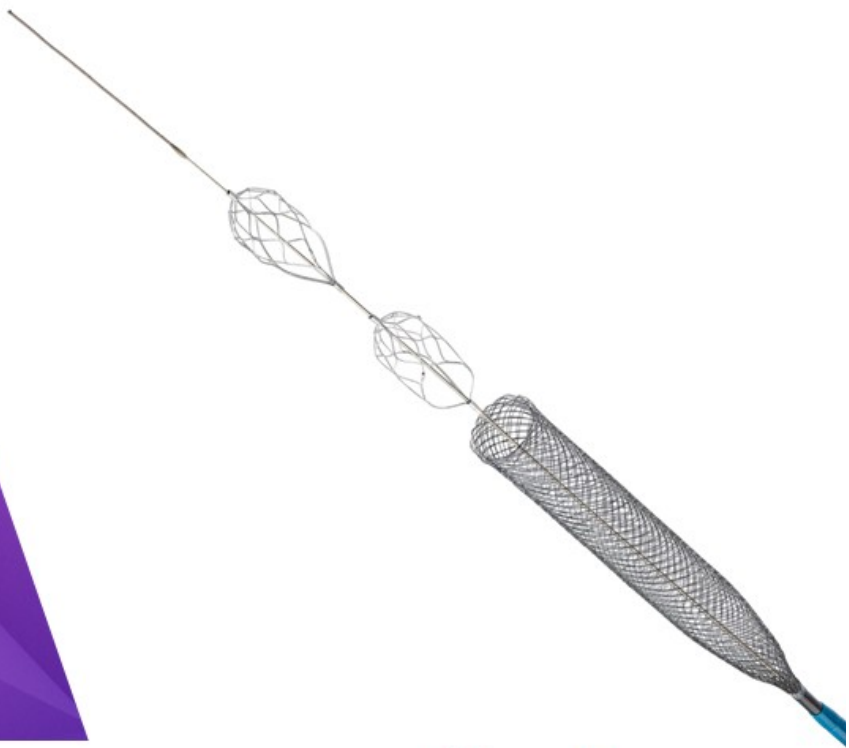
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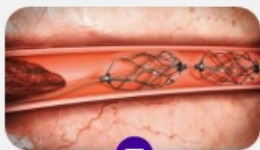


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# An Elegant Solution to a Complex Clinical Problem

Check out the full animation and additional product details



After the basket wire assembly is delivered distal to the location of the thrombus, two nitinol self-expanding baskets are deployed distal to the clot.



The baskets capture the clot and are retracted into a trumpet-shaped nitinol wire mesh.



With the clot entrained, the trumpet assembly is then collapsed into a minimum 7 Fr guide sheath through which the clot is withdrawn and removed from the body.

## Pounce™ Arterial Thrombo-embolectomy System

- Designed to capture and remove organized and unorganized thrombo-emboli in the arterial peripheral vasculature
- Off-the-shelf, stand-alone device – designed for use in time critical situations, with no additional capital equipment required. Packaged in one 'grab & go' configuration.
- Intuitive, simple set up, limited learning curve
- On-the-table solution designed to lower risk of bleeding complications associated with use of thrombolytics

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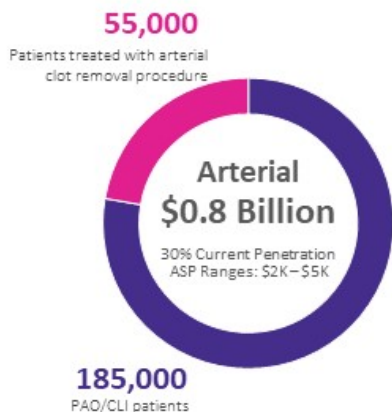
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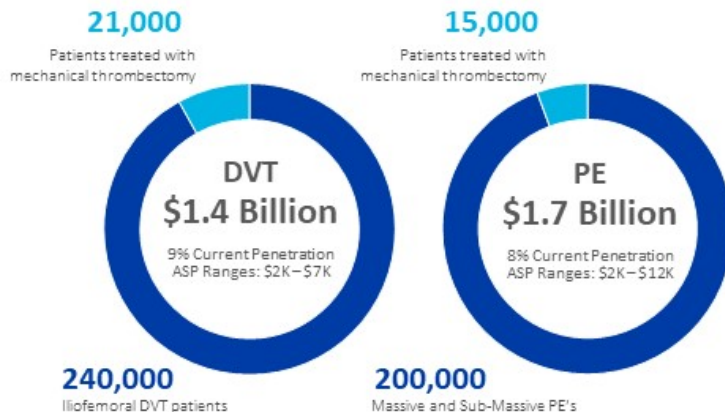


# There Are Large, Underpenetrated Market Opportunities In Clot Removal

## ARTERIAL CLOT REMOVAL U.S. MARKET



## VENOUS THROMBOEMBOLISM (VTE) CLOT REMOVAL U.S. MARKET



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Patient figures and ASP ranges based on Management Estimates as well as Public Health and Industry Data. Our devices have not received DVT and/or PE disease state clinical indication clearance at this time.

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# There's a Lot More Life Left in These Limbs



DVT is a major health problem affecting >800,000 U.S. patients/year<sup>(1)</sup>

Currently available technologies have shortcomings that limit broad-scale adoption

Delays in treatment can impact longer-term outcomes and elevate risk of post-thrombotic syndrome

**Get In. Get Out.  
Get on With Life.**

**Clinical Indications:** Indicated for mechanical de-clotting and controlled and selective infusion of physician specified fluids, including thrombolytics, in the peripheral vasculature

**Device Status:** FDA Clearance 2020; CE Mark approval 2021  
19-patient study with 12-month follow-up  
Market evaluations scheduled 2022

(1) Virani SS, Almonro A, Benjamin EJ, et al. Heart Disease and Stroke Statistics-2020 Update: A Report From the American Heart Association. Circulation. 2020;142(9):e198-699.

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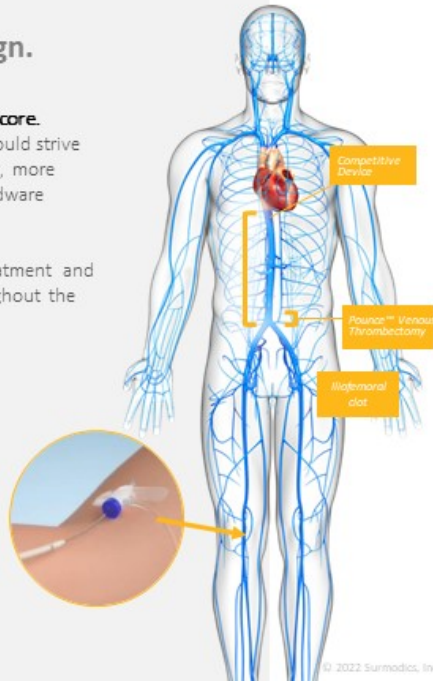
# Pounce Venous Thrombectomy: Patient First

## Atraumatic design.

**Designed to separate, not core.**  
Venous thrombectomy should strive to be faster, more efficient, more intuitive and minimize hardware impact on anatomy

**The goal:** Enable faster treatment and greater accessibility throughout the healthcare system

**10 Fr access:**  
Lower profile reduces concerns about popliteal access, anatomical impact, and closure complications.



## Because a vein is an organ.

**Reduced landing zone:** Pounce venous thrombectomy requires a shorter landing zone compared to the longer coring mechanism and collection bag of competitive mechanical device



**Minimal hardware footprint:** Rounded outer edge of the flexible basket is the only point where metal meets tissue

**Self-adapting radial force:** Basket maintains consistent circumferential force in veins ranging from 6-16 mm diameter

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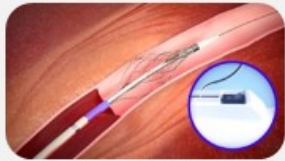
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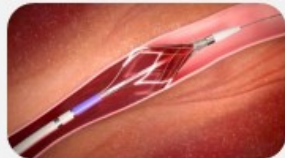
# Pounce Venous Thrombectomy: Product Design

## See it in action.

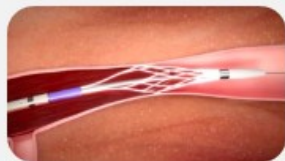
View the animation and device specs



Expand the basket using the handle dial.



Activate the extraction screw



Pull the catheter through the clot

**Dual-action Mechanical Thrombectomy** separates clot from vein wall and extracts it at the point of collection— *without* removing the device from the patient

**1 Wall-to-wall clot capture**  
Consistent spring tension basket separates clot from the vein wall and channels it to a window on the catheter lumen

**2 Motorized removal**  
The 25,000-RPM extraction screw draws clot from the basket and rapidly removes it from the patient



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Sublime™ Radial Access  
Guide Sheath



Sublime  
RX PTA **014**



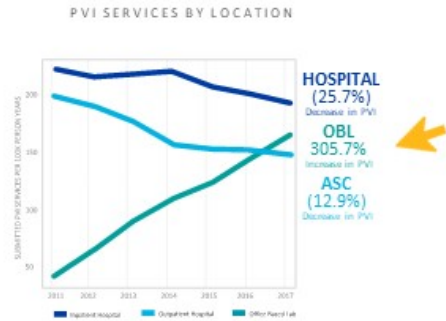
Sublime  
RX PTA **018**



# Targeting the Greatest Needs and Largest Opportunities

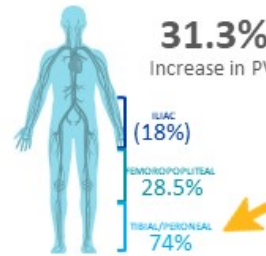
Perfect for the OBL: Radial is less invasive, fewer complications, rapid recovery, faster throughput

When a limb is on the line, you absolutely, positively have to get there (from any access site).



Peripheral Vascular Interventions (PVIs) are rapidly shifting to office-based labs

CHANGE IN PVI PROCEDURE VOLUME BY ANATOMICAL LOCATION



Majority of PVI procedure growth is focused below the knee (BTK)

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Schramm KM, DeWitt PE, Dyal S, et al. Recent Trends in Clinical Setting and Provider Specialty for Endovascular Peripheral Artery Disease Interventions for the Medicare Population. J Vasc Interv Radiol. 2020;31(4):614-621.e2.

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# Radial Access Technology Can Accelerate the Shift to OBLs

Learn more about the proven benefits of radial access



## Lasting impressions last.



**REDUCED COMPLICATIONS**  
50–80% relative risk reduction in access site complication<sup>1,2</sup>



**RAPID RECOVERY**  
Quick ambulation and early discharge frees up staff, beds and resources to increase volume<sup>1,4</sup>



**REDUCED BLEEDING**  
47% reduction in major bleeding and a 77% reduction in complications when using radial access<sup>1,3</sup>



**POSITIVE EXPERIENCE**  
Patients prefer transradial approach because they experienced less pain and greater walking ability post-procedure<sup>1,5</sup>

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1. As compared to transfemoral access/intercoronary procedure. 2. Jolly SS, Yusuf S, Gomm L, et al. Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndrome (RIVAL): a randomised, parallel group, multicentre trial. *Lancet*. 2011;377:1420-30. 3. Panaritis G, et al. Radial Versus Femoral Access for Coronary Interventions Across the Entire Spectrum of Patients with Coronary Artery Disease: A Meta-Analysis of Randomized Trials. *JACC: Cardiovascular Interv*. 2014;6(2):248-258. 4. and the SM. McKinley G, et al. The Value of Transradial: Impact on Patient Satisfaction and Health Care Economics. *Interv Cardiol Clin*. 2009;4(1):107-115. 5. George K, B Shabbir R, Cohen D, et al. Effect of transradial access on quality of life and cost of cardiac catheterization: a randomized comparison. *Am Heart J*. 2010; 158(3): 410-416.



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# Sublime™ Radial Access Expands The Market By Enabling Radial Access

## Radial Access PTA Catheter U.S. Market

<1,000

Patients treated with radial access interventions



125,000

Patients treated with 014" PTA interventions

13,000

Patients treated with radial access interventions



150,000

Patients treated with 018" PTA interventions

## Radial Access Guide Sheath U.S. Market

70,000

Patients treated with radial access interventions



810,000

Patients treated with ATK or BTK Interventions

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Simply Surmodics

Simply Driven

Simply DCB

Simply Pounce

Simply Radial

Simply Solid

Simply Strong

Small text: Patient figures and ASP ranges based on Management Estimates as well as Public Health and Industry Data

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# Sublime™ Platform Can Get You There From Any Access Site

Why will SUBLIME products make you jump for joy?



**When It Absolutely, Positively Has To Get There.**

**When a limb is on the line, physicians need to be confident they can tackle tough lesions.**

- Sublime™ Guide Sheath beats the competition:
  - Kink resistance – 60% better kink resistance<sup>1</sup>
  - Radial Strength – 15% stronger<sup>1</sup>
  - Torque Transmission – 1.3X better torque response<sup>1</sup>
- Sublime™ PTA Balloons provide superior lesion crossing capabilities at longer lengths than others
  - Crossability<sup>1</sup> and pushability<sup>1</sup> exceed other PTA balloons
  - Our 250 cm 014" Sublime™ RX PTA catheter is 50 cm (25%) longer than any other commercial 014" PTA balloon



<sup>1</sup>Based on average measurements from bench testing by Surmodics, Inc. Data on file. Scan QR code to view competitive testing.

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# Medical Device Coatings

## Performance COATINGS



HYDROPHILIC



HEMOCOMPATIBLE



DRUG-DELIVERY

See why we're  
the best

Watch video



# The Magic Is In The Coating

Surmodics' coatings are critical to the successful delivery of medical devices used in complex procedures where maneuverability and control are essential



## Hydrophilic

Low friction and low particulates to improve deliverability



## Hemocompatible

Active and passive coatings; customizable to blood compatibility and durability requirements



## Drug-Delivery

Durable and biodegradable coatings using proprietary polymers to control delivery rates and mechanical properties

## Estimated Distribution of Surmodics' Royalty Revenues

### ROYALTY REVENUE DISTRIBUTION<sup>1</sup>

<10%

25%-35%

**Structural Heart**  
Royalty Rev = <10%  
CAGR = 12-15%



**Neurological**  
Royalty Rev = 25-35%  
CAGR = 6-10%

**Cardiovascular**  
Royalty Rev = 25-35%  
CAGR = [1]-2%

**Peripheral Vascular**  
Royalty Rev = 25-35%  
CAGR = 4-6%

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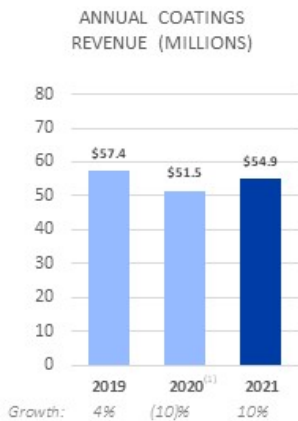
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<sup>1</sup> CAGRs = Needham & Associates and Company estimates (prior to COVID-19 Pandemic)  
<sup>2</sup> Based upon Surmodics' historical royalty revenue mix

# A Stable Foundation For Future Growth

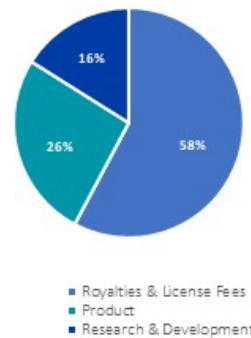
## Medical Device Coatings

- Over 150 license agreements among 100 customers
- 30 U.S. patents issued; 64 International patents Issued
- Royalty rates for new licenses typically range from 2-3% for the device application
- Product gross margins on the high end of medical device industry averages



*(1) Impacted by COVID-19 as well as patent expiration for our 4th generation coating*

REVENUE BREAKDOWN



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# In Vitro Diagnostics (IVD)



**AMP UP THE SIGNAL.**  
DIAL DOWN THE NOISE.

# Leading Provider Of Components for IVD Tests and Microassays

Check out our full line of products



Protein stabilizers, diluents & blockers



ELISA substrates



Microarray slides & surfaces



Antigens & antibodies from DIARECT™ part of BBI solutions™



Stop solutions & support reagents

## In Vitro Diagnostics

- Our components are used in test kits sold by the majority of the top ten global in vitro diagnostics companies
- > 1000 unique customers in several categories: Kit manufacturers, R&D institutions, Distributors and OEM's
- Point of care testing and regulatory changes are disrupting the market and represent opportunity for market share growth

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 SURMODICS

# Our Business Model Creates Long-lasting Partnerships



### Development Partners

Partnering with customers during test development allows us to supply high performance critical raw material components for new immunoassay tests



### Focus on Quality

Our focus on quality ensures streamlined manufacturing and consistent assay performance throughout the commercial life of the product



### Customer Service

Gold standard customer service, technical support and regulatory expertise keep customers loyal to Surmodics IVD

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# Continued Outstanding Results

## IN VITRO DIAGNOSTICS



- Our IVD business is expected to continue to deliver mid-to-high single digit revenue growth annually
- Strong and growing customer base with broad portfolio of differentiated products
- Operating margin has improved each of the past three years to approximately 51% of revenue, or \$13.8 million in FY2021
- The \$15-\$17B global immunoassay market is expected to grow 3-4%, annually
- Recent M&A transactions have valued diagnostics suppliers at 14-16X EBITDA<sup>(1)</sup>

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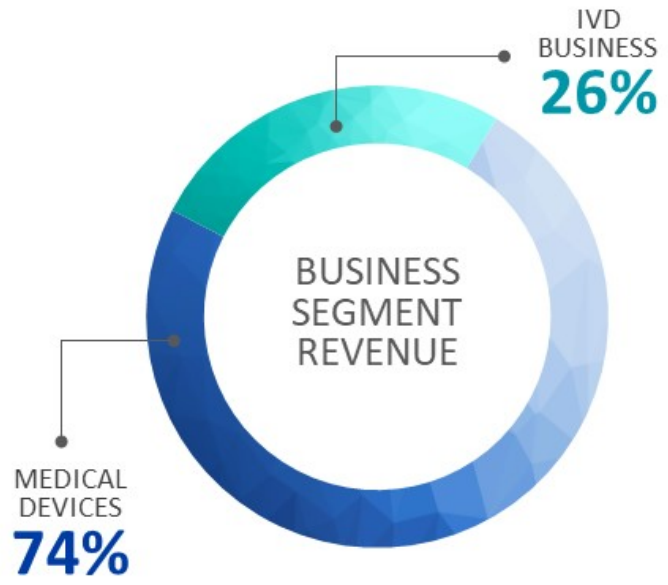
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<sup>(1)</sup>Recent precedent transactions



## Surmodics Business Segments

For the twelve months ended September 30, 2021





# History of Strong Financial Performance

## Funding our Growth Investments from Within:

Our solid balance sheet and financial performance has self-funded our growth-driving portfolio investments

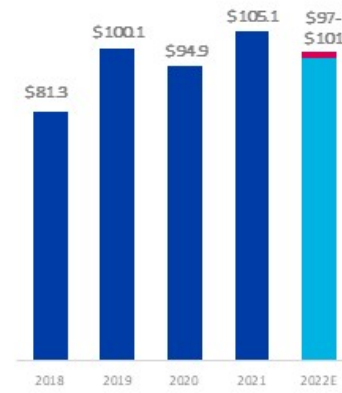
- \$40.9 million of cash/investments as of September 30, 2021
- Operating cash flow of \$15.4 million and Adjusted EBITDA of \$12.0 million for fiscal 2021

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

QUARTERLY REVENUE (MILLIONS)



ANNUAL REVENUE (MILLIONS)



(1) Includes \$10.8 million related to the successful completion of a milestone in our SurVeil™ DCB agreement with Abbott

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# 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)	September 30, 2021
Cash	\$31.2
Available-for-sale Investments	\$9.7
Revolving Line-of-Credit	\$15.0
<b>Total</b>	<b>\$55.9</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 platform
- Radial access platform

**Validate Commercial Opportunity**

- Build infrastructure to support commercialization of our Pounce™ and Sublime™ products

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# Financial Guidance

(As presented Nov. 10, 2021)



## 2022 Financial Guidance



## Long Term Objectives

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

### Total Revenue: \$97 million to \$101 million, including:

- \$4.5 - \$5.0 million of SurVeil™ DCB license fee revenue (compared with \$16.0 million in fiscal 2021)<sup>(1)</sup>
- \$2.0 - \$2.5 million of Pounce™ and Sublime™ product sales

### GAAP Loss per Share<sup>(2)</sup>: \$(2.05) to \$(1.55), including:

- Approximately \$10 million to support commercialization of our Pounce™ and Sublime™ products
- Approximately \$10 million of additional R&D investments to accelerate strategic initiatives

### Non-GAAP Loss per Share<sup>(2)</sup>: \$(1.75) to \$(1.25)

Consistent double-digit revenue growth beginning in fiscal 2023, driven by expected commercialization of SurVeil™, Pounce™ and Sublime™

(1) Our fiscal 2022 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 2022 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 2022 acquired intangible amortization totaling \$0.30 per share, net of tax.

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# Appendix



# Strategic Agreement with Abbott



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## 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)
- Option to negotiate agreement for Sundance™ below-the-knee (BTK) DCB
- 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
- Received Abbott's good faith estimate of U.S. product launch quantities
- 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



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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 Q4 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

~78% of the estimated total \$35M – \$40M TRANSCEND Clinical Study costs were incurred through Q4 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:  $\$25M \times (\sim 51\% \cdot \sim 18\%) = \$8.4M$
- TRANSCEND completion milestone:  $\$10M \times \sim 51\% = \$5.1M$

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

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

## 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%	~83%			~100%

## Revenue Recognition Schedule

Revenue (\$ in millions)	FY 2019A	FY 2020A	FY 2021A	FY 2022E
Upfront License Fee	\$8.4	\$3.5	\$2.6	\$1.8 – \$2.0
TRANSCEND Completion Milestone	5.1	1.4	1.0	0.7 – 0.8
CE Mark Milestone	-	7.0	1.1	0.8 – 0.9
Clinical Report Milestone	-	-	11.3	1.2 – 1.3
PMA Approval Milestone <sup>(2)</sup>	-	-	-	-
<b>Total Surveil Upfront &amp; Milestone Revenue</b>	<b>\$13.5</b>	<b>\$12.0</b>	<b>\$16.0</b>	<b>\$4.5-\$5.0</b>
<b>Cumulative Revenue</b>	<b>\$17.9</b>	<b>\$29.9</b>	<b>\$45.9</b>	<b>\$50.4-\$50.9</b>
<b>% recognized*</b>	~51%	~65%	~76%	~82-84%

- (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  
 (2) PMA milestone revenue would be approximately \$25M if the milestone is met in fiscal 2022

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

# 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)

## IN VITRO DIAGNOSTICS



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

## VASCULAR INTERVENTIONS



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

## MEDICAL DEVICES



**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)



# Clinical Advisors



**Gary Ansel, MD, FACC**  
Clinical Advisor — Interventional Cardiology  
Healthcare Insights



**Stephen Black, MD**  
Clinical Advisor — Vascular Surgeon  
St. Thomas Hospital



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



**Raghu Kolluri, MD, MS, RVT**  
Clinical Advisor — Vascular Medicine & Vascular Labs  
Ohio Health Heart and Vascular Service



**Michael Lichtenberg,**  
Clinical Advisor — Interventional Angiologist  
Klinikum Hochsauerland



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



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



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



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



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