Surmodics Builds Thrombectomy Portfolio with Acquisition of Vetex Medical Limited

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Deal adds second FDA 510(k) cleared device to thrombectomy platform

- *Easy-to-use, stand-alone, single session mechanical thrombectomy for removal of venous clot in highly attractive, rapidly growing and significantly under-penetrated market*
- *FDA 510(k) cleared (Dec. 2020) and CE Mark Certification (May 2021)*
- *12-month follow-up data of 19-patient feasibility trial presented at American Venous Forum (March 2021) all primary endpoints met with no safety issues*[1]
- *Positions Surmodics with two FDA-cleared mechanical thrombectomy devices to treat arterial and venous vasculature and IP for potential indication expansion*

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Jul. 6, 2021-- Surmodics, Inc. (NASDAQ: SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, announced today that it has acquired privately held Vetex Medical Limited. The Galway, Ireland based medical device developer and manufacturer has focused exclusively on venous clot removal solutions. The transaction expands Surmodics' thrombectomy portfolio with a second U.S. Food and Drug Administration (FDA) 510(k)-cleared device, the ReVene™ Thrombectomy Catheter.

The ReVene mechanical thrombectomy catheter is specifically designed to remove large, mixed-morphology blood clots commonly found with venous thromboembolism (VTE). The device's dual action technology efficiently removes mixed-morphology clot in a single session, minimizing the need for thrombolytics and without capital equipment.

"This acquisition demonstrates our commitment to the expansion of our thrombectomy platform to remove thrombus in venous vascular beds, with an exciting technology that offers significant improvements over current therapies," said Gary Maharaj, President and Chief Executive Officer of Surmodics. "Surmodics is now well positioned with two ground-breaking, FDA-cleared mechanical thrombectomy devices to treat both arterial and venous thrombosis. The synergies between the Vetex technology and their talented team, with our capabilities on our Pounce thrombectomy technology enables us to accelerate our thrombectomy platform development for the future treatment of pulmonary embolism (PE)."

"The ReVene Thrombectomy Catheter has the potential to significantly expand the use and accessibility of venous mechanical thrombectomy by allowing physicians to intervene early and complete the procedure in a single session," said Stephen Black, principal investigator and leading enroller of the VETEX feasibility study and Consultant Vascular Surgeon at Guy's and St. Thomas' NHS Foundation Trust, London. "The ease of use, intuitive design and efficient performance of this device enables it to become the first-line treatment and a confident choice by venous interventionalists."

Under the terms of the acquisition agreement, Surmodics acquired Vetex with an upfront payment of $39.9 million. Additional payments of up to $7 million, $3.5 million of which are guaranteed, may be made upon achievement of certain product development and regulatory milestones. The upfront payment was funded using cash on hand and $10 million from Surmodics' $25 million revolving credit facility. The acquisition will be dilutive on a GAAP and non-GAAP basis in Surmodics' fiscal 2021 and is expected to be accretive on a non-GAAP basis, excluding acquired intangible asset amortization expense, beginning the second half of fiscal 2023. The company expects fiscal 2021 acquisition-related costs and acquired intangible asset amortization expense to range from a total of $0.10 to $0.12 per share. Surmodics plans to provide updated fiscal 2021 guidance, including the impact from the Vetex acquisition, during its third quarter earnings announcement.

Surmodics expects to initiate clinical evaluation activities for the Pounce Arterial Thrombus Retrieval System for removing clot in peripheral arteries in the second half of fiscal 2021 and for the ReVene™ Thrombectomy Catheter for removal of clot from veins in fiscal 2022. A projected timeline for further commercialization will be announced later this fiscal year.

About Venous Thromboembolism (VTE)

VTE is an underdiagnosed and serious, yet preventable medical condition that can cause disability and death. VTE includes deep vein thrombosis (DVT), which occurs when a blood clot forms in a deep vein, usually in the lower leg, thigh, or pelvis, and PE, which occurs when a clot breaks loose and travels through the bloodstream to the lungs. In the United States, over 900,000 people present with VTE each year, of which approximately 650,000 are diagnosed with DVT.[2] The current standard of care for treating VTE is conservative medical management with anticoagulant drugs designed to prevent further blood clotting.

While anticoagulation remains the most widespread therapy for DVT, interventional treatment has demonstrated the potential for better outcomes in select patients. Currently available interventional DVT treatment options include the use of thrombolytic drugs to dissolve clot, with or without the use of a mechanical device, or capital equipment-based mechanical devices that use fragmentation and/or aspiration to create a core through the center of the clot. Purely stand-alone mechanical devices are catheter-based systems designed to capture and remove clot from the venous anatomy. Because thrombolytic agents thin the blood, they present a bleeding risk for many patients and can require prolonged hospital stays and ICU monitoring. Without effective treatment, patients are at risk for pulmonary embolism or long-term complications. Up to 50 percent of patients with symptomatic DVT will develop post-thrombotic syndrome (PTS) within two years, which causes chronic limb pain, swelling, heaviness, fatigue, and in extreme instances, limb ulceration.

The FDA requires specific indications for devices to be marketed for treatment of certain aspects of VTE such as DVT and PE. The ReVene Thrombectomy Catheter is indicated for mechanical de-clotting and controlled and selected infusion of physician specified fluids, including thrombolytics, in the peripheral vasculature. The device currently is not indicated for the treatment of DVT or PE.

About Vetex Medical Limited

Vetex Medical Limited was a privately held company headquartered in Galway, Ireland, focused on developing innovative, effective, and efficient solutions for removal of venous thromboembolism to improve clinical outcomes and quality of life for patients. The ReVene Thrombectomy Catheter is the company's first innovation product specifically engineered for use in the treatment of venous disease. For more information, visit www.vetexmedical.com.

About Surmodics, Inc.

Surmodics is the global leader in surface modification technologies for intravascular medical devices and a leading provider of chemical components for in vitro diagnostic (IVD) immunoassay tests and microarrays. Surmodics is pursuing highly differentiated medical devices that are designed to address unmet clinical needs and engineered to the most demanding requirements. This key growth strategy leverages the combination of the Company's expertise in proprietary surface technologies, along with enhanced device design, development, and manufacturing capabilities. The Company mission remains to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota. For more information, visit www.surmodics.com. The content of Surmodics' website is not part of this press release or part of any filings that the company makes with the SEC.

Safe Harbor for Forward-Looking Statements

This press release contains forward-looking statements. Statements that are not historical or current facts, including statements about potential expansion of our thrombectomy platform to remove thrombus in different vascular beds, our thrombectomy platform development (and its potential acceleration) for the future treatment of PE, the potential for the ReVene Thrombectomy Catheter to significantly expand the use and accessibility of venous mechanical thrombectomy, the potential for the ReVene Thrombectomy Catheter to significantly expand the use and accessibility of venous mechanical thrombectomy, the potential for the ReVene Thrombectomy Catheter to be a first-line treatment choice, the anticipated financial impacts of the Vetex acquisition, expectation about the timing of initiating clinical evaluation activities, anticipated future disclosures and announcements by the company, and the company's growth strategy, 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 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. 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.

References:

1. Black S, et al. VETEX European study of the ReVene Thrombectomy Catheter. Presented at VENOUS 2021, the annual meeting of the American Venous Forum. March 17, 2021.

2. Blood Clots: A Serious but Preventable Medical Condition. CDC Fact Sheet. https://www.cdc.gov/ncbddd/dvt/documents/blood-clots-fact-sheet.pdf. Accessed June 5, 2021.

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