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VentureMed's FLEX Vessel Prep™ System safely and effectively modifies Obstructive Plaque and Stenoses to facilitate Delivery of Drug Therapies to treat Peripheral Arterial Disease

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CEOCFO: ***Mr. Paulson, what is the overall vision at VentureMed Group Inc? What is your focus right now?***
Mr. Paulson: The overall vision is to improve outcomes for patients suffering from peripheral arterial disease, and extend the time between repeat arteriovenous access procedures for hemodialysis patients, with a device that helps to safely and effectively prepare a vessel to optimize delivery of the definitive therapy.

CEOCFO: ***What are the challenges in preparing and what have you devised that will help?***
Mr. Paulson: One of the big challenges in treating peripheral vasculature disease is that many of the therapies and devices used today were developed for use in coronary vessels, and peripheral vessels have a different biology and are in a different anatomical location. Historically, endovascular, or minimally invasive, approaches to open obstructed peripheral arteries have resulted in high levels of restenosis or reoccurrence of the vessel occlusion.

Over the past several years, drug therapies have emerged as an effective definitive therapy to treat peripheral arterial disease and maintain arteriovenous access for hemodialysis. Drug coated balloons and drug-eluting stents deliver an anti-restenotic drug to inhibit the post-procedure inflammatory response that can cause vessels to re-obstruct and re-close. The data also has demonstrated that to effectively deliver or transfer the drug from either a drug coated balloon or a drug eluting stent, the wall of the device must be in contact with the inner wall of the vessel. This is the reason vessels must be prepared prior to delivering the definitive therapy - obstructive plaque, be it soft or calcific, and fibrous stenoses, are barriers to drug transfer and must be modified to create pathways that allow the drug to diffuse to the vessel wall.

Over the years, a variety of devices have been used to open occluded vessels, including high pressure angioplasty balloons, specialty angioplasty balloons with wires or blades wrapped around the balloon, and atherectomy devices that debulk or remove plaque. These balloon-based vessel preparation devices apply focal force to expand and stretch the vessels, which often causes the vessels to tear or dissect. Similarly, atherectomy devices which apply mechanical force or laser energy to remove plaque, often inadvertently cut into the vessel wall and cause dissections and perforations.

If a dissection is severe enough, a stent, which is a small metal scaffold, must be deployed to repair the dissection and keep the vessel lumen open. Peripheral arteries, unlike coronary arteries where the chest wall protects the vessels from outside stress, are surrounded by muscle and bone in the legs – as people twist, torque, and turn, peripheral arteries undergo external stress and peripheral stents can fracture and collapse which then re-obstructs blood flow in the vessel. Approximately 30-40% of peripheral arterial revascularization procedures today are performed to address this recurrence of obstructions in stented vessels (i.e., in-stent restenosis).

What has been missing is a simple, effective, easy-to-use device that can quickly, safely, and effectively prepare peripheral arteries and modify obstructive plaque and fibrous stenoses, and facilitate delivery of the definitive therapy, including diffusion of drug therapies – that is what the FLEX Vessel Prep™ System is designed to do.

CEOCFO: ***How does the Flex Vessel Prep System work?***
Mr. Paulson: The FLEX System is used as part a traditional endovascular approach, and is designed to create linear, controlled-depth, circumferential micro-incisions in lesions or stenoses of any length or vessel morphology.

The FLEX treatment element, located on the distal end of the device, has three flexible struts. Along the proximal end of each strut is a microsurgical blade with a cutting height of approximately 0.25mm. When the treatment element is deployed in the vessel lumen, it expands with a radial force of just over one atmosphere of pressure, which allows the microsurgical blades on the struts to engage in the obstructive lesion or stenosis, but not with enough force to stretch, tear or dissect the vessel.

"An elegantly simple, safe, and effective device with the potential to fundamentally change the way peripheral arterial revascularization and arteriovenous access procedures are performed." J. Robert Paulson, Jr.

Once the treatment element is deployed, the FLEX device is pulled back (in a retrograde motion) from the distal to the proximal end of the obstructive lesion or stenosis. The three struts of the FLEX treatment element function dynamically and independently of the other – each strut individually "flexes" like skis on a ski slope during the pullback, adapting to each patient's vessel anatomy and morphology. The FLEX device creates continuous, controlled-depth, circumferential micro-incisions along the entire length of the treated lesion or stenosis. These micro-incisions improve vessel compliance by releasing the circumferential tension in the diseased portion of the vessel, and operators have the discretion of doing multiple passes with the FLEX device based on each patient's vessel morphology.

The improved vessel compliance allows the definitive drug-coated balloon or drug-eluting stent therapies to be delivered at lower inflation pressures, significantly reducing the risk and severity of vessel tears or dissections. In addition, these micro-incisions create channels or pathways to facilitate diffusion of the drug therapies into the vessel to reduce the risk of restenosis.

This approach contrasts with other vessel preparation devices that are engaged at the proximal end of obstructive lesions and are advanced by pushing forward through the lesion, which is a bit like pushing on a rope through a cylinder, without knowing what lies ahead of you. This approach can challenge operators' ability to visualize and control the path and location of the vessel preparation devices.

CEOCFO: ***How did this method come about? Was it that someone had a eureka moment one day and you then you had to figure out how to do it?***
Mr. Paulson: VentureMed's founder, Dr. John Pigott, is a vascular surgeon. Dr. Pigott performed thousands of endovascular peripheral procedures over the course of his career and, for many years, had used atherectomy devices to prepare vessels and modify plaque before delivering the definitive therapy. Atherectomy procedures can be challenging and complicated to perform due to the variable and unpredictable nature of peripheral arterial disease, which can include areas of calcified plaque, soft (neointimal) plaque, and mixed plaque morphology in the same patient. The mechanism of

action for atherectomy devices varies – some rotate or sand-off calcific plaque, while others cut or debulk both calcific and soft plaque.

Dr. Pigott realized cutting atherectomy devices, which are used in both calcified and soft plaque, were making cuts with a depth of 0.25-0.30mm. Pushing these cutting atherectomy devices through tortuous vessel anatomy also required the use of embolization devices to capture debris sheared off during the cutting process that could otherwise flow "downstream" and increase the risk of blockages or clots that could cut off blood flow or even cause strokes. An embolic protection device is like an inverted umbrella that must be placed in the in the vessel below the lesion prior to using the atherectomy device. The embolic protection device must then be retrieved after the atherectomy portion of the endovascular procedure, but prior to delivery of the definitive therapy.

Dr. Pigott believed there had to be a simpler, easier approach given the objective was to create controlled-depth, circumferential micro-incisions of approximately 0.25mm in in the target lesions and do so while maintaining visualization of the device when modifying the plaque or stenosis. The result was the innovative FLEX design described above. FLEX is a wonderful example of a physician who personally experienced the challenges and unmet clinical needs of a complex and challenging procedure, was able to envision the critical elements of a simple device to address these clinical challenges of vessel preparation across the spectrum of patient anatomies, and then translate that vision into the design and development of the FLEX System.

CEOCFO: ***Where are you in the development and/or commercialization process?***
Mr. Paulson: The FLEX Vessel Prep System is FDA-cleared and CE Marked to treat peripheral arterial disease and stenoses of arteriovenous fistulas and grafts, and recently received an expanded indication for the treatment of in-stent restenosis. In October, we added an experienced team of medical device sales professionals to launch our second-generation FLEX System in the U.S. and plan to begin a limited commercialization in Germany in early 2021.

CEOCFO: ***What is the market opportunity? How many procedures might be done annually that could use your device?***
Mr. Paulson: The treatment of peripheral arterial disease is a three-billion-dollar global market. Approximately eight hundred thousand revascularization and lower limb amputation procedures are performed annually in the U.S. In addition, there are approximately 700,000 endovascular procedures performed in the U.S. annually to restore AV access for patients undergoing hemodialysis for end-stage renal disease.

An important part of this opportunity is the fact that peripheral vascular stents, used in to repair the tears and dissections from traditional vessel preparation procedures, frequently re-occlude, requiring a follow-up revascularization procedure. Thirty to forty percent of peripheral revascularization procedures performed are to treat a reclosure or a restenosis inside the stent.

CEOCFO: ***What has been the response from doctors/surgeons/***
Mr. Paulson: The FLEX device is simple, intuitive and makes sense. The simplicity of the FLEX device contrasts with the complexity of other vessel prep devices in the market. That said, physicians often express an initial skepticism that FLEX micro-incisions will be effective across the spectrum of peripheral arterial occlusions or arteriovenous stenoses. Our real-world FLEX clinical data in over seven hundred patients demonstrates very consistent safety and efficacy outcomes, including:

- Long (≥15 cm) diffuse, mixed morphology lesions which are challenging to treat with other vessel preparation devices, and often requires the use multiple devices; and

- In-stent restenosis, which is challenging to address with, and/or contra-indicated for, mechanical atherectomy devices, and limited effectiveness with balloon-based angioplasty devices.

While our real-world data is compelling, the key to overcoming the initial skepticism is getting the FLEX device into physicians' hands and allow them to see and experience the effectiveness vessel prep with FLEX as part of performing peripheral revascularization procedures on their patients.

CEOCFO: ***What type of training might a physician need to use the device?***
Mr. Paulson: One of the most compelling features of the FLEX System is simplicity - it is very intuitive, easy-to-learn and simple to use. Endovascular peripheral revascularization procedures typically are performed by vascular surgeons, interventional cardiologists, and interventional radiologists. These physicians specialize in endovascular procedures, all of which require the same basic approach using guiding catheters, guide wires, and other devices inserted over the guidewires and through the guiding catheters. The FLEX device utilizes the same procedural approach, with no additional equipment required.

Because FLEX is used as part of the same endovascular procedures performed by these physicians every day, there is no need for extensive training sessions or cadaver workshops to learn how to use the device. In preparation for commercial launch of our second-generation FLEX device, our team has developed a series of online and mobile app-based FLEX training videos and materials. These training tools allow physicians and their staff to be trained remotely, even when a company representative is unable to attend a procedure, as is the situation in many hospitals during the current COVID pandemic.

CEOCFO: ***You personally have as long history in the industry. What have you learned that helped you navigate through so far and that you will be able to continue to draw on as the commercialization is happening? What have you learned over the years?***
Mr. Paulson: So much! Over the course of my career, I have had the opportunity to work with teams that created, designed, developed, and commercialized a variety of sophisticated and complex medical devices and systems, including image-guided neurosurgical and spinal surgery systems, intracardiac arrhythmia mapping and navigation systems, and systems that delivered precise doses of thermal energy to treat urological conditions.

I was attracted to VentureMed by the large unmet clinical need, and the simple elegance of the FLEX System. While the device is simple and straightforward, the market is complex and competitive. Successfully commercializing an innovative new device like FLEX in today's rapidly evolving healthcare market requires a disciplined design and development process on the front-end; generating compelling and timely real-world clinical data that demonstrates both safety and efficacy, improved healthcare economics, and; executing commercial marketing and sales strategies that effectively communicate the FLEX value proposition and how that addresses a recognized unmet clinical need.

The most important ingredient in this recipe for success is people – recruiting and retaining individuals with the background, skill sets, experiences, and passion to execute these inextricably intertwined strategies. It requires a culture where each member of each functional team is aligned on and committed to a common vision, embraces the challenges and opportunities of bringing a novel device to the market, are not afraid to take risks, communicate candidly and effectively with each other, and trust each other.

Large medical device companies have the resources to recruit and retain large teams of functional experts. In contrast, small venture-funded companies require small teams of people who have multi-functional knowledge and experience along the medical device life cycle continuum, from product design and development, executing clinical studies and obtaining regulatory approvals, and early commercialization followed by commercial scale-up. Each phase of this life cycle requires different experiences and skill sets, and often-times, individuals who are effective in one stage, are challenged during another stage. The "art" is to build and evolve small-company teams based on the milestones/deliverables required during each stage of a company's evolution. Optimally, you hire and develop people who not only know how to "read the score and conduct the orchestra", but also have the skills and interest to continue to "play the instruments" whenever they are required to do so.

CEOCFO: ***Are you seeking funding, investment, or partnerships at this point?***

Mr. Paulson: We have just begun the process of raising a series C round of capital to support the company's next phase of commercialization.

CEOCFO: ***There are so many new ideas today in health. How do you get the attention, particularly obviously, under COVID? What is the key?***
Mr. Paulson: The keys are having a value proposition that resonates with physicians and effectively demonstrating your device makes a difference in how physicians treat and care for their patients. While patient safety and improved outcomes are priorities number one and two, the device also must fit within the healthcare economics of physicians' practices. Healthcare economics involves considerations beyond payment for the device such as lower rates and severity of complications, shorter procedure times (which can mean reduced levels fluoroscopic radiation exposure for physicians and staff), and fewer ancillary devices. For FLEX, that means improving outcomes and reducing the cost and complications of revascularization procedures.

CEOCFO: ***Is it easier when approaching investors if you are doing something that is understandable, that people can wrap their heads around?***
Mr. Paulson: Yes. In the medical device venture capital world, what constitutes a compelling investment opportunity has changed immensely over the past ten to twelve years. Medical device companies today have access to an increasingly smaller share of healthcare venture capital investments as compared to other sectors like specialty pharma, biopharma and biotech, digital health, and tools and diagnostics. A medical device technology must stand-out and be compelling relative to the other ideas and opportunities each potential investor is considering. The keys are finding investors (i) for whom the company's product's distinctive value proposition and leadership team fit the firm's investment thesis, priorities, and timelines, (ii) whose expectations are aligned with the company's priorities, and (iii) who are confident in and will support the company throughout the process of delivering those value-enhancing milestones that will generate an appropriate return on investment. At the end of the day, it is always about a compelling investment opportunity in a large, accessible market with unmet needs, and the opportunity for investors achieve a meaningful liquidity event within their target timelines.