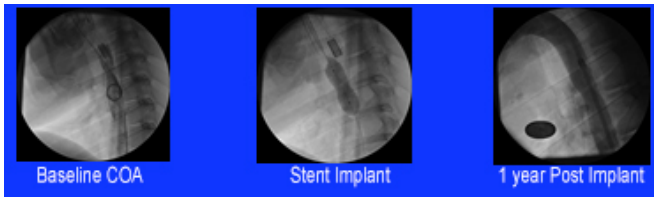
BIORESORBABLE STENTS FOR CONGENITAL HEART DISEASE

TREMEDICS MEDICAL DEVICES, LLC

Team: Tre Raymond Welch, PhD, Founder/CEO, who is a stent expert with multiple publications and patents on stent technology and has experience working in startup companies. SurendranathVeeram Reddy, MD is a Medical Advisor who is a Pediatric Interventional Cardiologist at Children's Health Dallas, TX. Joseph M. Forbess, MD, MBA is a Medical Advisor who is a Pediatric Cardiothoracic Surgeon. Kristine Guleserian, MD is a medical advisor, who is a Pediatric Cardiothoracic Surgeon at Medical City of Dallas, TX. Rhett Butler, BS, CPA, is a financial advisor to the company. Hayden Blackburn, TechFW Executive Director. He is currently the business Development advisor to the company. Ron Plummer, (Flex Medical) Volunteer / Product Manager. Jamie Wright, PhD, Operational Manager. **Technology:** We are solving the clinical need for degradable stents for congenital heart disease (CHD). CHD results in a heart defect causing lesions such as coarctation of the aorta (COA). The use of intravascular stents to address stenotic lesions has revolutionized the management of pediatric and adult CHD patients. Except for one stent, many of the metal stents used in pediatric and adult CHD patient population are used “off-label” to treat these obstructive lesions. These metal stents require at least 6 months and, in some cases, longer duration anticoagulant therapy. Long term, the metal stents can lead to chronic inflammation, restriction of vessel growth, late stent thrombosis, late in-stent restenosis, and stent fatigue fracture. These growing patients need follow-up surgical procedures to continue to force these stents to grow with the patient thus putting these patients at risk for stent fracturing and arterial dissection leading to aneurysms. If these patients are untreated these heart defects can lead to heart failure, stroke, aneurysms, and death. *For growing patients, a bioresorbable stent is needed so that the stent can maintain structural integrity during arterial remodeling and eventually disappear to allow for the subsequent natural growth of the vessel.* **Our solution to this unmet clinical need is Illusicor™. It is a bioresorbable stent that slowly degrades in the body enabling somatic vessel growth.** Preclinical studies have demonstrated safety of device deployment and long-term effectiveness throughout the stent degradation. We have 4 patents and 1 pending application application: US9155640B2, US9480586B2, US9943423B2, 10786373B2, Provisional-191122. **Market Size:** Over 944,000 pediatric patients have CHD (US) and 9.4 million globally. Coarctation of aorta (COA) prevalence is 31,000 US and 752,000 globally. CHD is growing at 5% per year. This is a $210 million market US with a stent price at $6,800. The expansion of this device beyond the US to South Asia is 28,000 COA procedures for less than 1 year of age and 168,000 procedures less than 20 years old. This translates into $1.1 billion service available market. The global market would be 752,000 procedures per year yielding an $5 billion total available market growing to a $6 billion market over next 5 years. **Regulatory & Manufacturing:** We have identified a contract manufacturer, Medical Murray, who has experience with bioresorbable stents clean room manufacturing. They will be testing the biocompatibility, shelf life validation, sterility testing, validation plans and packaging integrity for the stent.Our regulatory strategy is to file for Humanitarian User Designation and then Humanitarian Device Exemption (HDE) to the FDA. We chose this pathway because of the small number of incidences with children being approximately 2,000 patients per year that is less than 4000 patients per year required by the FDA guidelines. Once the HDE is approved, we can implant the device with an approved Institutional Review Board on the medical device to use in children and follow under post market surveillance for the device. Then we can convert to a PMA application to file with the FDA. **Marketing:** We plan to sell the stent directly to the hospital’s interventional catheter labs initially having identified 2 clinics willing to use for human studies. We are seeking strategic partnerships with distributors such as Cardinal Health for nationwide distribution. We have currently been published in several journals and startup columns with Dallas Innovates. **Revenue Model:** We will have losses through 2023 of $1.6 million. We should reach a breakeven point at 240 stents sold. Our reimbursement strategy is to use existing DRG codes for aortic stenting 252, 253, 254. We have applied for breakthrough device designation for Illusicor™. After the PMA submission, we plan to file for Medicare Coverage of Innovative Technology (MCIT). The MCIT proposal will provide national Medicare coverage on the same day as Food and Drug Administration (FDA) market authorization for breakthrough devices and coverage would last for 4 years. This new coverage pathway would offer beneficiaries nation-wide predictable access to new, breakthrough devices to help improve their health outcomes. **Exit Stragtegy:** A likely exit strategy is to merge with a large or medium size company such as Boston Scientific.



American Heart Association.

NIH National Heart, Lung, and Blood Institute

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