THE MARKET OPPORTUNITY

The TAVR Market is reported by both Goldman Sachs and Morgan Stanley to become a $7.4 Billion industry for valves by 2025, with a worldwide CAGR estimated at 19.8% (2014 to 2018) and worldwide market sales projection of $5 billion by 20201. These projections include growth through the inclusion of younger and lower-risk patient populations. The need for embolic protection will be critically important for this expanded, high volume group of patients. The high risk number of patients is significantly smaller than the low/intermediate patients. For scale, in the US, 30% of low-risk patients, 60% of Intermediate, and 80% of high-risk patient groups is the anticipated penetration of available patient populations by 20252. TMI conservatively estimates the Embolic Protection (EPD) market to be at a conversion rate of 50% or greater by 2018 during TAVR procedures. This represents a potential EPD Worldwide Market Opportunity by 2018 in the range of $300 Million plus and upwards of $860 Million by 2025, based on competitive average selling price (ASP).

THE CLINICAL PROBLEM

Left heart procedures, such as TAVR or Surgical Aortic Valve Replacements (SAVR), carry an increased risk for stroke due to embolic debris releasing into the bloodstream and traveling to the brain. Three well-known and understood problems exists: (1) The placement of a new aortic valve triggers blood-borne debris & ischemia in the brain, (2) Blood-borne debris causes brain tissue death (ischemia), and, (3) Procedural debris leads to stroke (ischemia in the brain). “Periperope stroke from cardiovascular procedures is associated with increased mortality and morbidity, prolonged hospitalization, and greater cost and it is often the procedural complication most feared by patients. In recent years, there has been increased attention to these serious adverse events and an increased acceptance that they are occurring at a higher rate than prior studies suggested…preliminary studies suggest that embolic protection and deflection devices appear to represent a promising adjunct to improve the safety of TAVI (Improving outcomes from TAVI. S. Messé, JAMA. 2016;316(6):587-588).”

THE UNMET CLINICAL NEED

The established evidence that 99% of all procedures in the SENTINEL data (JACC. 2016;10.023) show imaging evidence of new ischemic lesions in the brain is of great concern and demands attention. The clinical need for embolic protection devices due to the risk of stroke is well documented in the literature and discussed by key opinion leaders. In order to protect the brain, practitioners now openly emphasize the urgent clinical need for embolic protection devices during TAVR and other left heart procedures. Further, FDA attention to the matter suggests that there is great concern about the under-reported risk of stroke in TAVR procedures. Most importantly, as TAVR procedures expand into Low-and-Intermediate-risk patient groups, the requirement to protect the brain from procedural debris is greatly magnified. “Stroke remains a major predictor of mortality after TAVI. Cerebral protection devices might reduce brain injury as determined by diffusion-weighted magnetic resonance imaging (DWMRI)...the use of a cerebral embolic protection device during the procedure significantly reduced the number of cerebral lesions. (Effect of a cerebral protection device on brain lesions following TAVI in patients with severe aortic stenosis, The CLEAN-TAVI Randomized Clinical Trial, Haussig et al. JAMA. 2016;316(6):592-601).”

However, “The fact that this cerebral protection device (Claret Medical’s Sentinel Device) does not protect the left vertebral circulation is a limitation...” – CLEAN-TAVI: Haussig, MD, Prof. Linke, MD, et al: JAMA AUG2016. The unmet clinical need for complete protection of the entire brain remains to be solved. Protecting all ostia of the great arch vessels is needed as partial protection has demonstrated limited benefit only to defined Protected Territories and non-significant overall protection for the brain as an entire organ.


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With an unprotected left vertebral artery, unfiltered, debris-laden blood still flows into the brain and increases the risk of clinical stroke. The embolic protection devices commercially available with a CE Mark have shown evidence that protecting the brain does show benefit in reducing new ischemic lesions in the brain. However, there clearly exists a worldwide unmet clinical need to provide complete embolic protection for the entire brain and significantly reduce procedural debris impacting acute stroke and adverse cerebral ischemic events (silent stroke), such as in TAVR and SAVR.

THE POINT-GUARD™ SOLUTION

The POINT-GUARD™ Dynamic Cerebral Embolic Protection, is the first cerebral embolic protection device designed with Dynamic Double-Edge Sealing technology. This critical aspect allows for complete protection for the entire brain. POINT-GUARD™ delivers maximum coverage and protects the ostia of all great arch vessel arteries. By conforming and sealing to the aortic arch anatomy, it also addresses the known concern of residual cardiac flow which allows unwanted debris to travel to the brain by flowing around present commercially available embolic protection devices.

The innovative design of POINT-GUARD™ leverages adaptive mechanical forces to achieve wall apposition and stability, cover variable aortic arch anatomy and aortic disease, with precise positioning and deployment to achieve optimal primary sealing and maximum protection, thus providing the clinical operator with simple operation and ease of use. The POINT-GUARD™ is the only embolic protection device designed to address all key attributes and functional features desired of embolic protection during TAVR through: (1) Maximum filtering protection covering all great arch vessels; (2) Dynamic, Double-Edge Sealing to minimize unfiltered blood flow around device edges; (3) Precise placement and adaptive anatomical conformity; (4) Predictable delivery and retrieval; and, (5) Low interference with devices used in left heart procedures. These key-attributes and features differentiate the POINT-GUARD™ from all other known embolic protection devices. It will be the first embolic protection device to completely meet operator and clinical needs providing maximum protection for the entire brain.

COMPETITIVE LANDSCAPE

- Sentinel (Claret Medical) – delivery access via radial/brachial artery; deployed within Carotid arteries; incomplete protection (partial coverage of 2 of 3 great arch vessels; non-dynamic; CE Mark; FDA Clearance anticipated early 2017
- TriGuard (Keystone Medical) – No edge sealing allows residual flow; Non-dynamic; obstructive interfere with TAVR device; CE Mark
- Embrella (Edwards Life Sciences) – incomplete protection (partial coverage of 2 of 3 great arch vessels); delivery access via radial/brachial artery; no edge sealing; non-dynamic; CE Mark

REGULATORY & CLINICAL PATHWAY

The POINT-GUARD™ is a class III product under CE Mark and will be followed by a 510(k) pathway. The number of patients required is to be determined, but FDA now accepts a predetermined number of enrollments from EU clinical studies. The CE Mark for European study and commercialization will be pursued initially and is expected to require at least 50 patients with 30 day post-procedure follow-up.

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FUNDING TO DATE
Private Accredited Investors: $3 Million in Convertible Notes.

INVESTMENT OPPORTUNITY
The Company is currently seeking to complete a Series A offering of preferred stock contingent on investor terms and key Milestone targets.

USE OF PROCEEDS
The Series A funding will support company operations, corporate activities, and successful achievement of key milestones, including: (1) clinical product design freeze, (2) GLP Study & FIH Study, (3) design and execution of CE Mark and FDA 510k clinical trials, with sufficient funding (4) CE Mark Trial, and receipt of CE Mark to begin initial commercial sales in EU.

EXIT STRATEGY
Based on a successful first-in-human study, CE Clinical Study, and CE Mark, the company will be an attractive partner or acquisition target, as POINT-GUARD™ fills a strategic and critical need of the TAVR procedure. Medtronic, Boston Scientific, Edwards Life Sciences, and St. Jude Medical (Abbott) all currently market TAVR devices. It is anticipated that, upon FDA clearance of Claret Medical’s Sentinel device, there will be a quick acquisition/auction environment within the market. Likely acquirers are those companies with TAVR devices currently marketed.

KEY MILESTONES
- Pre-Clinical: In-Vivo Animal studies Q2 3 2016
- Design freeze; Clinical Development Initiated Q3 2016
- CE Study Preparation and Readiness Q1 2017
- CE Pre & Non-Clinical Requirements Q1 2017
- FIH & GLP Study Q2 2017
- EU Clinical Trial Q4 2017
- US Trial Preparation Q4 2017
- CE Clinical Trial Finishes & CE Dossier Q1 2018
- CE Mark Clearance & EU Product Launch Q3 2018
- US Trial Begins Q1 2019*
- FDA 510(k) Clearance & US product launch Q2 2020*

*Series B round of funding will be necessary for FDA Clinical Trial activities and EU full commercialization.