Heart valves are prone to degradation as a person ages. Acting as the gatekeeper for cardiac ejection to the entire circulatory system, the aortic valve is subjected to constant wear and tear. Therefore, the incidence rate of aortic stenosis (AS) in patients >75 years is 12.4%. There is no effective medical treatment for symptomatic AS, and without intervention, five year survival rates are between 15 and 50%. Surgical aortic valve replacement (SAVR) has proven effective, but is underutilized due to the inherent morbidity in the elderly. While SAVRs are performed in over 67,500 cases every year, 40.5% of AS cases are left untreated. Fortunately, the emerging minimally-invasive procedure transcatheter aortic valve replacement (TAVR) has expanded the patient population. With its approval in Europe in 2007, followed by the US in 2011, TAVR is gaining traction growing at a 38% compound annual growth rate (CAGR). Global TAVR revenues have steadily increased from $200 million in 2009 to $800 million in 2012, with projections to surpass $1 billion in 2013.

Despite its advantages, the nature of TAVR significantly increases the risk of perioperative stroke. Guiding the collapsed valve through the sclerotic aortic arch and deploying it atop the existing tissue creates an influx of embolic debris in circulation just proximal to the cerebral vessels. One method to reduce the incidence of neurological events is the addition of a cerebral embolic protection device to TAVR surgeries. Although novel technologies exist and have proven feasibility in early clinical trials, they suffer from multiple disadvantages that deter immediate widespread adoption. The current devices prolong procedure times, require alternate-site access, must be externally anchored, predispose patients to additional morbidity, and lack the filtering reliability required to drastically reduce neurological events. Therefore, the clinical need for embolic protection during TAVR remains unsolved.

Over the past two years, BioDesign has developed a novel embolic protection device to address the major shortcomings of the devices currently in the market. Our device, the Embolisher, is a completely deployable, biconical self-expanding filter stent to straddle the ostia of the cerebral vessels during TAVR. A biomedical textile filters cerebral blood flow and deflects stroke-causing particles downstream. The symmetric device is simple to deploy, leaves an ample working channel, and is retrievable via a patent pending mechanism. The device has been through multiple revisions, rigorous mesh selection and multiple attachment protocols, rendering a prototype nearly ready for animal testing.

Progress:

- Developed catheter tubing for deployment and retrieval
- Tested filtration efficacy on an aortic replication pump system with excellent results
- Licensed technology to the start-up company Cardioptimus, LLC
- Currently working on the 20th chassis revision
- Revising filtration mechanism and catheter system to improve manufacturability and decrease COGS