Part 1: "Elevator" Introduction

Avery Therapeutics, Inc. ("Avery") is a startup company dedicated to advancing tissue-engineered therapeutics to treat diseases and injuries and improve lives worldwide. Avery's lead product, MyCardia™, is a tissue-engineered heart graft in the pre-clinical development phase. MyCardia™ is positioned to be the world's first off-the-shelf allogeneic tissue-engineered product for heart failure. More than 26M people worldwide suffer from heart failure—the number one cause of morbidity and mortality in the developed world. MyCardia™ has demonstrated the ability to re-grow heart muscle and blood vessels and has the potential to improve heart function and quality of life for patients with heart failure.

Avery's base tissue-engineering technology has many applications in life-science and therapeutics applications. Avery intends to partner with research institutions and other companies through out-licensing to develop additional products and revenue.

Part 2: Market and Industry Analysis

The total worldwide market for heart failure is 26M patients and growing at a 13% compounded annual growth rate. Medical treatment costs for heart failure patients is estimated at $108B annually. Our target market is Class II-IV patients with heart failure caused by ischemic disease--these are patients whose symptoms are no longer manageable on drugs alone, amounting to 15M patients worldwide. Within this target market our strategy is to start in the 2500 patients per year in the US that are already undergoing open heart surgery for placement of a left ventricular assist device (LVAD). This will allow us to demonstrate the safety and efficacy of the device without a de novo procedure and with minimal additional surgical risk to the patient. We have presented our strategy to multiple groups of surgeons and cardiologists and they agree with this approach, which gives great potential benefit to the patient while minimizing additional risk. Following demonstration of safety of our technology as an adjunct to a ventricular assist device, we will have the clinical evidence to expand to use as a primary therapy using minimally invasive techniques. Once safety is demonstrated we will intend to approach multiple outside-US markets for use as an adjunct (15,000 ventricular assist devices placed per year) or as primary therapy (26M total).

The standard of care for heart failure patients are pharmacological management (ACE inhibitors, diuretics, etc) and surgical interventions such as left ventricular assist devices and heart transplants. Pharmacological management preserves an individuals cardiac function in Class I heart failure, but does nothing to treat the root of the disease and does not stop progression of the disease. At end stage disease left ventricular assist devices (LVADs), secondary pumps that supplement the heart to reduce the work load of the heart, may be implanted. Recovery of the heart occurs in only 1% of all left ventricular assist device cases. Heart transplants result in the greatest functional recovery but are limited by donor availability which has been stagnant at 2500 implants per year for many years

Part 3: Go-to-Market Plan

MyCardia™ has unique advantages that make it the ideal technology to meet the needs of its diverse group of customers. MyCardia™ is attractive to the patient owing to the potential significant recovery without the risks associated with long term device implantation. The level of benefit we have shown in pre-clinical models would translate to a significant improvement in patient quality of life. In our personal clinical trial experience and in talking with cardiothoracic surgeons, patient willingness to have surgery is a low hurdle. Patients with CHF are aware that surgical forms of treatment are inevitable and are generally willing to undergo surgery for potential improvement in quality of life. Avery has several cardiologists and cardiac surgeons who have handled, implanted (in pre-clinical models of heart failure) and reviewed pre-clinical results of MyCardia™ and they unanimously confirmed that they would be willing to use MyCardia™ in areas of ischemia alongside other surgical therapies. Further, they would use MyCardia™ for de novo therapy after benefit is demonstrated as an adjunct. Avery has worked with clinicians to develop clinically-relevant parameters for assessing the safety and efficacy of MyCardia™. The providers and payers require cost effectiveness, better patient outcomes, reduced complications and reduced return visits to the hospital. Avery is developing manufacturing partners and will work to scale up the technology to reduce costs and obtain high quality outcomes data to show that MyCardia therapy can save money long term, while providing greater benefit to the patient than existing therapies.

Avery has close relationships with top clinicians all over the country that are excited about testing and using MyCardia™. We will use these connections to find clinical sites for our clinical trials and to stimulate adoption of our technology at the top medical institutions. Once approved, Avery intends to outsource marketing and sales of MyCardia ™ to a company with existing sales channels.

MyCardia can be used alongside existing therapies including pharmaceuticals and left ventricular assist device (LVAD) and can extend time to or eliminate need for heart transplant. When used alongside LVAD, MyCardia has the potential to improve the heart to a level that LVAD can eventually be removed. Based on our pre-clinical results, MyCardia has greater potential for long term benefit to patients as compared to competing cell therapies in development.

Avery will also partner with companies through out-licensing as an additional source of product development and revenue.

Part 4: Technical Product Description and Plan

MyCardia(TM) is a tissue-engineered graft that is implanted on the surface of the heart to regrow heart muscle and blood vessels and improve heart function. MyCardia(TM) is positioned as an allogeneic, cryopreserved product such that the product is off the shelf (stored in a hospital freezer) and can be used in any patient. MyCardia will be implanted during open heart procedures or de novo using minimally invasive techniques.

Using gold-standard pre-clinical models of heart failure, we have demonstrated 30% improvements in the systolic (squeeze) and diastolic (filling) function of the heart. These are significant levels of improvement that would translate to improvement in quality of life. Further, we provide an advantage over existing therapies as there are currently no effective therapies for improving diastolic function. Additionally we have demonstrated the ability to manufacture MyCardia at a clinical size and have demonstrated the feasibility of implanting a clinical-sized graft using open surgical or minimally invasive techniques.

We have a strong team of collaborators and advisors in the scientific, clinical and business space that have helped us identify potential risks and have developed robust plans to overcome these risks. We have developed outlines for key studies that will evaluate important elements of the long term safety and efficacy of the technology, which is required for regulatory approval and customer adoption. One noteworthy element of these studies is that we have developed methods to assess quality of life in pre-clinical models and are using functional parameters that can be translated to people. We have hired experienced, highly respected regulatory and manufacturing experts and have identified a contract manufacturing organization that we will work with for scale up and validation of our technology such that it meets the FDA requirements for cGMP compliance. We have also identified a contract research organization with large volume capacity to perform additional pre-clinical study to collect additional safety and efficacy data for our pre-IND and IND submissions to the FDA.

Our product has superior benefit over existing therapies and provides advantages over other cell-based therapies in development. Our advantages include robustness for handling and application, ability to treat a large area continuously, recruitment of vascular supply, functional benefit and availability as an off the shelf product.

Our current intellectual property includes one issued patent and one pending patent. We have additional intellectual property that will be filed with the USPTO in the upcoming year and have trade secrets that have been developed through our years of experience in developing and manufacturing this technology. We have identified key suppliers from with we will license components used in the manufacture of our technology. These key partnerships provide us an advantage over competitors. Furthermore, all our supplies are provided to us at cGMP-grade, reducing our regulatory burden.

Part 5: Risk vs. Talent Narrative

We have mitigated risks related to technology and manufacturing through demonstration of safety and efficacy in pre-clinical models and demonstration of scale up and minimally invasive deployment in a human cadaver. Business and development risks have been mitigated through partnership with qualified suppliers and identification of experienced manufacturing and development partners. Our upcoming milestones include demonstration of closed-system bioreactor manufacturing, finalization of all supply and development agreements, pre-pre-IND meeting with the FDA and conduct of additional pre-clinical studies in support of a pre-IND package.

Management Team:

Steven Goldman, MD, Interim-CEO and Chief Medical Officer is a board certified cardiologist and brings over 40 years' of clinical and research experience to Avery Therapeutics. Dr. Goldman is co-inventor of MyCardia™ technology and brings significant experience in directing large multi-centered clinical trials.

Jordan Lancaster, PhD, Chief Scientific Officer leads product development efforts. Dr. Lancaster has expertise in cell and tissue engineering and is co-inventor of the intellectual property that is behind the company's lead product MyCardia™.

Jen Watson Koevary, PhD, Chief Operating Officer leads commercialization strategy and operations. Dr. Koevary's experience includes start up business development, managing funding programs, leading entrepreneurial education programs and biomedical engineering.

Avery's advisory team includes top quality clinical, business, scientific/technical and regulatory experts. Our scientific and clinical advisors have assisted with identifying the appropriate clinical populations and developing the pre-clinical and clinical testing strategy. Our regulatory consultant is actively assisting with preparation for FDA submissions. Our manufacturing consultant has helped us identify manufacturing partners and outline a plan for technology transfer to a contract manufacturer. Our business advisors have helped us develop an IP strategy and identify potential partners for financing and technology in- and out-licensing.

We have a qualified, dedicated team for the stage of development that we are currently in. We are extremely well covered in breadth and depth for our clinical and technology teams, a huge advantage at this stage where we are validating the technology and developing manufacturing and clinical translation plans. In the future our team will be strengthened by an experienced CEO that has demonstrated experience partnering with large pharma and growing successful companies.