MagPulse-A magnetic Drive LVAD

Product Description

Our product is an improved Left Ventricular Assist Device (LVAD), an auxiliary heart pump that will afford both a significantly lower life-cycle cost relative to current devices, and a better quality of life for heart-failure patients. The innovative MagPulse LVAD (Patent Pending) is based on a proprietary magnetic drive system that offers three main advantages over existing LVADs:

- *Greater Longevity: MagPulse adapts its response to changing pressure in the body on a stroke-by-stroke basis, thereby decreasing pressure on mechanical valves that limit an LVAD's useful life. Current state-of-the-art LVADs last two years on average, generally as a result of valve and membrane failures. This propriety design should extend the lifespan of the device to 8-10 years*
- *Improved Physiology: MagPulse mimics the patient's cardiac pulse pressure wave, providing a better match with human physiology, less dependency on drug therapy, and generally improved health*
- *Higher Energy Efficiency: MagPulse provides greater energy efficiency than comparable LVAD's, reducing dependency on heavy, restrictive batteries*

Recently our heart pump design was introduced to the Texas Heart Institute, where thousands of heart operations are performed every year. The head surgeon confirmed that MagPulse's innovative drive mechanism should indeed increase the lifespan of an LVAD. Surgeons further confirmed that the proposed LVAD may be an outstanding overall solution to this growing public health problem, potentially increasing patients' lifespan and quality of life.

Market opportunity

Our product is primarily directed to end-stage Congestive Heart Failure (CHF) patients. According to the American Heart Association (AHA) 400,000 people are diagnosed with CHF each year, 100,000 of those are end-stage cases. Since there are only about 2000-3000 heart donors available for these 100,000 people, the *Journal of Health Economics* estimates that if reliable, fully implantable, and wearable devices (like the one we are introducing) were available, at least 100,000 patients annually in the U.S. could benefit from this technology. Therefore, the addressable market for a superior heart pump is **100,000 units per year in the US**. In monetized value, our target market is estimated at **$7B per year in the U.S** (the Centers for Medicare and Medicaid rebate heart pumps at $70,000 per unit).

Of the $34.8B spent in the U.S on treating heart failure, the overwhelming majority is spent on physician's care, hospitalization, and drug therapy. CHF is the principal cause of 40,000 deaths per year and is a contributing factor in another 250,000 deaths. The median survival after CHF diagnosis is 1.7 and 3.2 years in men and women respectively. The 5-year survival rate is less than 50%. With our improved design we can also target patients who are not at the end stage but are using intensive drug therapy, a pool of over 1M additional customers who will benefit from a longer and more productive lifespan.

The annual growth rate for our market is estimated at 12% to 15% due to corresponding new cases of CHF diagnosed each year. The drivers for this market growth are longer lifespan, diabetes, diet and sedentary lifestyle

Company milestones, Sales and Marketing Strategy

- **Phase I – R&D (18-24 Months):** Prior to commercialization, our research must demonstrate that our design is in fact more durable and more adequate than existing heart pumps. Furthermore our product must be proven biocompatible, safe, and able to pass strict requirements set by the FDA. By the end of phase I we will have a prototype ready for the first animal trials.
- **Phase II – Pre-Clinical Trials (12-14 Months):** After meeting the requisite product development milestones we will proceed to phase II with the preclinical animal trials (bovine).
- **Phase III – Clinical Trials (24-36 Months):** FDA approval is required for *Bridge-to-Transplantation*, and subsequently *Destination Therapy.* The clinical trials phase must ultimately

demonstrate that the medical device is safe, effective, and superior both in performance and longevity to the current LVAD solutions. We will need a primary research hospital in which to carry out the FDA clinical trials. We have already demonstrated our prototype to leading heart surgeons at the Texas Heart institute, who expressed interest in collaborating on the development and clinical trial phases.

After FDA approval, we will outsource the manufacturing of our product and focus our marketing efforts to target cardiothoracic surgeons. These specialists not only *perform* the actual surgery but also choose which heart pump they want to use implant. They base their decision on personal experience, latest research, and word-of-mouth. We will target cardiothoracic surgeons through scientific conventions and medical journals, showcasing our superior drive mechanism supported with results from clinical trials. In addition, we will generate interest and momentum surrounding our product through our medical advisors, professionals who are already well connected to the cardiothoracic surgeon community. We will of course develop a direct sales force team targeting leading hospitals and healthcare providers.

Funding Requirements

- **Phase I** requires $5 million to further develop the design and prototype
- **Phase II** requires $10 million to hire medical staff, conduct the animal testing and further develop the product
- **Phase III** requires $15 million to go through FDA clinical trials.

Our initial funding requirement is the $5M needed for phase I. We will raise the additional funds beyond the initial $5M sought as we hit the development milestones of the product.

Exit Strategy

Within 3 to 5 years, we anticipate an opportunity to sell our technology to one of the large medical device firms. We could potentially sell our technology after each phase, at a valuation corresponding to its risk-adjusted net present value (rNPV). Alternatively, based on comparable LVAD firms, we may reasonably assume an enterprise valuation of approximately 4.5X revenue upon FDA approval of MagPulse.

Founding Team:

***Uri Mariash*, CEO**, is a second year MBA student at MIT Sloan. Prior to MIT, he served as an officer in the Israeli military intelligence where he led various R&D teams. He holds a Masters degree in Biomedical Engineering and a B.Sc degree in Electrical Engineering from the Tel Aviv University. Uri spent his summer at Cisco Systems working in the Emerging Technologies Group working on an emerging technology that is expected to become a $1B business for Cisco.

***Javier Donoso*, Co Founder**, is a second year MBA student at MIT Sloan. Prior to MIT, he was in charge of the international telecom projects for Iberia Airlines. His experience also includes working with McKinsey Madrid on retail M&A projects and market research project for Nokia USA. He holds a Master of Science degree in Electrical Engineering from Universidad Politécnica de Madrid.

Ellan Fei Spero*, *Co Founder is a PhD student in the HASTS program at MIT. She has done work in degradation of materials at both Cornell Universtiy (B.Sc, MS) and FIT (MA).

Glen Dow, D.O, currently under contract with Emergency Staffing Solutions to provide physician services in the emergency room at North Texas Hospital in Denton, Texas.

Board of Advisors:

William E. Cohn, MD, is the director, of the Minimally Invasive Surgical Technology at the Texas Heart Institute