Novel Lung Assist Device for Preterm and Term Neonates D. Sandejas¹, H. Matharoo²

Biomedical Engineering¹, Mechanical Engineering², McMaster University, Hamilton, Ontario, Canada Introduction: Every year, 500 000 infants in the US are affected by preterm birth, equating to 1 of every 8 babies born [1]. A major contribution of infant mortality among neonates is respiratory distress syndrome. Other associated problems include cerebral palsy, vision and hearing impairment, and developmental delay [1]. Current technologies, such as mechanical ventilation, surfactant replacement therapy, and ECMO, have limited benefits and may cause future health complication for patients.

The lungs are the last organ in the body to develop, contributing largely to complications of preterm birth. Neonates lack the appropriate surface area and surfactant in the lungs, causing a deficiency of oxygen in the body [2]. Our proposal is to introduce a novel lung assist device (LAD) which provides a non-invasive technique for oxygen gas transfer, allowing natural lung development and limiting health complications.

Technology: The lung assist device is an apparatus which uses the umbilical vessels to pass blood through a series of parallel single oxygenator units (SOUs) which extend the gas exchange area, supplying oxygen to the infant. Each SOU is a microvascular network of channels in contact with a gas permeable membrane for blood oxygenation in ambient air (Figure 1).

Blood is withdrawn from the umbilical artery, passed through the LAD, and returned through the umbilical vein. The oxygen partial pressure gradient between ambient air and deoxygenated blood provides a venue for hemoglobin saturation.

The LAD allows more time for the lungs to fully develop, giving neonates the opportunity to bypass complications associated with current technologies.

Market: The yearly cost of preterm birth in the US reached \$26 billion dollars in 2005, about 1.3% of the national healthcare expenditure for that year [1]. This has attracted many investors to the market.

Barrier to entry into this section of the health care market presents difficulties due to the established nature of companies, with access to funding for intense research and development. This has created an interest in perfecting neonatal intensive care unit techniques, amassing many accomplishments with volume targeted or pressure sensitive ventilation. The problem is that the technology is peaking. The incremental change from current research and development does not address the entire problem. The LAD is a new approach that will spark innovation in non-invasive respiratory therapy.

Neonatal intensive care units cost upwards of \$2000 per unit, as well as operating costs. Medical bills associated

with these costs, and costs of potential future complications put hardships on affected families, many of which already have existing financial burdens of medical care.

Commercialization Strategy: To increase awareness of the LAD, participation at various conferences will be required. Marketing the LAD as a cost effective, preventative treatment is our main goal. Meeting with hospital management and staff, and showcasing the LAD is essential and will attract interest from doctors in the field.

Industrial manufacturing of the oxygenators will be completed through injection molding, costing \$91 per LAD, which can support a neonate weighing 700 grams. The selling price per unit of LAD will be \$168. An estimated 500 thousand LADs will be sold annually, generating a revenue of \$84 million. Revenue will be invested in expanding business operations, research and development, and finally, providing profit for shareholders.

It is unlikely that our company will be forced to exit the market, since the factors affecting neonatal birth are unknown and will create a continuous requirement for care. However, should exiting the market become a necessity, our exit strategy would involve transferring the ownership of the company, and/or liquidating assets.

References: [1] Preterm Birth. Centers for Disease Control and Prevention. Revised December 9, 2013. <www.cdc.gov/reproductivehealth/maturnalinfanthealth/p retermbirth.htm> Accessed October 27, 2014

[2] Early Lung Development. Stocks, J. et al. Lancet Respiratory Medicine. 1:9, November 2013.



Figure 1. The lung assist device is comprised of a series of single oxygenator units connected in parallel.