

Executive Summary **Skin Tissue Replacement**

RepliDerm Inc. will produce a synthetic dermal replacement to treat burns, diabetic ulcers, and other serious wounds. The goal of the dermal replacement is to create a matrix scaffold for new blood vessels to form. After the matrix is completely vascularized, a very thin epidermal graft will be applied over the matrix. Once this is done, the wound will heal and have all of the same properties as normal skin, except for sweat glands and hair follicles. This dermal replacement is a 6 inch by 4 inch sheet constructed of bovine collagen implanted with vascular endothelial growth factor (VEGF) microspheres. The VEGF microspheres decrease the amount of time needed for the body to vascularize the matrix compared to just collagen alone. Quicker vascularization means a shorter stay in the hospital and a smaller hospital bill for the patient.

It is estimated that it will take RepliDerm Inc. approximately 15 years and cost \$351,000,000 to pass the FDA trials that are required for bringing a product such as this to market. The FDA approval process is the most expensive and lengthy process standing between RepliDerm Inc. and a viable product on the market. RepliDerm Inc. determined that a large portion of time and effort should be put into pre-FDA testing. Combining a staff of 1 Ph.D. and 7 lab technicians with many experiments gives RepliDerm the best chance of passing the FDA evaluation on the first try, and thus saving money by not having to correct mistakes in the middle of the evaluation.

RepliDerm Inc. will need a Fixed Capital Investment of about \$8,900,000 and a total capital investment, including the FDA approval process, of \$360,000,000.

RepliDerm sheets cost \$1870 per sheet. This price is found using an economic model that accounts for existing products in the market and the advantages that RepliDerm offers over its competitors. This price is comparable to that of other similar products on the market. The average burn patient needs about 12 sheets (6" by 4") to cover their wounds. The average diabetic patient needs 1 sheet (6" by 4") to cover their wounds. RepliDerm Inc. expects to sell roughly 27,000 sheets in year one, 68,000 in year two, 126,000 in year three, 162,000 in year four, and 209,000 in year five. Given these sales projections, RepliDerm Inc. expects to break even in year three.

RepliDerm is headquartered in Fairfield, California. The reason for locating RepliDerm Inc. in Fairfield is due to the large number of National Institutes of Health grants that are garnered by companies in this area. The NIH grants will be RepliDerm Inc.'s main source of start up capital.