

## Medical Products and Therapies based on Regenerative Tissue are Poised for Breakout

### Executive Summary:

- **The potential for market growth of applications for regenerative tissue is significant.** There have been tremendous technological advances recently in the methods for constructing tissue and scaffolds for the growth of tissue based on human cellular material intended for applications ranging from human heart valve repairs and reconstructions, vascular tissue repairs and replacements, to membrane replacement barriers for use in the treatment of traumatic brain injury. Therefore, we believe there is notable and growing potential for applications of regenerative tissue therapies.
- **Markets for regenerative tissue technologies and products are large and expanding.** Many market surveys value the total market for products based on regenerative tissue near US\$10 billion for 2015, with annual growth rate at or above 10%. Large upside potential is possible in the event the U.S. Food and Drug Administration (FDA) approves additional applications or on discoveries of new applications.
- **FDA and other regulatory agencies have begun approving regenerative tissue treatments.** Since approvals of skin grafts based on dermis derived from donated human allograft skin for wound and burn victims prior to 2000, there have been a lot of approved products for various applications, including orthopaedics and cosmetic surgery as well as organ and heart valve repairs. These products often combine cellular therapies and bio-scaffolds, with bio-scaffolds offering unique delivery platforms.
- **In addition to harvesting and transplanting human tissue, there are emerging technologies for formation of structures, beginning from single cells by using raw animal tissue.** Specific examples include engineering tissues for cardiovascular tissue replacements, bone and cartilage growth in knee and hip joints, engineered skin samples for wound repairs, materials for organ grafts and replacements, together with replacements for the cornea, and many others are being explored and developed, with some of them already entering the approval process.
- **China represents a fast-growing geographical market.** Demand for certain tissue regeneration and heart valve repair products in China is estimated to be greater than that in the U.S. and Europe combined. There is strong market demand and interest from Chinese surgeons for new products in view of the hundreds of thousands of heart-related surgical cases conducted in the country yearly and the up to 50% failure rate in certain applications within a 12-month period if synthetic products are used.
- **Engineered materials based on nanotechnologies will be the key for explosive growth going forward.** While many products based on harvesting and transplanting tissue within a patient or between patients are already in use, we believe the most explosive growth opportunities for regenerative tissue will rely on the ability to create new tissue using engineering from stem cells and other primitive material components. In our view, small companies with innovative technologies for tissue engineering from cells and scaffolds will be the sources of the most important new products, while large companies aim at acquiring these small companies at key moments in technology development. We believe investors could realize huge returns by investing in promising small companies prior to them being acquired.
- **Technologies of major industry players are generally outdated.** The “Big Four” suppliers of heart valve repair products depend mainly on technologies developed in the 1980s though they have already invested in advanced technologies. New technologies pioneered in the last decade or so are expected to replace the old ones, as they offer better costs and benefit for patients.