Regenerative Medicine: Revolution in the Making

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It requires dedicated focus on one niche market to be successful in the biotech age. This article explores the technologist’s journey to success.

A perilous route
From a simplistic perspective, it could be said that the world is undergoing its third technology revolution. Starting with the industrial revolution in the 18th century and proceeding through the information revolution, mankind has now arrived at the biotech revolution. More specifically, it stands in the front-line trenches with regenerative medicine and stem cells. The medical device industry has undoubtedly benefited from the first two revolutions, now is the time for it to seize the next big opportunity.

An important question to ask here is: Are there any hints that the regenerative medicine paradigm is making any inroads into health-care markets? The answer can only be a resounding “Yes.” It is not just enthusiastic noises from the scientists and lashings of media hype. Geoffrey Moore, in his landmark book Crossing The Chasm, describes the perilous route a new high technology must journey if it is to become an overwhelming success. The “technology adoption life cycle” that Moore elucidates is as true for the regenerative medicine industry today as it was for the Silicon Valley companies of the 1980s and 1990s. In brief, the chasm represents the gulf between the early adopters of a technology, that is, the enthusiasts who must always have new toys, and the rest of the population who make up the mainstream market.

The early pioneers
The first wave of regenerative medicine companies (then better known as tissue-engineering companies) operating in the years from 1990 to 2002 failed to cross this chasm. For example, the leading commercial pioneers, Organogenesis (Canton, Massachusetts, USA) and Advanced Tissue Sciences (La Jolla, California, USA), despite hundreds of millions of dollars of investment, product approval from Food and Drug Administration and massive potential markets, filed for protection under Chapter 11. In the United States, Chapter 11 allows companies to continue to operate shielded from creditors while they restructure their finances. In part, as a consequence of the fate of the leading pioneers, other companies also failed to thrive and thus were also lost in the chasm. Fortunately others, including Intercytex (Manchester, UK) and Genzyme Biosurgery (Cambridge, Massachusetts, USA), have been much more successful in navigating the chasm. Even Organogenesis and Advanced Tissue Sciences (now Smith & Nephew) have emerged from Chapter 11 protection with new leaders and essential injections of capital and are now moving forward once again.

The regenerative medicine industry is in the process of crossing the chasm for a number of reasons not merely because of rebranding; “tissue engineering” is no longer deemed to be a cool marketing expression. One of the important factors for success is increased focus by the companies instead of chasing multiple targets. The original pioneers were each vying to engineer absolutely everything including skin, blood vessel, bone, liver and nerve, each product requiring a high complexity of research, development and manufacture. The associated financial outlay was enormous and unsustainable. Today the individual companies are focussing on highly specialised niches where they can dominate. For example:

- Cell therapies to reverse the effects of stroke by ReNeuron (Guildford, UK)
- Skin for patients with severe burns from CellTran (Sheffield, UK)
- Living blood- vessel shunts for kidney dialysis patients developed by Cytograft (Novato, California, USA)
- Urinary bladders from Tengion (King of Prussia, Pennsylvania, USA).

The strategy seems to be: win the niche market and then conquer the broader regenerative medicine market. However, taking on medical device and pharmaceutical companies and successfully displacing them from an established sector will undoubtedly require vision, superior products, innovative manufacturing, investor nerve and great leadership. The industry has undoubtedly learnt from its past disasters and is gearing up for a fresh assault on the chasm. Watch this space. The chasm will one day be far behind us!

References

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