

Regen Medicine Prepares for Growth Spurt

Novel Business Models, Emerging Players, and Transformative Products Starting to Have Impact

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The regenerative medicine market, still at an early stage of its evolution, is likely to grow exponentially from its current base of \$1.8 billion to

potentially more than \$10 billion by 2020. Historically, the market has been limited to applications in spine fusion and skin/wound and cartilage repair, but this is likely to change as numerous novel cell-based therapies enter the market and address

unmet medical needs.

Cell-based therapies include fully formed artificial tissue (synthetic bladders, etc.) and stem cell therapies in which stem cells (typically drawn from bone marrow) are introduced to the body in order to repair or heal ailments. Such novel therapies may disrupt segments of the \$750 billion pharmaceutical and \$200 billion medical-device markets, creating significant new growth opportuni-

ties for regenerative medicine players.

If some of these therapies reach their promise, we are likely to see dramatic changes in the management and treatment of certain chronic diseases and significantly lower overall healthcare costs. These innovations have considerable implications for traditional players in the pharmaceutical and medical-device industries—particularly regarding current business models and market approaches.

A Nascent Market To Date

The regenerative medicine market started in the late 1980s and early 1990s when the first cell-based therapies were introduced in the skin/wound repair area. None of these early therapies had significant impact on the market due to ineffective marketing, high prices, manufacturing problems, and other go-to-market hurdles. For example, **Organogenesis'** initial launch of Apligraf failed in 2002, and the company was forced to file for bankruptcy. However, since then the company has grown stronger. Organogenesis is now approaching \$100 million in sales.

Organogenesis' recovery demonstrates that regenerative medicine is transitioning from early adoption to broader market acceptance as players learn, sometimes the hard way, how business models and go-to-market strategies originally borrowed from the biopharma and medical-device industries must be tailored specifically for regenerative medicine.

Several other firms have, likewise, struggled for years to find profitable ways to provide regenerative solutions. After observing other companies' initial difficulties, **Medtronic** entered the regenerative medicine market in 2002 and introduced BMP (bone morphogenic protein, used in spine fusion), which became the first blockbuster regenerative medicine product with sales of over \$600 million four years after launch.

This success story demonstrates the value of regenerative medicine and the importance of proper business planning to ensure rapid adoption. However, despite increasing product success, regenerative medicine remains a relatively small market, limited to specialized application areas.

Unmet Needs in Chronic Diseases

The next wave of regenerative medicine is likely to include cell-based therapies that have potentially significant but, largely, incremental impact on chronic medical conditions. For example, in vascular applications, the next wave of therapies will include relatively simple applications such as those for repairing arteriovenous fistulas damaged by regular needle access, as required by dialysis patients with renal failure.

After this wave, we are likely to see the first truly disruptive cell-based therapies. Targeting cardiovascular conditions, these therapies will be aimed at repairing damage to the heart and vasculature associated with myocardial infarction, coronary arterial disease, and congestive heart failure

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(CHF). Today, all of these conditions are considered irreversible and chronic—warranting a lifetime of expensive therapies, medical devices, and monitoring.

By arresting degeneration or restoring functionality, however, regenerative medicine solutions could transform medical care for such problems. Beyond the cardiovascular example, novel cell-based therapies promise to target challenging chronic conditions in neurology (e.g., brain and spine repair) and metabolic diseases (e.g., diabetes). These therapies, however, are not likely to enter the market soon.

Congestive Heart Failure

Regenerative medicine is likely to have a profound effect on chronic disease conditions that today contribute to significant expenditures in healthcare. CHF is a case in point. This chronic disease is responsible for \$35 billion in direct expenditures in the U.S. alone—primarily driven by repeat hospital visits following acute episodes of destabilization.

Scientia estimates that if regenerative medicine can arrest CHF or reverse/restore heart functionality for even 20% of patients, treatment costs could be reduced by more than \$8 billion per year by 2020. Regenerative technologies could potentially lead to even greater cost savings for care in other chronic diseases such as diabetes.

Home-Brew Solutions

While regenerative medicine could dramatically impact healthcare in the mid-to-long term as these novel therapies go through clinical trials, a new breed of regenerative medicine is already practiced in the EU and emerging economies.

In those areas, clinics offering regenerative (mostly cell-based) therapy claim to provide a wide range of medical solutions for chronic conditions such as cardiac disease, Alzheimer and Parkinson diseases, and diabetes. Most of these clinics have created their own home-brew systems for harvesting, culturing, processing, and (re)introducing cells to patients, despite limited clinical data supporting the efficacy or safety of the treatments.

This home-brew segment, which generally operates below the radar of regulatory authorities, demonstrates that there is a significant demand for regenerative medicine—regardless of whether the therapies have been scientifically shown to work.

Scientia's research indicates that these clinics will see higher levels of regulatory scrutiny over time and will be required to submit clinical evidence of efficacy and safety for their therapeutic approaches.

In May of 2009, the Chinese Ministry of Health placed legal curbs on stem-cell treatments in the country. Its new approval process requires companies to submit clinical data in order to offer service. However,

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enforcement will likely be an issue, given the number of hospitals and clinics offering these services and China's large size. In addition, the penalties are relatively light (suspension of medical license and fines), which means current practitioners may have little motivation to discontinue operations.

Still, the popularity of these home-brew therapies and individuals' willingness to pay for them show significant demand for

regenerative medicine on a global basis.

The regenerative medicine field reverberates with potential implications for various stakeholders in the pharma/biotech and medical-device markets. It presents a challenge to the status quo and could well alter current competitive market dynamics.

Many regenerative medicine players are emerging from unexpected fields and have limited background or competence in

either pharma or medical devices. This new breed of players is creating new markets and using novel go-to-market approaches and business models.

In order to remain competitive, these companies must view regenerative medicine from a strategic perspective. It is imperative that they prepare for the changes likely to occur over the next 10+ years as many of these therapies hit the market. **GEN**

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