

REGENERATIVE MEDICINE MARKETS *(SAMPLE COPY, NOT FOR RESALE)*

Trends, Industry Participants, Product Overviews and Market Drivers



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1. Overview

1.1 Statement of Report

Astounding new advancements in the ability to repair or replace damaged human tissue and organ functions are being made. The field of regenerative medicine has reached a point in its growth where progress is not only seen in headlines but experienced by thousands of patients who are receiving disease-altering therapies every day. Besides, new data are being made available from late-stage clinical trials of regenerative medicines to treat cardiovascular disease, stroke, ALS, critical limb ischemia, cancer and a number of debilitating autoimmune diseases. In addition, companies such as GE Healthcare and Cellular Dynamics International are specializing in the science of cellular reprogramming and cellular signaling to control the fate, or differentiation, of cells for specialized functions. Due to these developments, scientists can now produce living human heart cells, liver cells, endothelial cells and neural cells to test the safety and toxicity of newly discovered drugs, understand the biologic mechanisms of disease, as well as discover new molecules and biologics with therapeutic potential.

As such, the purpose of this report is to describe the emerging field of regenerative medicine. The areas covered in this study include: available and emerging technologies in the field, the U.S. and global market size for regenerative medicine products, and the profiles of companies that are focusing on regenerative medicine sector. The main objectives of this analysis are:

- Estimate the current and future U.S. and global markets for regenerative medicine.
- Examine market drivers that have resulted in the global race for regenerative medicines.
- Assess market opportunities and the potential market pertaining to the disease indications.
- Discuss product development challenges in relation to regulatory constraints, legislative constraints and technical challenges.
- Analyze the need for regenerative medicine for the different disease indications.
- Understand the impact of current products and the future of regenerative medicine industry.
- Provide insight into the regenerative medicine products in the pipeline and the companies that strive to bring these products to the market in the immediate future.
- Evaluate global activity in regenerative medicine with specific contributions from the top-ranking five countries: U.S., Japan, Germany, U.K. and Sweden.
- Analyze the segments in regenerative medicine such as scaffolds, cells and tissues and biomolecules.
- Gain insight into the current applications of regenerative medicine in bone, heart, neurons, pancreas, eye and tooth.
- Explore drug discovery efforts in relation to regenerative medicine.
- Analyze the usual hurdles regenerative medicines are encountering to reach the market and the right path to the market for these products.
- Review the current licensing, investing and partnering activities in regenerative medicine sector.
- Assess business models and requirements for a successful regenerative medicine industry.
- Examine funding scenario for the regenerative medicine sector.
- Identify the key players in the regenerative medicine industry and their contribution to this emerging therapy.

Key questions answered in this study are:

- What according to the U.S. National Institute of Health (NIH) are the products that come under the phrase “regenerative medicine”?
- What disease conditions offer the greatest potential for regenerative medicines?
- What is the current global market for regenerative medicine?
- How much of clinical development activities are taking place globally in regenerative medicine sector?
- How many companies are involved in the development of regenerative medicine products?
- How many patents have been issued for regenerative medicine products?
- How long would it take to develop tissues on demand?
- What market drivers are responsible for the global race in regenerative medicine?

- Which healthcare segments can make an easy entry into the regenerative medicine market?
- What regulatory and technical challenges are being confronted by the regenerative medicine industry?
- Which countries are in the forefront of developing regenerative medicine?
- What are the current promising developments in regenerative medicine sector?
- Which countries have made strong commitments to achieve supremacy in the race for these future-medicines?
- What is the latest position of the clinical studies and product pipe line in regenerative medicine sector?
- How long it will take for the regenerative medicine therapies to become the standard of care to replace all damaged tissues and organ systems in the body?
- How much of venture capital fund was invested into the regenerative medicine sector?
- What is the financial commitment made by governments other than the U.S., such as Japan, China, South Korea and Singapore?
- What is the potential population in the U.S. for cell therapies?
- Do the developing countries which comprise the largest populations offer scope for the regenerative medicine product?
- What are the probable top-ten applications of regenerative medicines in the developing countries?
- What are the top-ten regenerative medicine products available in the market place?
- What are the available wound healing regenerative medicine products in the market?
- What are the cartilage regeneration products available in the market?
- How many companies are involved in the development of skin, cartilage, bone, urological products?
- How many companies are focused on the development of regenerative cardiovascular products?
- How many companies are engaged in the development of regenerative neurological products?
- How many firms concentrate on pancreas, liver and kidney products?
- Which firms are involved in the development of ophthalmic products?
- Which companies are focused on the development of dental regenerative products?
- Which companies are focusing on the manufacture of growth factors?
- Which companies are involved in marketing drug screening products for toxicology tests?
- Which companies are associated with developing biomaterials in relation to regenerative medicine?
- Is there an easy market path to products of regenerative medicine?
- How many companies develop autologous and allogeneic cell therapy products?
- What are the different business models suitable for the different types of regenerative medicine products?
- What are the requirements for the commercial manufacturing of regenerative medicine products?
- What are the different funding sources in the U.S. for the development of regenerative medicine products?

This report contains:

- Current market opportunities for regenerative medicine products.
- Product development challenges confronted by the regenerative medicine industry.
- A brief discussion on the need for regenerative medicine and the advantages of cell therapy over the conventional pharmaceutical medicines.
- A brief note on the current state of regenerative medicine.
- The future direction of the emerging regenerative therapy treatments.
- The overall picture of pipeline products in regenerative medicine sector and the companies involved.
- A brief note on the projected time-line for regenerative medicine.
- A market projection for global regenerative medicine products.
- A short note on the potential number of U.S. patients requiring regenerative therapy as based on an estimate from the American Heart Association, the American Autoimmune Disease Association, American Burn Association, etc.
- A detailed discussion on the potential market for regeneration therapies in the thickly populated but economically weak developing countries.
- Listing and explaining the most popular regenerative medicine products in the market.
- Presentation of the global picture of the regenerative medicine industry with particular reference to the leading countries, such as U.S., Japan, Germany, U.K. and Sweden.

- Number of firms engaged in regenerative medicine (RM) products for skin, cartilage, bone and neurological applications in the above five leading countries.
- Number of RM firms focusing on cardiovascular applications in the five leading countries.
- Number of RM firms concentrating on neurological applications in the five leading countries.
- Number of RM firms specializing on pancreas, liver and kidney applications.
- Leading RM firms in ophthalmic applications.
- Leading firms focusing on biomaterials used in regenerative therapy.
- A detailed discussion on RM product's path to market.
- A detailed account on business models and requirements for a successful RM industry.
- A brief note on in-house and contract manufacturing options for an RM industry.
- A note on global funding for RM industry.
- A brief introduction to U.S. federal funding for RM in the past, present and future.
- A brief discussion on international collaboration on RM research.
- In-depth profiles of 90 companies involved in research and development (R&D) of products in biomaterials, cell therapy products and tools related to RM.

1.2 Scope of this Report

This report provides a thorough overview of regenerative medicine (RM) sector together with analyses of the funding trends, intellectual property, market opportunities and emerging areas of applications, therapeutic pipeline, research collaborations, partnership activities, and guidelines for establishing new ventures in this emerging field. The report enables the reader gain in-depth knowledge about the various ongoing research programs carried out in the U.S. universities and other research centers. Since regenerative medicine is an emerging field, only about five countries such as the U.S., Japan, Germany, U.K. and Sweden seem to play an important role, and this report gives the details such as the number of firms and the types of products manufactured in these five focus countries. The various business models in cell therapy have been described in detail so that the companies expanding their operations can have an insight into the best model suitable for their new ventures. This study also covers the companies that are actively developing and marketing RM products. Other TriMark Publications reports related to different healthcare segments can be found at <http://www.trimarkpublications.com>.

1.3 Methodology

The author of this report is a retired college professor with three decades of experience in teaching biochemistry, biotechnology, pharmacology, environmental biology and horticulture. The detailed study of this report is based mainly on the publications of primary research on regenerative medicine, as well as information from venture capital firms. For the publicly held companies, the annual reports, 10-K filings and financial reports were examined. Information available from the proprietary databases at Biotechnology Associates and from the private data stores of TriMark Publications was also used in preparing this report. Important data sources include American Heart Association, American Autoimmune Related Disease Association, American Burn Association, *World Stem Cell Report 2011 and 2012*, Swedish Governmental Agency for Innovative System (VINNOVA) and research centers from the U.S. universities. The market data given in this report are based on available market data from press releases and company annual reports. Company profiles were gathered from the annual reports, conference proceedings and Internet searches. The information set forth in this study was obtained from sources that we believe to be reliable, but we do not guarantee the accuracy, adequacy or completeness of any information, any omission or the results obtained by the use of such information.

Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects and Sector Snapshots that we publish annually. We extract relevant data and analytics from TriMark's research in the past three years as part of this data collection. We also extract qualified data feeds from e-questionnaire responses and primary research responses for this compilation.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government affiliated trade releases, and other published information as part of its secondary research materials. The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations. The report conclusions are verified through intensive interviewing of the top-ranking companies in the industry.

TriMark Publications Report, Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report in TriMark Publications includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly-available data and proprietary databases.
- Formulating a study outline with the assigned writer, including important items, as follows:
 - Market and product segment grouping, and evaluating their relative significance.
 - Key competitors' evaluations, including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
 - End-user research to evaluate analytical significance in market estimation.
 - Supply chain research and analysis to identify any factors affecting the market.
 - New technology platforms and cutting-edge applications.
- Identifying the key technology and market trends that drive or affect these markets.
- Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.
- Completing a confirmatory primary research assessment of the report's findings with the assistance of expert panel partners.

1.4 Executive Summary

The regenerative medicine (RM) market continues to witness significant advances in clinical efficacy, regulatory approval and product commercialization of cell based therapies. Affirmative results engendered from the application of adult stem cells have resulted in greater government and private sector investment in research and development of new cell therapies, including the continued advancement of existing treatments. The regenerative medicine market includes firms that harvest, process, purify, expand, cryopreserve, store or administer stem cells. According to Biotechnology Associates, globally, regenerative medicine products generated revenues of about \$ [REDACTED] in [REDACTED] and the market has the potential to grow and earn more than \$ [REDACTED] in [REDACTED].

The key RM products for cardiovascular and vascular applications are autologous Imylocel-T from Aastrom, adult stem cells from Cytori, concentrated cardiac stem cells from Capricor, Multistem from Athersys, JVS-100 from Juventas, AMR-001 from Neostem, ALD-201 from Cytomedix, allogeneic mesenchymal stem cells from Mesoblast, etc. According to the estimates, these cardiology and vascular products generated revenues of about \$ [REDACTED] in [REDACTED] and these and the upcoming products will be able to enjoy a market value of about \$ [REDACTED] in [REDACTED].

The emergence of tissue engineering over the past few decades has created considerable interest in exploiting the potential of cell-based therapy in orthopedics. The market leading companies involved in tissue-engineered bone products are Medtronic, BioMimetic Therapeutics, Inc., BioSet, Inc., Cerapedics, Inc., Kuros Biosurgery AG, etc. According to the estimates of Biotechnology Associates, the orthopedic segment of RM market earned about \$ [REDACTED] in [REDACTED] and with increased utilization of the products; the market is to gain a value of \$ [REDACTED] in [REDACTED].

Medtronic's INFUSE bone morphogenetic protein is the largest-selling product in the musculoskeletal industry that has changed the bar in terms of bone healing, and it is now under fire for complications related to off-label use. Though there are nearly 200 bone replacement products on the market, there is no other product that comes close to INFUSE in being able to consistently and reliably regenerate bone. The only other bone morphogenetic protein (BMP) on the market is Stryker Corporation's OP-1, acquired in [REDACTED] by Olympus Corporation. Olympus intends to distance itself from INFUSE by renaming the product Opgenra and calling it an eptotermin alfa instead of a BMP. BioMimetic Therapeutics, Inc. is awaiting FDA clearance for its Augment Bone Graft, a betatricalcium phosphate with recombinant human platelet-derived growth factor (rhPDGF-BB) for foot and ankle fusions.

Also focused on the foot and ankle market is privately owned BioSET, Inc. with its proprietary B2A, a synthetic peptide that mimics the effect of BMP-2 on bone growth and healing. Cerapedics, Inc. is also moving ahead with its i-FACTOR, a technology that incorporates an organic bone mineral (ABM), a natural hydroxyapatite, with a small amino acid polypeptide (P-15) suspended in a hydrogel carrier. Kuros Biosurgery AG, a Swiss company, is focused on developing a growth-factor technology based on a parathyroid hormone (PTH) variant. Meanwhile, Pfizer, Inc.'s subsidiary Wyeth, which provides BMP-2 to Medtronic, is presently in a Phase II IND trial evaluating BMP for treating osteoporosis.

Advances in bioengineering research have resulted in the widespread application of the regenerative dentistry into general dental practice to produce novel treatments and dramatically improve patients' quality of life. Many RM dental products are currently in use in the U.S. They include Osbone, Ceracell and Osseolive from Zimmer, AlloDerm GBR from Biohorizons, AlloSorb from Riemser, Biogran from Biomet and Gintuit from Organogenesis. According to Biotechnology Associates, such RM products with extensive applications in dentistry generated revenues of about \$ [REDACTED] globally in [REDACTED] and they are predicted to earn about \$ [REDACTED] in [REDACTED].

Human skin products were in fact the first commercially available and clinically applied organ substitutes. Skin autografts can be taken from unaffected areas and then applied to the wounded areas of the skin of the same individual. However, these autograft skin products face a lot of problems. Allogeneic skin grafts collected from cadavers also face immunogenic rejection and need to be replaced. Therefore, bioengineered skin products are likely to provide a more permanent solution. Currently, many tissue-engineered human skin products are commercially available for clinical applications. The common examples are Apligraf, Epicel, Dermagraft, Alloderm, Transcyte, Orcel, Integra DRT and Epistem. Some other skin products are currently under clinical trial. One example is StrataGraft developed by StrataTech Corp. According to Biotechnology Associates, these tissue-engineered skin products generated revenues of about \$ [REDACTED] in [REDACTED] and they are likely to earn about \$ [REDACTED] in [REDACTED].