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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. Whereas before, remedies for damaged tissue or organ functions due to congenital deformities, injuries, diseases or simple wear-and-tear relied upon either the body's ability to repair itself (or not), or a surgeon's skilled hands. Now, the area of regenerative medicine promises to revolutionize humanity's ability to remediate countless physical maladies that have perpetually afflicted humans and other animals. Compared to a select few life forms—like the starfish—man-made solutions for tissue repair and organ replacement haven't come close to nature's solutions. And where there once was no solution even offered by nature, researchers are now at the cusp of overcoming such limitations by literally regrowing damaged tissue and restoring organ functions through the use of tissue engineering and stem cell therapy. This is the promise of regenerative medicine.

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.
- 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.
- Evaluation 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?
- 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.
- Key RM players in dental applications.
- Leading companies in the field of drug discovery using cells and tissues as tools.
- 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.
- Listing of all the diseases with potential applications for regenerative medicines.
- 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. The appendix part of this analysis carries an exhaustive list of consultants who are in this field for several years offering consultancy services for new entrants into this field. 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 2008 and 2009*, 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

This study discusses the current state and activities of an up-coming and fast-developing knowledge field of regenerative medicine (RM). RM has been made possible by tissue engineering and, therefore, much of the discussion in this study is about both tissue engineering and regenerative medicine (TERM). TERM focuses on medical treatments to repair tissues and organs using bioengineered materials, cellular technologies and some forms of implants. The report also aims to identify the future initiatives that would stimulate knowledge creation and innovation processes leading to new therapies and products beneficial to patients in a global perspective.

The science of tissue engineering includes the development of therapeutic solutions based on a combination of scaffolds based on biomaterials, cells and tissue and biomolecules. Although, the report mentions several countries in this sector, only five of these countries (U.S., Japan, Germany, U.K., and Sweden) are the focus-countries of this analysis. In these focus-countries, there are about 303 companies actively engaged in regenerative medicine and 77 of these companies are engaged in the development of organ-specific and tissue-engineered products. About 230 companies are pharmaceutical industries focusing on drug discovery and development by using stem cells. Some of them are developing drugs to be used in regenerative medicine. Some are engaged in the development of tools

required for used in TERM applications. There are also some companies focusing on biomaterials for RM applications.

Almost all categories of RM companies are found in the U.S., but the country's strength is more pronounced in neurology, pancreas, kidney and liver applications. Germany is strong in skin, cartilage, bone and urological applications. Only the U.S. and Germany have projects in cardiovascular applications in clinical trials. Japanese companies are sound in skin, cartilage, bone, cardiovascular and urological applications. Companies in U.K. are active in skin, cartilage, bone and urological applications. As the companies currently engaged in biocompatible materials may face severe competition, they too are likely to enter the RM field. Although a huge market has been predicted for RM products in future, for many companies, this is still wishful thinking than a reality. The specific challenges for RM firms to reach the market include: public and political acceptance, selection of type of cell source, types of business model, and benefits/drawbacks of a firm's specific geographic location.

Today, Europe has a common regulation aiming at advanced-therapy medicinal products that include products based on genes, cells and tissues and centralized marketing authorization procedure. Europe, thus, faces a much improved regulatory situation. There are, however, variations as to policies, volume of investments, profile areas and applied research in the five focused countries. The U.S. leads in scientific output in terms of publication volume. Asian countries such as China, South Korea and Taiwan also are displaying an interest in this emerging field.

Among the individual research organizations, Harvard University is outstanding in the field of stem cell research. Other than the U.S. organizations, the top universities in stem cell research are located in countries like Japan, Sweden, England, Switzerland, Germany, Singapore, Italy and Canada. In stem cell research relating to neuroscience, the top non-U.S. organization is the Japanese Kyoto University in third position and the Swedish Karolinska Institutet is the top European organization.

In biomaterials research fields, the U.S., Japanese, German and Singaporean research environments hold the most prominent positions. The Universities of Toronto, Kyoto, Singapore, Bern, Seoul, Michigan, Bologna and Texas hold top positions in the statistics depending on biomaterial field. Swedish researchers are strong in the field of osteointegration, and in this field, Gothenburg University seems to outperform most other organizations.

This study provides separate comprehensive analytics for the U.S., Japan, Germany, U.K. and Sweden. Annual data are provided for tissue engineering and regenerative medicine products for the years 2008 to 2013. The report profiles 90 companies including many important players globally such as Amgen, Inc., Arthersys, Inc., Bioheart, Inc., Biomet, BioMimetic Therapeutics, Inc., Cellartis AB, Cellerix, Celgene Corporation, Cytori Therapeutics, Inc., Gamida Cell Ltd., Genzyme Corporation, Geron Corporation, Organogenesis, Inc., Osiris Therapeutics, Inc., Reneuron Group plc, Stryker Corporation, etc. The aim of this study is to provide, an overview of the global commercial landscape in regenerative medicine, the strength of the participating companies, and the scope for the hopeful new entrants into the sector. The time is ripe for the pharmaceutical giants to enter the new field and contribute their might to the development of cell therapies for the betterment of human health.

