



# STEM CELL 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

The purpose of this report is to describe the specific market segments of the medical research space using stem cells for R&D purposes. This study reviews all of the generally accepted analytical methods that are currently in use for preparing and using stem cells, and it examines the use of stem cells in developing new therapies for disease. The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for stem cells.
- Understanding the different sectors of stem cells, such as embryonic, adult and cord blood.
- Obtaining a complete understanding of the individual stem cell platforms from their basic principles to their clinical applications.
- Discovering feasible market opportunities by identifying high-growth applications in different stem cell areas.
- Focusing on global industry development through an in-depth analysis of the major world markets for stem cell technology, including growth forecasts.
- Presenting market figures regarding the current value of stem cells, market projections, market share, key players, and sector growth rates.

Key questions answered in this study are:

- What are the main stem cell business strategies adopted by leading stem cell companies?
- What are the benefits of various stem cell technology platforms?
- What is the current status of the cell therapy market?
- What is the therapeutic potential of cell therapy?
- What are the major and minor steps required for the success of cell therapy?
- Who are the current players and forces driving cell therapy?
- What is the science behind cell therapy?
- How can new stem cell technologies facilitate improved patient care?
- What are the main types of stem cell technologies that are currently available?
- Who are the current key players in this marketplace?
- Which stem cell market areas have the greatest potential for growth?

This report contains:

- Detailed analysis of recent trends in the stem cell marketplace.
- In-depth profiles of the leading companies with stem cell tools and technologies.
- A forecast for the stem cell market in the biotechnology and diagnostic industries.
- Views and principles on the stem cell industry from leading industry experts.
- Analysis of potential new stem cell applications in the clinical sector.
- Market predictions and trends analysis concerning U.S. expenditures on stem cell solutions.
- Analysis of commercial stem cell business strategies.
- The latest news and M&A developments in the stem cell marketplace.
- A comprehensive overview and insight into stem cell business strategies for growth in foreign markets.
- Examination of proprietary technologies and company strategies shaping the market for adult, embryonic and fetal stem cell products.
- Discussion of opportunities arising out of advances in hematopoietic stem cell transplantation.
- Analysis of global regulatory issues that are dictating where and how embryonic stem cell research is conducted.

## 1.2 Scope of the Report

A thorough overview of the biology of stem cells is provided, together with analyses of the funding trends, intellectual property, market opportunity, emerging areas of application, therapeutic pipeline, and key centers for stem cell research worldwide. This study emphasizes companies that are actively developing and marketing stem cell-related therapeutic agents. Activity and trends in research markets, including the numbers of institutions that use stem cells and the factors that influence purchasing, are addressed in this report. Other TriMark Publications reports related to the area of stem cells can be found at <http://www.trimarkpublications.com>.

## 1.3 Methodology

The author of this report is a Ph.D. in biochemistry from the University of Minnesota, with many decades of experience in scientific writing and as a medical industry analyst. He has been a senior director of several large regional and national healthcare laboratories. The editor has a Ph.D. in molecular and cellular biology with a focus on mobile genetic elements, promoters and parasite genetics from Tulane University, with postdoctoral training and experience in molecular entomology from the USDA Agricultural Research Service and non-coding RNA/computational genetics from the University of Leipzig in Germany.

Company-specific information is obtained mainly from industry trade publications, academic journals, news and research articles, press releases and corporate websites, as well as annual reports for publicly-held firms. Additionally, sources of information include the non-governmental organizations (NGOs) such as the World Health Organization (WHO) and governmental entities like the U.S. Department of Health and Human Services (HHS) and U.S. federal agencies such as the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Where possible and practicable, the most recent data available have been used.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information 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 or omission or for the results obtained by the use of such information. Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals regarding commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this report.

### *Primary Sources*

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects, as well as Sector Snapshots that we publish annually. We extract relevant data and analytics from TriMark's research as part of this data collection.

### *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.

### *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 from the industry being analyzed.

#### 1.4 Executive Summary

A stem cell is an extraordinary type of cell that has the ability to self-renew for long periods of time and to differentiate into specialized cells under appropriate physiological or experimental conditions. Traditionally, stem cells have been classified as either embryonic or adult (tissue-specific or cord blood) stem cells. Recent understanding of stem cell biology may provide new approaches to the treatment of a number of diseases as well as tissue/organ injuries, including cardiovascular disease, neurological disease, musculoskeletal disease, diabetes and hematopoietic disorders. Stem cell fate is determined by both intrinsic regulators and the extracellular environment (niche), and their expansion and differentiation *ex vivo* are generally controlled by growing them in a specific configuration (monolayer or three-dimensional culture). Differentiation is a process vital to enable stem cells to be used for therapeutic purposes in which unspecialized cells become specialized cells with restricted developmental potential.

The current market opportunity in stem cell therapeutics and technology resides entirely in the sale of reagents, media, cells, consumables and services to the research community and to individuals (*i.e.*, cord blood banking). There is currently no FDA-approved *bona fide* stem cell therapeutic. However, the FDA recently approved the first Phase I clinical trial for an embryonic stem cell-based therapy; Geron, a Menlo Park, California-based company, announced the clearance of the clinical trial, a treatment for spinal cord injury, in [REDACTED]. A number of other companies are also developing cell therapies in various therapeutic segments that are discussed in this report. TriMark forecasts that stem cell-based therapeutics will impact the market in three to five years, primarily based upon cord blood stem cells and adult stem cells (first to impact the market) harvested and expanded *ex vivo*. The medical indications most likely to be impacted by stem cell therapeutics are hematopoietic transplantations, hematological malignancies, cardiovascular and ischemic conditions. Over the next ten years, TriMark forecasts human embryonic stem cell (hESCs)-based therapeutics to be FDA-approved and to impact the marketplace.

The stem cell marketplace today can be subdivided into three major segments based on end-user applications:

- Toxicity screening for drug discovery and development.
- Autologous cell therapy.
- Allogeneic cell therapy.

There are three basic types of stem cell products:

##### ***Hematopoietic Stem Cells***

- Capable of regenerating functional bone marrow, particularly in cancer. Cord blood stem cells fall into this category.
- Of therapeutic value in aplastic anemia, leukemia, lymphoma, sickle cell anemia and ischemia.

### *Neural Stem Cells*

- Capable of differentiating into nerve and brain tissue.
- Of therapeutic value in neurodegenerative diseases such as Parkinson's and Alzheimer's and neural damage such as spinal injuries.

### *Mesenchymal Stem Cells, Pancreatic Islet Stem Cells*

- Capable of differentiating into bone, cartilage, fat, and pancreatic  $\beta$ -cells.
- Of value in orthopedic diseases and diabetes.

Focus is upon the lineage and, therefore, the functionality of the stem cell. This is of particular importance in regenerative medicine, in which stem cells are used for cell therapeutic applications and, thus, the lineage of the stem cell and its potential for differentiation into a given cell type is crucial. A unique feature of the stem cell marketplace is the large number of potential applications—and thus market segments—that can be carved out using the plasticity of various types of stem cells. Given the current market opportunity that exists for the harvest, storage, and clinical utilization of cord blood, a number of cord blood banks (both public and private) have been created in both the U.S. and the rest of the world. The following is an overview of the current state of the stem cell market:

- A near-term market opportunity for stem cell products exists in drug toxicity screening.
- Academic researchers perform the majority of the research, which is complemented by some research in pharmaceutical and biotechnology companies.
- The product and service offerings that constitute the market today are: growth media, culturing reagents/supplements (such as LIF, growth factors), freshly isolated stem cells, previously created stem cell lines, stem cell clones sold for research purposes, and custom services.
- In the cell therapy/regenerative therapy markets, there is a \$ [REDACTED] to \$ [REDACTED] market for bone marrow transplantation (BMT). This corresponds to over [REDACTED] BMTs currently performed worldwide per year with [REDACTED] in the U.S. alone. The total market for hematopoietic stem cell transplants for treating hematological disorders is valued at approximately \$ [REDACTED].
- Industry experts expect adult stem cell-based therapeutics to be first in the market, with several clinical trials in progress around the world, according to the clinical trial registry ClinicalTrials.gov. However, embryonic stem cells hold greater therapeutic promise, especially for type I diabetes and cardiovascular disease. Companies like Geron, which has recently been approved for the first embryonic stem cell clinical trial, as well as ES Cell International and NovoCell, are expected to dominate the market by [REDACTED].
- Industry experts expect that approximately \$ [REDACTED] will be spent on stem cell research worldwide by [REDACTED]. Spending on stem cell research should reach \$ [REDACTED] in [REDACTED] and \$ [REDACTED] in [REDACTED], of which [REDACTED]% of the budget will be spent on media and consumable supplies in the U.S. alone. Sales in the U.S. stem cell therapeutic market are expected to reach more than \$ [REDACTED] by [REDACTED] and upwards of \$ [REDACTED] by [REDACTED].