



# 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 the Report

Stem cells for research and development (R&D) is the specific focus of this TriMark Publications market research report. The stem cell market can be categorized into two main modalities: tools and cellular therapy. Tools are meant for basic research in stem cell biology, development of protocols for stem cell differentiation, methods development, as well as basic research activities in the induced pluripotent stem cell (iPSC) area. Cell therapy has been used to treat over ██████ patients in ██████ and ██████ patients in ██████ using the top ██████ cell therapy products alone. Every major type of stem cell is covered, including pluripotent embryonic stem cells, induced pluripotent stem cells (iPSCs), embryonic germ cells, fetal stem cells, umbilical cord stem cells, adult stem cells, hematopoietic stem cells, mesenchymal stem cells, gut stem cells, liver stem cells, epidermal stem cells, neural stem cells, pancreatic stem cells and eye stem cells. The stem cell sector is a gradually evolving landscape consisting of basic and translational research activities in academic institutions as well as companies engaged in the development and commercialization of technologies/tools for stem cell research and the development of bona fide cellular therapies. Dozens of stem cell treatments are moving through clinical trials and showing early success, raising hopes that some could reach the market within five years. As such, the global stem cell industry is primed to experience significant growth through the next decade. Additionally, this report surveys almost all of the companies known to be marketing, manufacturing or developing medical imaging equipment and supplies in the world. Detailed tables and charts with sales forecasts and market share data are also included.

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 This 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 holds a Ph.D. in biomedical sciences from the University of Massachusetts Medical School, and completed postdoctoral work at The Rockefeller University in New York and at Harvard Medical School. 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. The co-editor is a retired college professor with three decades of experience in teaching biochemistry, biotechnology, pharmacology, environmental biology and horticulture.

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 Publication's 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**

The stem cell sector is a gradually evolving landscape consisting of basic and translational research activities in academic institutions as well as companies engaged in the development and commercialization of technologies/tools for stem cell research and development of bona fide cellular therapies. The sector includes two major segments: tools and cellular therapy. Tools are meant for basic research in stem cell biology, development of protocols for stem cell differentiation, methods development, as well as basic research activities in the iPSC area. The stem cells manufactured by the industry find applications in cellular research, developing cell therapy products and drug discovery/toxicity testing. The top cell therapy products alone have been used to treat over patients in and patients in . These products alone generated revenues of \$ in , \$ in and \$ in . Dozens of stem cell treatments are moving through clinical trials and showing early success, raising hopes that some could reach the market within five years. Many of the trials focus on heart disease and inflammatory conditions, some of the biggest markets in medicine.

The stem cell market segment also includes the growing utilization in traditional drug discovery and development. This market is driven mainly by the acceptance that screens for new medicinal entities are more bona fide when performed on cells that are part of the target organ, and hence the use of stem cells to generate these target cells permits more targeted, more relevant screening in drug discovery. Stem cells are also finding their use in the production of cell types that are sentinels for *in vivo* drug toxicity, such as hepatocytes and cardiomyocytes. The cell culture industry relies on reagents, media and sera for culturing of human cells and maintaining them for long-term use. The market for reagents, media and sera accounted for about \$ in with the potential to reach \$ in .

Cellular therapeutics is again categorized by the origin of the cellular therapeutic that is being deployed: autologous or allogeneic. These two segments will exist together in the near-term of cellular therapy and the general outlook is that for some disease categories, autologous cellular therapy will offer value, whereas for others, such as acute myocardial infarction/heart attack and stroke, the autologous model is not an option and allogeneic cells must be utilized.

It is interesting to note that autologous cellular therapy (including autologous cancer vaccines) depict the ultimate in personalized medicine wherein the therapeutic agent is obtained from the patient itself. While autologous cell therapies are not fully personalized as an end-product, they utilize a patient's own biological source material and thus are certainly more similar to personalized medicine than those universally manufactured from common ingredients in large-scale lots. In the long run, we can expect the allogeneic cellular therapy marketplace to be much larger in size *vis-à-vis* patient populations, scope of therapeutic classes addressed, and the revenues generated from the sector.

The application of cord blood for many disease classes, principally hematological malignancies and inborn errors of metabolism, is a good benchmark for cell therapy. This field's growth has been mainly driven by the increasing number of diseases addressed, development of technologies and protocols for cellular processing, cryopreservation, and recovery, as well as clinical protocols for administration of cord blood for maximal clinical impact.

Today, there are about [REDACTED] units of cord blood banked within public cord blood banks around the world. These units are meant for transplantation (infusion in both pediatric and adult populations) and some fraction is meant for research. The price of a unit of cord blood for infusion is about \$[REDACTED]. This price point sets one potential benchmark for cost analysis and modeling for stem cell therapeutics in the future. For an adult, two cords are needed per stem cell therapeutic regimen (as a means to increase the total nucleated cell number infused). Cord blood banking is another segment of the industry that has been witnessing a slow but steady growth. In [REDACTED], the cord blood banking market was valued at \$[REDACTED] with the potential to reach \$[REDACTED] in [REDACTED]. There were [REDACTED] public cord blood banks in [REDACTED] and with a compound annual growth rate (CAGR) of [REDACTED]%, this number rose to [REDACTED] in [REDACTED]. The growth in private cord blood banks was relatively robust with a CAGR of [REDACTED]%. The number of private cord blood banks was only [REDACTED] in [REDACTED] and this rose to [REDACTED] in [REDACTED].

There are more than [REDACTED] cell therapy products commercially marketed by companies in the U.S. including: Dermagraft, Osteocel, PureGen, BioDfactor, BioDfence, Provenge, Carticel, Epicel, Nucel, Appligraf, GINTUIT, Trinity, Grafix, DeNovoET, Prokera and AmnioGraft. Provenge is the only cell-based immune therapy and it does not fall under the stem cell therapy category. Two more stem cell products (HemaCord and Clinimmune) were recently awarded a BLA by the FDA and are now being commercially available in the U.S. by the non-profit entities that own these products.

There are many other stem cell therapy products commercially distributed by firms in select countries in Europe, including: MySkin, CryoCell, ReCell, Carticel, Epicel, MACI, ChondroCelect, AlloStem, BioSeed-C, co.don chondrospheres, Epidex, EpiGraft and Diabecell. Furthermore, there are two point of care medical devices (by Therakos and Cytori) commercially marketed in Europe for cell-based treatments.

There are an equal number of stem cell therapy products commercially distributed and only available in other similarly regulated countries including: Cupistem (S. Korea), Heartcelligram (S. Korea), Cartistem (S. Korea), J-TEC Epidermis (Japan), J-TEC Cartilage (Japan), J-TEC Corneal Epithelium (Japan), Prochymal (Canada and NZ) and CureXcell (Israel). This excludes stem cell therapy products commercially sold in countries such as China and India where currently the regulations for these products are less defined.

The stem cell therapy products marketed in the U.S. and Europe in total were anticipated to generate about \$[REDACTED] in revenues in [REDACTED]. If the revenue for Provenge is not included, the bona fide stem cell sector was expected to generate in the range of \$[REDACTED] in [REDACTED]. Globally, stem cell therapy markets generated revenues of about \$[REDACTED] in [REDACTED] and the market is favorably positioned to reach about \$[REDACTED] in [REDACTED]. Regardless of the relative small size of the sector, it is marching towards the right direction as this is twice what the sector is estimated to have generated in [REDACTED]. While no stem cell therapy products obtained regulatory approval between [REDACTED] and [REDACTED], the sector had eight such approvals between [REDACTED] and [REDACTED]. The largest market for stem cells is the U.S. with

the total revenue generated in [REDACTED] reaching \$ [REDACTED]. The present growth rate indicates that the U.S. market has the potential to reach \$ [REDACTED] in [REDACTED]. Another major market for stem cell therapy is Europe, which generated nearly about \$ [REDACTED] in [REDACTED] and it has the potential to reach about \$ [REDACTED] in [REDACTED].

The investment scenario in stem cell research is also rather encouraging as the U.S., Europe and other countries globally making substantial investment in stem cell research. According to [REDACTED], the U.S. spent \$ [REDACTED] on human embryonal stem cell research and \$ [REDACTED] on non-embryonal stem cell research in [REDACTED]. Totally, the U.S. invested about \$ [REDACTED] on stem cell research. According to [REDACTED], the worldwide funding for research on stem cell research and regenerative medicine in [REDACTED] was approximately \$ [REDACTED] and this is likely to grow to \$ [REDACTED] in [REDACTED].

SAMPLE