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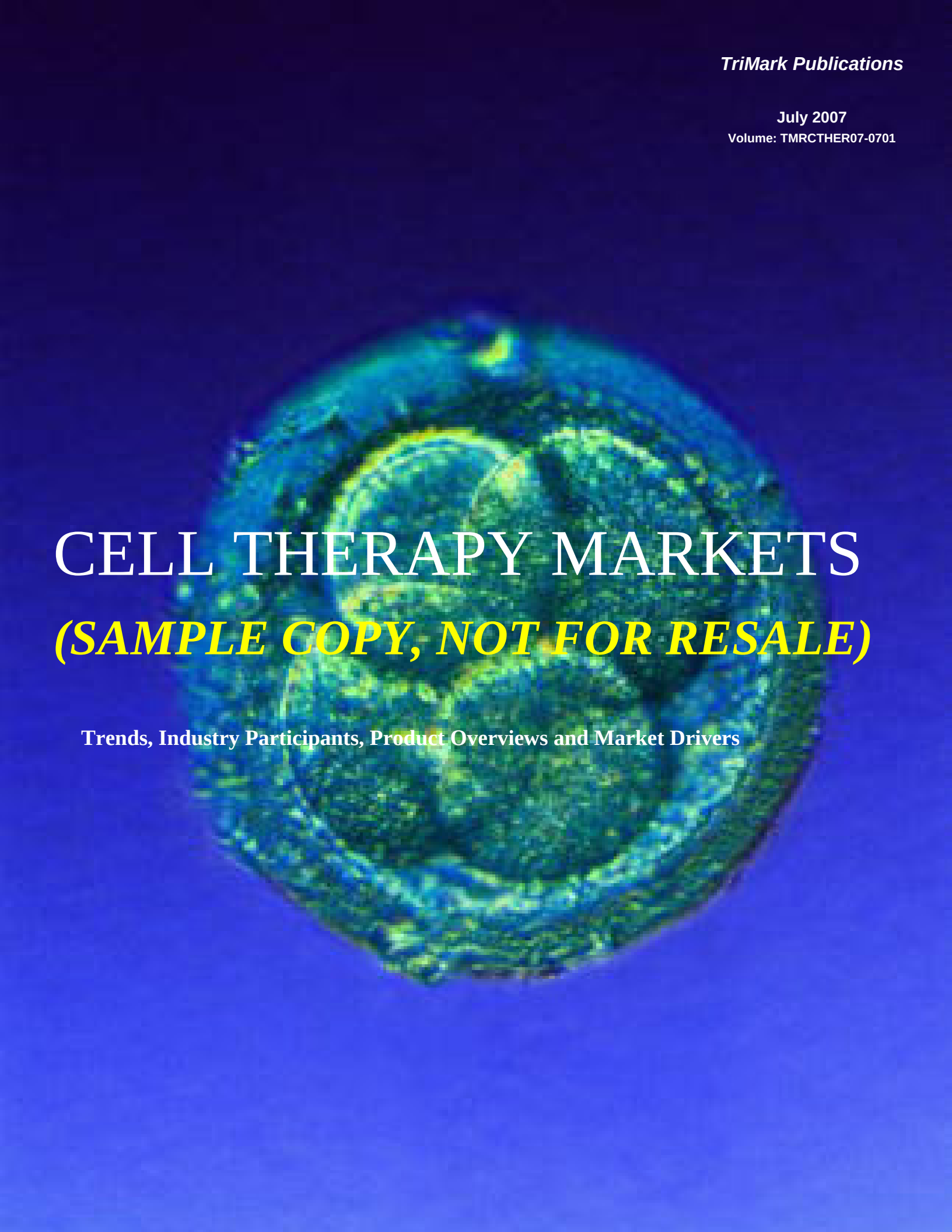

CELL THERAPY MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers

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1.1 Statement of Report

The purpose of this report is to describe the specific market segments of the cell therapy sector. This study reviews all of the generally accepted clinical and analytical methods that are currently in use today for implementing cell therapy techniques. It examines this new scientific technique and their reagents and supplies as utilized in hospitals, research laboratories and biotechnology companies.

1.2 About this Report

The two most important areas where cell therapy is used are in the hospital and the clinic. Growth areas of interest for cell therapy are biotechnology platforms. The emphasis in this analysis is on those companies and products that are actively developing and marketing instrumentation, reagents and supplies for cell therapy. The reader should consult other TriMark Publications reports at http://www.trimarkpublications.com for a detailed discussion of the important individual market segments, which are related to the biotech.

The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for cell therapy testing.
- Understanding the different sectors of cell therapy testing, such as growing cells, cell sources and the manufacturing segment; and, separately, looking at a description of the instruments, reagents and supplies marketed by major companies in each segment. The report discusses the market size, growth rates and market components for instruments and reagents, controls and consumables used in this area.
- Obtaining a complete understanding of the individual cell therapy platforms from their basic principles to their clinical applications.
- Discovering feasible market opportunities by identifying high-growth applications in different therapeutic areas, focusing on the biggest and expanding markets.
- Examining on global industry development through an in-depth analysis of the major world markets for cell therapy measurement technology, including growth forecasts.
- Presenting market figures regarding the current value of cell therapy testing, market projections, market share, key players and sector growth rates. The source of this information is the most current data derived from the global pharmaceutical industry.

By purchasing this report, you will have:

- An understanding of the most exciting cell therapy market segments, current and future.
- The latest information on leading products and research and development (R&D) initiatives.
- Familiarity with recent developments and their effects on selected markets.
- Knowledge of the cell therapy market as an area of growth, research and investment.
- An extensive review of the market for clinical cell therapy equipment and supplies used in the clinical hospital market for testing cell therapy concentrations.
- Details on the market for screening reagents and instruments for analysis of individual components in blood, serum or plasma.
- Defined dollar volume of sales, both worldwide and in the U.S. of the market, and analysis of the factors that influence the size and the growth of the market segments.

Key questions answered in this study:

- How can cell therapy measuring tools and technologies facilitate improved patient care?
- What are the main types of cell therapy technologies that are currently available?
- Who are the current key players in this marketplace?
- Which cell therapy market areas have the greatest potential for growth?
- What is the current state of the cell therapy market?
- Which biotechnology and diagnostic companies are investing in new cell therapy technology platform solutions?
- What are the main cell therapy business strategies adopted by leading companies?
- What are the benefits of various cell therapy technology platforms?
- Who holds the proprietary rights to the cell therapy market technology platforms?
- How is this technology currently being applied and utilized?
- In the U.S., Japan and the E.U., what regulatory processes apply to cell therapy technologies?
- How will new cell therapy technologies reduce healthcare expenditures?
- How will new cell therapy technologies affect R&D spending?

This examination contains:

- Detailed analysis of recent trends in the cell therapy marketplace.
- In-depth profiles of the leading companies with cell therapy tools and technologies.
- Forecasts for the cell therapy market in the biotechnology and diagnostic industries.
- Views and principles on the cell therapy industry from leading industry experts.
- Analysis of potential new cell therapy applications in the clinical sector.
- Market predictions and trends analysis concerning U.S. expenditures on cell therapy solutions.
- Projections of cell therapy market sizes for European and Asian markets.
- Projections for future applications of non-invasive tests in cell therapy related screening.
- Analysis of commercial cell therapy business strategies, such as co-branding.
- The latest news and M&A developments in the cell therapy marketplace.
- A comprehensive overview and insight into cell therapy business strategies for growth in foreign markets.
- An in-depth examination of the subsections of each cell therapy market segment is conducted.
- An overview that introduces the various kinds of stem cells, gives definitions, and discusses political, regulatory aspects, and the major developments.
- Analysis of applications including current and potential cytokine and cell therapies.
- A discussion of current products, as well as many that are still in clinical trials.
- An industry structure analysis including companies in the field and their focus.

Analysis includes charts and graphs measuring product growth and trends within the marketplace. Company-specific information, including sales figures, product pipeline status and R&D trends, is provided. Also, this study will:

- Assess cell therapy market drivers and bottlenecks, from medical and scientific community perspectives.
- Discuss the potential benefits of cell therapy for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the cell therapy market and analyze the current size and growth of individual segments.
- Provide current and forecasted market shares by company.
- Discuss profit and business opportunities by segment.
- Provide strategic recommendations for near-term business opportunities.
- Assess current commercial uses of the cell therapy market.

1.3 Scope of the Report

This analysis emphasizes companies that are actively developing and marketing instrumentation, reagents and supplies for performing cell therapy tests. The reader should consult other TriMark Publications reports at http://www.trimarkpublications.com for detailed discussions of important individual market segments related to the protein analysis market, such as clinical chemistry testing, high-growth diagnostic test markets, blood gas and electrolytes, over-the-counter diagnostic testing markets, and point-of-care testing.

1.4 Objectives

The goal of this report is to review the market for cell therapy products using screening reagents and instruments for analysis of individual components in tissue samples, blood, serum or plasma. It defines the dollar volume of sales, both worldwide and in the U.S., and analyzes the factors that influence the size and the growth of the market segments. Also examined are the subsections of each market segment, including the research labs, hospital labs and commercial laboratories. Additionally, the numbers of institutions using this type of cell therapy and the factors that influence purchases are discussed. The study surveys almost all of the companies known to be marketing, manufacturing or developing instruments and reagents for the cell therapy market in the U.S. Each company is discussed in extensive depth with a section on its history, product line, business and marketing analysis, and a subjective commentary of the company's market position.

1.5 Methodology

This examination is based upon interviews with sales and marketing professionals of companies in the cell therapy marketplace. They were queried, some several times, about their companies' products and marketing strategies, as well as their overall thoughts about their industry segment. Information also was obtained from discussions with founders, CEOs and vice presidents of some of the companies discussed in the report. Descriptions of the laboratories and patient facilities were derived from interviews with laboratory directors and technologists in these areas.

Other sources of information included trade association publications and meetings, product brochures and catalogs, and company literature. We have also gathered statistical information from the U.S. government, the World Health Organization, and private foundations. Annual reports, 10k filings, and financial reports were used as the basis for data reported on publicly held companies. The author of this report is a Ph.D. in biochemistry with years of experience in science writing and as a medical industry analyst. The editor is a doctoral level clinical scientist. He has over thirty years of experience in laboratory testing and instrument and reagent development technology, as well as extensive experience in senior level positions in biotech and medical service companies.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. 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, 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 with regard to commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this study. The information in this report is also based upon direct experience with sales and marketing professionals of companies in the point of care instruments and reagents market. People from many companies mentioned in this analysis were considered thoughtfully about their companies' products and marketing strategies, as well as their overall thoughts about their industry segment. The structure of the laboratory facilities was derived from familiarity with scientists and technologists working in these areas.

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 of 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 our 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 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 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 databases, proprietary databases, direct meetings and personal interviews with key personnel.

- Formulating a study outline with the assigned writer, including important items:

    - 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.

- Launching a combination of primary research activities, including two levels of questionnaires, executive-direct focused, company-specific, and region-specific communications to qualified and experienced senior executives worldwide.

- Completing a confirmatory primary research assessment of the report's findings with the assistance of Expert Panel Partners from the industry being analyzed.

1.6 Executive Summary

Cell therapy technologies and methods have already started to play an important role in the practice of medicine. Hematopoietic stem cell transplantation is replacing the old fashioned bone marrow transplants. Cell therapy is bound to become a part of medical practice. Unlike organs, cells are a potentially renewable resource for body repair. Advances in understanding cell biology, for instance, in the conditions needed for successful cell culture, and in the biochemical and genetic signals cells need for differentiation, have made cell therapy (including stem cell therapy) a scientific and clinical possibility.

Stem cells have two important properties that distinguish them from other kinds of cells; they can proliferate, possibly indefinitely, without changing their phenotype, and they can also spontaneously change—a process known as differentiation—into one or more new cell types. Differentiation takes place either directly or in several distinct steps. Cell therapy, including stem cell therapy, has the potential for healing and repairing the body. Many diseases, such as heart failure, stroke, Parkinson's disease, and diabetes, are marked by the loss of cells, which could be renewed by transplantation. Added to this, cells have applications in drug discovery as models for pre-clinical work that could complement or even replace animal testing. They are also an important tool in studies of basic human biology, which underpins the search for better medicines.

Cell therapy technologies overlap with those of gene therapy, cancer vaccines, drug delivery, tissue engineering and regenerative medicine. Various types of cells used, methods of preparation and culture, encapsulation and genetic engineering of cells are discussed. Sources of cells, both human and animal (xenotransplantation) are discussed. Methods of delivery of cell therapy range from injections to surgical implantation using special devices.

Much of the promise of cell therapy comes from stem cells, but this is still very much an emerging field with most activity being concentrated in universities, research institutes, and small biotech companies. While there are many clinical trials ongoing, most of these are with bone marrow derived stem cells and none with embryonic stem cells.

Cell therapy market drivers include:

- An aging population with both chronic health problems and an interest in aesthetic medicine ("feel better, look better").
- Increase in diseases where existing drug therapy does not provide a cure, diabetes, Alzheimer's disease, Parkinson's disease, *etc.*
- Increased attention given to "incurable" neurodegenerative disease/trauma, *e.g.*, amyotrophic lateral sclerosis (a/k/a *Lou Gehrig's* disease), spinal cord injury.
- Need for better models for pre-clinical testing in the pharmaceutical industry so they can more readily "fail early, fail cheaper".
- Increased interest in aesthetic/cosmetic procedures—$1.1 billion spent on Botox® in the U.S. last year, eight million Americans have cosmetic procedures each year and the market is growing in Europe.
- The life sciences/biotech industry is developing or has many of the tools for commercialization of cell therapy, *e.g.*, cell culture capacity, bioprocessing, cell surface markers, separation technologies, cell-based assays. These are currently dedicated to the manufacture of biologics (monoclonal antibodies, vaccines and recombinant proteins) but could readily be adapted.
- The growth of the biotech industry in the past decade has laid some of the groundwork for understanding safety and regulatory issues involved in taking a biological product like a cell therapy to market.

Cell therapy market barriers involve:

- For stem cells in particular, there is still a lack of basic understanding on what factors differentiate cells to the one of choice and keeps them differentiated, on how they engraft, survive, and carry out their function in therapy.
- It is not at all clear which stem cell and from what source might be the best therapeutic option or how "pure" a cell population should be. Nor is it clear if undifferentiated, lineage committed, or terminally differentiated cells ought to be used in therapy.
- There are technical issues over the cell expansion, large scale manufacture, storage and shipping of cell-therapy based products. Moreover, there is no clear route to the commercialization of stem cell therapy at the present time, although some companies can produce cells to GMP standards.
- The best method for delivery of cells into the body is still a subject for debate and further investigation.
- The correct dosage of cells to have a therapeutic effect is an issue.
- Safety issues involve whether the presence of animal components in the culture medium might introduce contamination, immunogenic responses to allogeneic (donor) cells, tumorigenic potential of stem cells.

- Ethical concerns and lack of harmonized regulation at national and international level surround the use of certain cells—especially those derived from human embryos or fetuses.

- The regulation of cell-based products remains unclear in many locations and there is a lack of harmony. They may be regulated as a medical device, a biologic or a medicinal product. New legislation is being discussed, both in Europe and the U.S. This uncertainty will have an adverse effect on reimbursement which could limit market expansion.

- Lack of investment in development after Phase 1 clinical trials. Media hype, especially on stem cells, may have led to over-expectation which may scare off some investors.

- For successful market development, culture change is needed—pharma reps will need a lot of training, and surgeons do not like to learn new methods of working. Products must be easy to use.

The value of the cell-based therapy markets was $[redacted] in [redacted], and is expected to increase to $[redacted] in [redacted], and $[redacted] in [redacted], growing at an annual rate of [redacted]%. The worldwide market for the important sub-sector of cell therapy, including stem cell, cytokine and growth factor therapies is estimated at $[redacted] in [redacted] and, rising at a compound annual growth rate (CAGR) of [redacted]%. The total market is expected to reach $[redacted] in [redacted].

The number of companies involved in cell therapy has increased remarkably during the past few years. More than [redacted] companies have been identified to be involved in cell therapy and [redacted] of these are profiled in part II of the report along with tabulation of [redacted] alliances. Of these, [redacted] are involved in stem cell therapy. The first off-the-shelf cell therapy approved by the FDA was for wound treatment. Recently, a bone morphogenic protein (BMP) has been approved for the acceleration of spinal fusions.

