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# MEDICAL NANOTECHNOLOGY 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

Nanotechnology has reached critical mass. Nowhere is this more evident than in medicine. Rising medical costs, demands for less-invasive procedures and pressures for immediate feedback of medical conditions, all point to nanotechnology as offering a new approach in healthcare. According to U.S. National Science Foundation estimates, by 2015 the annual global market for nano-related goods and services will top \$1 trillion, thus making it one of the fastest-growing industries in history. Assuming that these figures prove to be accurate, nanotechnology will emerge as a larger economic force than the combined telecommunications and information technology industries at the beginning of the technology boom of the late 1990s. This report covers the specific segments of the medical nanotechnology markets, with particular emphasis on those segments where this emerging technology is or shows the potential to be most impactful.

Nanotechnology, a field of science and technology that aims to control matter at the atomic, molecular and macromolecular level, potentially has far-reaching and paradigm-shifting implications for biology, drug discovery and medical technologies. The discipline has already yielded healthcare discoveries that have been used for drug delivery and diagnostic purposes. In this study, we describe various nanotechnologies under development for biological and medical purposes and assess their potential. Moreover, this analysis is arranged to provide an overview of the regulatory issues faced by the medical nanotechnology industry and focuses on how specific segments within the industry are poised for high future growth.

### 1.2 About This Report

This report presents an overview of the medical nanotechnology markets with the latest information regarding emerging new products, how the technology may affect older products and technologies, and an analysis of sector trends. It will analyze the medical nanotechnology markets for development opportunities involved in medical products and procedures, therapeutic and diagnostic markets, products, patent and business strategies, and the outlook for nanotechnology in medicine. Forecasts of the medical nanotechnology markets and an analysis of products in the worldwide medical nanotechnology markets and the directions to which the technology is leading will provide a basis for understanding the significant developments and future possibilities within medical nanotechnology.

The principal objectives of this report are to:

- Identify viable technology drivers through a comprehensive look at various platform technologies for the medical nanotechnology markets.
- Obtain a complete understanding of the important medical nanotechnology platforms, and the application of these unique capabilities to the successful development of nanotech products to diagnose and treat diseases, including the most active areas of product development in drug delivery and *in vivo* imaging.
- Discover feasible market opportunities via an identification of high-growth applications in different medical nanotechnology markets areas, with a focus on the biggest and expanding markets for drug delivery.
- Focus on global medical nanotechnology industry development through an in-depth analysis of the major world markets for these modalities, including forecasts for growth.
- Present market figures regarding the current potential value of the medical nanotechnology markets, projections and growth rates.
- Examine in depth the use of medical nanotechnology product and market development, and show specific examples of their use in commercial development and the repositioning of therapeutic agents and products.

By purchasing this examination, the reader will have:

- An improved understanding of the current state and likely future of the most important medical nanotechnology market segments.

- The latest information on the leading companies engaged in R&D and product development in the most promising medical nanotechnology product pipelines, including products for diagnostics, imaging and drug delivery.
- A comprehensive perspective of the exciting recent medical nanotechnology market developments and revelations and how this technology is already having an impact.
- Knowledge of how nanotechnology is addressing unmet needs in the pharmaceutical industry, including the reformulation of drugs to improve their bioavailability or toxicity profiles.

This study will cover the following categories of medical nanotechnology market segments:

- Nanotools, nanocapsules, dendrimers, nanoporous and nanostructured materials, nanodevices, nanosensors and quantum dots, nanoarrays, nanotubes and liposomes.
- Global market for nanotechnology products.
- Role of medical nanotechnology in driving market changes.
- Nanotechnology patent issues.
- Categories of medical nanotechnology products.
- Nanotechnology in drug delivery.
- Nanotechnology in diagnostics and sensors.
- Nanotechnology in imaging.
- Key technology findings for medical uses of nanotechnology.
- Business trends in the industry including M&As, key players and venture capital.
- Important technology trends in medical nanotechnology.
- Medical nanotechnology market regulation and reimbursement.

There is a general discussion of current issues:

- Assess the market drivers and bottlenecks, from the perspective of the medical, technological and scientific communities.
- Discuss the potential benefits of medical nanotechnology for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the medical nanotechnology markets and analyze the current size and growth of individual segments.
- Discuss profit and business opportunities in the medical nanotechnology markets segment.
- Provide strategic recommendations for near term business opportunities.
- Assess current commercial uses of the medical nanotechnology markets.

We answer the following questions in this report:

- What are the near term business opportunities in the medical nanotechnology markets?
- What are the current and forecasted sizes of the medical nanotechnology markets?
- What are the business models currently used by companies in the medical nanotechnology markets?
- How will manufacturers, researchers, physicians, patients and payers influence the medical nanotechnology markets?
- What are the drivers and bottlenecks influencing the medical nanotechnology markets?
- What are the current and emerging technologies used in the medical nanotechnology markets?
- Who holds the proprietary rights to the medical nanotechnology markets, especially in such a multidisciplinary environment?
- What are current applications of these technologies?
- What regulatory processes must medical nanotechnology undergo in the U.S., Japan and Europe?
- How will new or emerging medical nanotechnologies change treatment and payment paradigms?
- How will medical nanotechnologies reduce adverse clinical reactions and decrease total patient care cost?
- How will medical nanotechnology reduce healthcare expenditures? Or will it?
- How will medical nanotechnology impact diagnostic testing?
- What is the role of nanotechnology in drug development?



- Which medical nanotechnology product categories are driving growth?
- How are biomarkers being developed using nanotechnology?
- What companies are developing nanotechnology drug delivery systems?
- What nanotechnology platforms are being used in point of care diagnostic testing?

This report contains:

- A comprehensive overview of those categories of medical nanotechnology that are, or will be revolutionizing the treatment of cancer, biodetection of disease markers, molecular imaging, cardiovascular diseases, implant technology, tissue engineering, drug, protein, gene and radionuclide delivery.
- Full descriptions of the technologies involved and how these differ from existing and emerging technologies.
- An analysis of the technological approaches undertaken by the various competitors and industry and the end-user response to these products.
- Regulatory issues and legislation affecting use and marketing of products.
- Profiles of selected competitors in each nanotechnology category.
- A description of government initiatives in medical nanotechnology.

### 1.3 Scope of the Report

The emphasis in this study is on those companies that are actively developing and marketing medical products utilizing nanotechnologies. The report does not include an analysis of the broader segments of nanotechnology like electronics, textiles, chemicals, coatings and structural material. The reader should consult other TriMark Publication reports at [www.trimarkpublications.com](http://www.trimarkpublications.com) for a detailed discussion of the important individual market segments which are related to the products discussed here that utilized these technologies, such as specific testing and medical device equipment, molecular diagnostic testing, clinical chemistry, cancer testing, point of care diagnostic testing and other exciting new drug delivery methods.

This examination reviews the market for medical products based on emerging nanotechnologies. It defines the dollar volume of sales in the U.S. market and analyzes the factors that influence the size and the growth of the market segments. The study details market sizes and growth rates, as well as other emerging world markets. The analysis discusses activity and trends in nanotechnology and goes on to discuss in detail the trends that have developed which have stimulated this market.

The report surveys many of the companies known to be marketing, manufacturing or developing medical nanotechnologies and products, in the U.S and worldwide, for the selected segments identified. In addition to leading companies, special effort was made to include mention of smaller companies and companies located around the world, that are having or potentially could have an impact on their industry far in excess of their current size. Each company is discussed in depth with a section on the history of the company, the product line, business and marketing analysis, and a subjective commentary of the position of the company in its market.

This analysis does not examine the following markets:

- Nano-enabled tools (atomic force microscopy (AFM)).
- Nano-mass spectroscopy.
- Dip-pen nanolithography.

### 1.4 Methodology

The information in this review is based upon primary data obtained from interviews with sales, marketing professionals, and executives of companies in the medical nanotechnology field. People from many of the companies mentioned in this report were queried, some several times, about their companies' products and marketing strategies as well as their overall thoughts about their industry segment. Information was also obtained from interviews with founders, CEOs and vice presidents of some of the companies discussed in the report.

Sources of information for the study were trade association publications and meetings, product brochures, and catalogs and company literature. Where the companies under discussion were publicly held, an examination of the annual reports, 10k filings and financial reports were used as the basis of the data reported. Important data sources include the Health for All Database of the World Health Organization (WHO), data published by the statistical office of the European Communities (Eurostat), as well as various health data from the United Nations (UN) and the Organization for Economic Cooperation and Development (OECD). Where possible and practicable, the most recent data available have been used.

The author of this report has decades of experience in scientific writing in peer-reviewed journals and as a medical industry analyst. Moreover, he has consulted for FDA- and E.U.-regulated companies to help accelerate their product development to market. The senior editor is a Ph.D. who has many years of experience in clinical science, as well as extensive experience in senior-level positions in biotech, pharma and medical service companies.

Some of the statistical information was taken from Biotechnology Associates' databases (a global information and consulting company specializing in analysis of biotech and medical information) 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.

*Primary Sources:* TriMark collects information from hundreds of databases 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 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 members 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 its 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 of 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.

### 1.5 Executive Summary

Nanotechnology is rapidly affecting many areas of medicine and life science, the most prominent of which are currently in drug delivery, diagnostic imaging, clinical diagnostics and the use of nanomaterials in medical prostheses. A number of medical nanotechnology products have been introduced to the market within the last five years, and a growing number are in the development pipeline of pharmaceutical, biotech and start-up companies. Momentum is steadily building for the successful development of additional nanotech products to diagnose and treat disease.

Nanotechnology is an emerging sector of science that will have far-reaching implications for biosciences, drug discovery and medical technologies. The potential for developing new products is so large that there appears to be a paradigm shift forming in the way medical devices and other related medical diagnostic products will be developed in the next decade. The comparison to the technology explosion that occurred with the development of the transistor is not over-reaching. Technology platforms which are now used in medical treatment will be transformed into devices that will solve current limitations of size, sensitivity and cost.

#### *Key Findings*

- Nanotechnologies are currently being applied to target cancer, cardiovascular disease and central nervous system (CNS) disorders, but these approaches to new therapies are primarily in the development stage. One notable exception is the Abraxis nanotechnology product for breast cancer.
- Nano-enabled drug delivery systems are the fastest-growing sector of medical nanotechnology. Pharmaceutical companies are attempting to improve the targeted delivery of older, established, approved products in order to extend their commercial life cycle.
- Regulatory authorities are supporting nanotechnologies that can improve the development of pharmaceuticals and diagnostic agents. Many regulatory policies are currently being reassessed to ensure innovation and safety when utilizing nanotechnologies.
- Many governments are keen to apply nanotechnology across pharmaceuticals, drug delivery and healthcare monitoring in an effort to reduce R&D costs and enhance levels of productivity.
- Nanomaterials are being utilized to develop more sensitive and specific POC diagnostic tests, primarily through the development of new flow-through sensors. Nanowires and cantilever assay systems will expand the market by helping to shift diagnostic tests from central laboratories to the point of diagnostics.
- Nanomaterials for dental and bone implants have been one of the most successful medically-related areas of nanotechnology product development.

#### *Market Drivers*

- Growing governmental support for research and development in nanotechnology.
- Advances in nanoscale technologies have the promise to solve unmet medical needs; for example, in adding cancer drugs to cross the blood/brain barrier.
- New approaches to drug delivery can extend the useful commercial life of established therapeutic agents.
- New nanomaterials in dental and bone graphs are emerging as commercial successes.

- Investment capital and pharma collaborations are increasing the interest in start-up nanotechnology research companies.

### **Market Restraints**

- Cost factors where some products that lend themselves to nanotechnology, *e.g.*, creams and cosmetics, tend to be viewed as commodities, unless niche marketing is applicable, *e.g.*, anti-aging creams.
- Fear of new nanotechnology or the improper use and positioning of nano products is causing some public concern about safety issues.
- Need for new manufacturing support and testing methodologies and equipment to keep pace with nanotechnology in R&D.

Medical nanotechnology is redefining traditional health-related fields like imaging, diagnostics, drug delivery, regenerative medicine and biomaterials. Moreover, nanotechnology is driving the development of new generations of novel medical products. Many of these advances will offer improved outcomes for patients, therapies for difficult-to-treat diseases or conditions, improved drug manufacturing efficiency or better use of valuable medical professional resources. With at least 18 nanomedicines already approved and progressively more in active development, the next five years should see a steady succession of new nanotech-based drugs, imaging agents and diagnostic products entering the marketplace. The most active areas of medical nanotechnology are in drug delivery and *in vivo* imaging.

Nanotechnology is addressing unmet needs in the pharmaceutical industry, including the reformulation of drugs to improve their bioavailability or toxicity profiles. For instance, [REDACTED] drugs have been approved based upon Elan's nanocrystal technology. Nano-particles have also been designed to effectively target disease sites for treatment, including Abraxane, a breast cancer treatment developed by American Pharmaceutical Partners.

Although levels of financing from public markets and private investments have declined recently, in part because of adverse market conditions, the investment community is taking nanotechnology seriously. No fewer than [REDACTED] new stock indices have been launched to track nanotech. Nanomedicine markets will be complex and competitive as companies employ nanotechnology to extend patent term, exclusivity and market life. Impediments to nanotechnology commercialization include the creation of effective strategies to untangle complicated intellectual property situations, the effective licensing and commercialization of nanotech products and the better understanding of safety, health and environmental risks.

Worldwide, more than [REDACTED] companies and research institutes are researching with nanotech, in all industry sectors. When restricted to turnover and services, there are about [REDACTED] companies. It is estimated that companies with products restricted to nanotechnology products number about [REDACTED]. The R&D spending worldwide for nanotechnology was \$[REDACTED] in [REDACTED] and increased to \$[REDACTED] by [REDACTED]. The global market for all types of nanotechnology products from all sectors was \$[REDACTED] in [REDACTED], growing to \$[REDACTED] by [REDACTED] (a CAGR of [REDACTED]% between [REDACTED] and [REDACTED]).

Nanomaterials, particularly nano-particles and nanocomposites, dominated the nanotechnology market in [REDACTED], accounting for over [REDACTED]% of the market. Nanotools accounted for [REDACTED]% of the market, and nanodevices the remaining [REDACTED]%. Nanotools, which include the nanolithographic tools used to produce the next generation of semiconductors, are projected to grow at a much faster rate than either nanomaterials or nanodevices, and as a result their market share should increase to [REDACTED]% by [REDACTED].

End-user markets for nanotechnology in [REDACTED] were:

- Environmental remediation ([REDACTED]% of the total market).
- Electronics ([REDACTED]%).
- Energy ([REDACTED]%).
- Biomedical applications ([REDACTED]%).
- Other ([REDACTED]%).

The nanomedicine market was \$ [REDACTED] in [REDACTED], increasing at a CAGR of [REDACTED]% to \$ [REDACTED] in [REDACTED]. Drug delivery is [REDACTED]% of the market. Over [REDACTED] nanomedicine drug delivery systems are on the market. Three systems of drug delivery account for sales of \$ [REDACTED] in [REDACTED]:

- Neulastia.
- Pegasys.
- PEG-Intron.

The strongest driver for nanomedicine products is in the drug delivery arena where nanomedicine is poised to deliver to the market evolutionary as well as revolutionary products. Some products could be available immediately while others will appear on the distant horizon. As companies develop drug delivery products and begin to seek commercial applications for them, securing valid and defensible patent protection will be vital to the long-term survival of these companies.

Major factors that will drive commercialization in the near future are:

- Federal funding for university research in nanotechnology.
- The drug industry's desire for novel drugs and therapies.
- An increasing understanding of the molecular basis of disease.
- The expiration of blockbuster drug patents using standard methods of delivery.
- Bottlenecks facing early-stage nanomedicine commercialization efforts.
- The significance of patents to a start-up.
- The impact of the Bayh-Dole Act.
- The nano-patent "gold rush".
- Personalized medicine and nanodrugs.
- The role and interplay of federal agencies (FDA, EPA, Patent Office).
- The effect of emerging "patent thickets" on commercialization.