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RESPIRATORY THERAPEUTICS AND DEVICES MARKETS

(SAMPLE COPY, NOT FOR RESALE)

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1. Overview

1.1 Statement of Report

In the respiratory therapeutics and devices market, continuing new advancements in the ability to detect and manage respiratory diseases are being made. The respiratory disease space is one of the most profitable sectors of therapeutics, and it is expected to be growing vigorously into the future. This TriMark Publications report analyzes various respiratory therapeutics and devices markets, with special attention paid to therapeutic remedies for chronic obstructive pulmonary disease (COPD), asthma and cystic fibrosis. Also addressed in this study are therapeutics for upper respiratory infections such as: allergic rhinitis, influenza, respiratory syncytial virus, sinusitis, and pharyngitis/tonsillitis. From respiratory devices side, key segments covered include: continuous positive airway pressure (CPAP) devices, ventilators, nebulizers, oxygen concentrators, humidifiers and reusable resuscitators. This review covers the leading market players, the competitive landscape, and the emerging pipeline products in the respiratory therapeutics and devices markets. Specifically, areas examined in this study include: available and developing technologies in the field, the U.S. and global market size for respiratory therapeutic products, and the profiles of companies that are focusing on the respiratory therapeutics and devices market. This review analyzes the size and growth of the therapeutic respiratory disease category, including the factors that influence the various market segments within it. Detailed charts with sales forecasts and market share data for the U.S. and global respiratory therapeutics and devices markets are included.

Also examined are:

- Major drug classes in treating respiratory diseases.
- Leading therapeutics and players.
- The respiratory pipeline and analysis of future therapeutics.
- Respiratory care industry market analysis.
- SWOT analysis of the respiratory market.
- Main drivers for respiratory therapeutics.
- Main restraints for respiratory market.
- Challenges of respiratory therapeutics going forward.
- Emerging market: Focus on Chinese health biotechnology market.
- Summary of market strengths, weaknesses, opportunities and threats.
- Key companies participating in this sector.

This market report analyzes the size and growth of the respiratory therapy market, examining the factors that influence the various market segments and the dollar volume of sales, both in the U.S. and worldwide. The respiratory disease market has been divided into the following parts for examination:

- COPD.
- Asthma.
- Upper respiratory infections such as allergic rhinitis, influenza, respiratory syncytial virus, sinusitis, and pharyngitis/tonsillitis.

This choice of disease states is based upon the available therapeutic advances and the number of companies interested in that segment of the respiratory disease market.

1.2 About This Report

This report includes the following features for each major respiratory disease market:

- Develop business strategies by understanding the trends and developments that are driving the respiratory therapeutics market globally.
- Design and develop your product development, marketing and sales strategies.

- Exploit mergers and acquisitions (M&A) opportunities by identifying market players with the most innovative pipeline.
- Develop market-entry and market expansion strategies.
- Identify key players best positioned to take advantage of the Emerging market opportunities.
- Exploit in-licensing and out-licensing opportunities by identifying products, most likely to ensure a robust return.
- What's the next big thing in the anesthesia and respiratory devices market landscape?
- Make informed business decisions from the in-depth analysis of the global.
- Respiratory therapeutics market and the factors shaping it.

1.3 Scope of the Report

The goal of this study is to review the market for respiratory disease therapeutics and disease management equipment and supplies. This market analysis answers the following key questions:

- Which companies are utilizing new, cutting-edge therapeutics to develop, validate and market drugs for clinical use in respiratory disease management?
- What are the current impediments to incorporating promising therapeutic entities into clinical practice?
- Which new therapeutics show the most promise for regulatory approval?
- What are the economic challenges to gaining approval? And what kind is best?
- How does regulatory oversight drive approval and adoption of new drugs?
- Which strategic alliances show the greatest synergy in bringing respiratory therapies to the market?
- Which shared technologies are driving the most encouraging development of new respiratory therapeutic methods?
- Estimate the current and future U.S. and global markets for respiratory disease.
- Examine market drivers that have resulted in the global race for new respiratory disease therapeutics.
- 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.
- Understand the impact of current products in medical ventilator market.
- Analyze the need for respiratory management and care devices.
- Analyze the pulmonary function test market.
- Analyze the continuous positive airway pressure therapy market.
- Analyze the humidifier market.
- Analyze the long-term oxygen treatment market.
- Provide insight into the respiratory products pipeline and the companies that strive to bring these products to the market in the immediate future.
- Evaluate global activity in respiratory care with specific contributions from the top-ranking five countries: U.S., Japan, Germany, U.K. and China.
- Analyze the segments in therapeutics for major diseases like COPD, asthma, and cystic fibrosis.
- Gain insight into the current applications of major drug classes in treating respiratory diseases.
- Explore drug discovery efforts in relation to respiratory diseases.
- Analyze the usual hurdles new therapeutic products 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 the respiratory disease sector.
- Assess business models and requirements for a successful pharmaceutical industry.
- Identify the key players in the respiratory disease sector.

Key questions answered in this study are:

- What are the products that come under the phrase “respiratory therapies”?
- What disease conditions offer the greatest potential for respiratory therapy technology platforms?
- What is the current global market for respiratory therapies?

- How much of clinical development activities are taking place globally in respiratory therapies sector?
- How many companies are involved in the development of respiratory therapy products?
- How many patents have been issued for respiratory therapies products in infectious disease?
- What market drivers are responsible for the global growth in therapy and management of respiratory disease?
- What regulatory and technical challenges are being confronted by the respiratory therapies industry?
- What are the current promising developments in respiratory therapies disease sector?
- What is the latest position of the clinical studies and product pipeline in the respiratory therapies disease sector?
- How long it will take for the respiratory therapy technology platforms to become the standard of clinical practice to replace older and less efficacious medicines?
- How much of venture capital funding was invested into the respiratory therapies sector?
- What is the potential population in the U.S. for respiratory disease diagnosis?
- What are the top ten respiratory therapies products available in the market place?
- How many companies are involved in the development of respiratory therapies products?
- How many firms concentrate on asthma products?
- Which firms are involved in the development of COPD products?
- Which companies are focused on the development of cystic fibrosis products?
- Which companies are focusing on upper respiratory therapies products?
- Which companies are associated with developing respiratory care management products?
- What are the different business models suitable for the different types of respiratory therapies products?
- What are the requirements for the commercial manufacturing of respiratory therapies products?
- What are the different funding sources in the U.S. for the development of respiratory therapies products?

This report contains:

- Current market opportunities for respiratory therapy products.
- Product development challenges confronted by the respiratory therapies industry.
- A brief discussion on the need for respiratory therapies and the advantages over the conventional clinical approaches.
- The future direction of the emerging respiratory therapies products.
- The overall picture of pipeline products in respiratory therapies sector and the companies involved.
- A note on the projected time-line for respiratory therapies products.
- A market projection for global respiratory therapies products.
- Listing and explaining the most popular respiratory therapies products in the market.
- Presentation of the global picture of the respiratory therapy products market with particular reference to the leading countries, such as U.S., Japan, Germany, U.K. and China.
- Number of firms engaged in respiratory therapies products.

This examination surveys most of the pharmaceutical companies known to be currently marketing, manufacturing or developing products for the respiratory market for both therapy and disease management, in both the U.S. and the world. Each company is discussed in depth, with sections on its history, product line, business and marketing analysis, and a subjective commentary of the company's market position. The U.S. is the focus of this report. Primary attention is paid to leading players and therapies in the COPD, asthma, cystic fibrosis, and upper respiratory disease segments.

1.4 Objectives

The main objectives of this analysis are in identifying viable technology drivers through a comprehensive look at platform technologies for respiratory disease management, including the respiratory pipeline and analysis of future therapeutics:

The COPD Market

- Upcoming COPD therapeutics.
- Phosphodiesterase inhibitors.
- Long acting muscarinic antagonists.
- Long-acting beta-agonists.
- Mediator antagonists.
- Leukotriene-B4 inhibitors.
- Chemokine inhibitors.

The Asthma Market

- Upcoming asthma therapeutics.
- Bronchodilators.
- Corticosteroids.
- Cytokine blockers.
- Chemokine antagonists.
- Phosphodiesterase inhibitors.
- Kinase inhibitors.
- Mast cell inhibitors.

The Cystic Fibrosis Market

- Upcoming cystic fibrosis therapeutics.
- New therapies for CF.
- Gene therapy for cystic fibrosis.
- Novel CFTR modulation.
- Anti-inflammatory cystic fibrosis therapy.
- Anti-infective agents in cystic fibrosis.
- Mucoactive agents in cystic fibrosis.

The Influenza Market

- Upcoming influenza treatments.
- Discovering feasible market opportunities by identifying high-growth applications in different clinical disease areas.
- Focusing on global industry development through an in-depth analysis of the major world markets for respiratory disease management, including growth forecasts.

The emphasis in this report is on the use of therapeutic products for respiratory disease management. The reader should consult other TriMark Publications reports (see <http://www.trimarkpublications.com>) for detailed discussions of important individual market segments related to the medical devices and supplies markets. For example, TriMark has separate reports on *Cardiac Rhythm Management Devices World Markets*, *Disposable Medical Supplies Markets*, *Disposable Syringe Markets*, *Home Medical Testing Devices*, *Orthopedics Markets*, *Patient Monitoring Markets*, *Plastic Surgery Markets* and *Sleep Disorders* focused on insomnia, sleep apnea, restless leg syndrome, bruxism, narcolepsy and sleepwalking.

1.5 Methodology

The author of this report holds a Ph.D. in respiratory medicine/immunology from the Royal College Surgeons of Ireland and has completed post-doctoral studies and lecturing in Trinity College Dublin and University College Cork. The author has many decades of experience in scientific writing and as a medical industry analyst. As an expert in the respiratory disease field, she has managed many research programs, and has held senior scientist positions in academia. The author has significant experience in international scientific writing, and has peer reviewed cutting edge research.

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. Additional sources of information include non-governmental organizations (NGOs) such as the World Health Organization (WHO) and governmental entities such as the U.S. Department of Health and Human Services (HHS), 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 it publishes annually. TriMark extracts relevant data and analytics from its 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.

1.6 Executive summary

Specific Objectives of this report are to:

- Examine the current and future respiratory therapeutic and device market and provide a critical analysis of its advantages and disadvantages.
- Give a detailed account of the current respiratory disorders that are the main players in this market and provide descriptions of first line therapies, devices required and future therapeutics.
- Provide a detailed understanding of the principles of respiratory therapeutics.
- Evaluate the global economic impact of current therapeutics, patient expirations and future potentials.
- Therapeutics with potential currently in clinical trials or pipeline.
- Present market sales figures, identifying submarket figures and predicting the future of the respiratory therapeutic and device market.
- Outlining the markets strengths, weaknesses, opportunities and threats.
- Investigate the Chinese market with respect to the overall pharmaceutical business and more specifically the respiratory industry.

The respiratory therapeutic and device market is highly competitive and is compiled of a large range of drugs and devices that cater for patients with both acute and chronic symptoms. Currently, the total market is generating high revenues and this has the potential to increase as respiratory illness prevalence increases globally. Penetration into Emerging markets will also see an increase in revenue in the future.

Global pharmaceutical sales in [REDACTED] were estimated at \$ [REDACTED], a significant increase from \$ [REDACTED] in the previous year. The U.S. market dominated with \$ [REDACTED] in sales, Europe claimed \$ [REDACTED] and the rest of the world commanded \$ [REDACTED]. Respiratory therapeutics was the sixth most competitive market and was valued at \$ [REDACTED] in [REDACTED] with a growth figure of [REDACTED]%. Respiratory market growth was driven by sales in asthma and COPD therapeutics which made up over \$ [REDACTED] of this market. Allergic rhinitis had the second largest sales figure with just over \$ [REDACTED] globally.

The main submarkets of the respiratory therapeutic and device market are COPD, asthma and allergic rhinitis. Globally there are over [REDACTED] people living with COPD or asthma. The COPD/asthma market is predicted to reach international sales of \$ [REDACTED] by [REDACTED] with a compound annual growth rate (CAGR) of [REDACTED]% ([REDACTED]). Over the last number of years the annual growth rate has been higher at [REDACTED]% in the major markets including the U.S. and was driven by intense marketing of combination therapeutics. These agents continue to dominate the market and in [REDACTED] combination therapeutics of inhaled corticosteroids and long-acting beta-agonists (LABAs) demanded a market share of \$ [REDACTED] globally.

The main respiratory therapeutics on the market today are:

- Combination therapies (Advair/Seretide, Symbicort and Combivent).
- Corticosteroids (Pulmicort, Nasonex/Asmanex and Flovent/Flixotide).
- Leukotriene inhibitors (Singulair).
- Beta-2 agonists (Xopenex, Salamol and Ventolin).
- Antihistamines (Clarinet/Aerius, Allegra/Telfast and Zyrtek).
- Monoclonal Antibodies (Synagis and Xolair).

- Anticholinergics (Spiriva).

In the short-term, however, it is predicted that between now and [REDACTED], the market will be unstable. This is mainly due to important patents expiring, and the wait for newer therapies to enter the marketplace. The coming years will also see competition for dominance within key areas such as asthma and COPD. New therapies for treatment of cystic fibrosis are critical in increasing its dominance in the respiratory field.

Respiratory diseases are increasing in prevalence globally. According a National Health Interview Survey in [REDACTED] that was performed by the Department of Health and Human Services, Centers for Disease Control and Prevention and the National Center for Health Statistics:

- [REDACTED] % of U.S. adults have been diagnosed with emphysema.
- [REDACTED] % of U.S. adults have been diagnosed asthma and [REDACTED] % currently have asthma.
- [REDACTED] % of U.S. adults have been diagnosed with sinusitis.
- [REDACTED] % of U.S. adults have been diagnosed with chronic bronchitis.

The survey revealed that there is also a gender imbalance when it comes to respiratory disorders:

- Women are more likely to be diagnosed with asthma, sinusitis and chronic bronchitis than men.
- Men are more likely to be diagnosed with emphysema, than women.

There is also a differential prevalence of respiratory diseases amongst certain ethnic groups in the U.S.:

- Asian U.S. adults are less likely to be diagnosed with asthma, chronic bronchitis or sinusitis than Blacks or Whites.
- Hispanic adults have lower incidents of asthma and sinusitis than non-Hispanic White or non-Hispanic Black adults.
- Hispanic adults are less likely to be diagnosed with emphysema or chronic bronchitis than non-Hispanic Whites.

Socio-economic background was also found to play a role in the National Health Survey with respect to respiratory diseases.

- Adults with a University degree are less likely to be diagnosed with chronic bronchitis or emphysema.
- Lower income adults tend to have higher rates of asthma, emphysema and chronic bronchitis.

Smoking is a major contributing factor to developing respiratory illnesses such as COPD and is known to exacerbate conditions such as asthma. There has been a significant increase in COPD cases in developing countries and this is associated with a more prevalent smoking culture. Meanwhile in the developed world it is estimated that up to [REDACTED] % of COPD deaths are attributed to smoking.

- [REDACTED] % of U.S. adults are current cigarette smokers.
- [REDACTED] % of U.S. adults were former smokers.
- [REDACTED] % of U.S. adults have never smoked.