The Future of Monoclonal Antibodies Market – Market Forecasts to 2015, Competitive Benchmarking, Product Pipeline and Deals Analysis

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MAbs are one of the fastest growing segments in the pharmaceutical industry. In 2008, MAbs recorded sales worth $27.4 billion indicating a growth rate of 23.9% over 2007.

Global Monoclonal Antibodies Market: Executive Summary

Monoclonal Antibodies (MAbs) was the fastest growing segment of the global pharmaceutical market in 2008. Application of MAbs ranges from various oncology indications to autoimmune diseases. Gradually, MAbs are beginning to pave their way into the treatment of Central Nervous System (CNS) disorders such as Alzheimer’s disease and metabolic disorders such as Diabetes. Since the launch of Orthoclone OKT3 in 1992, 23 MAbs have been launched in the US market.

High unmet needs associated with the conventional therapies have compelled patients to switch over to the more effective and safer MAbs.

GBI Research finds that conventional therapies such as chemotherapies, hormonal therapies and NSAIDs have a long history of poor safety profile due to their systemic-action characteristics. Further, due to their systemic action, they failed to impart the desired effect at the site of action. These unmet needs have propelled researchers to develop MAbs, which specifically target the site of action. Due to this competitive advantage, MAbs are preferred over conventional therapies in disease conditions, which require drug action at specific targets.

The utilization of MAbs increased over the last few years due to increased awareness of these drugs among physicians and patients. In addition, successful MAbs such as Rituxan, Avastin and Remicade have received regulatory approvals for multiple indications, which further increased the patient base. New MAbs that have been launched into the market over the last couple of years such as Simponi and Ilaris have opened up new patient bases. Simponi is indicated for patients diagnosed with active psoriatic arthritis and active ankylosing spondylitis. Similarly, Ilaris is indicated for patient’s cryopyrin-associated periodic syndromes.

Therefore, GBI Research foresees huge market potential associated with MAbs.
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3.2.2 Drug Prices

Mabs prices are fixed at a very high level. For example, the annual cost of therapy for Soliris for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) is $XXX. Similarly, Raptiva, which is indicated for plaque psoriasis, has an annual cost of therapy of around $XXX. Further,

![Figure 3: MAbs Market, Global, Annual Cost of Therapy ($), 2000-2015](image)

In 2008, MAbs annual of cost of therapy was estimated at $XXX indicating a CAGR of approximately XX% between 2000 and 2008. By 2015, the cost is forecast to reach $XXX.

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Source: GBI Research
3.7 Global MAb Market Drivers

3.7.1 Gradual Growth in the Uptake of MAb스 Have Driven the Monoclonal Antibody Sales Growth

MAbs uptake has been rapid in cancer indications such as HER over-expressing breast cancer, B-cell non-Hodgkin’s lymphoma, metastatic NSCLC and metastatic colorectal cancer. In these indications, systemic therapies such as chemotherapies are also available as treatment options.

3.7.2 Improved Side-effect Profiles and Tolerance of MAbs Therapy

Murine MAbs were the first antibodies developed through hybridoma technology. However,

3.7.3 Lack of Effective Conventional Therapies Accelerates Utilization of MAbs

Chemotherapy drugs are cytotoxic in nature. They are given either orally or through intravenous infusion. One of the serious side effects
5 Global MAbs Market: Pipeline Analysis

5.1 Introduction

Recent developments of MAbs in immunology are paving the way for a wide range of new therapies. MAbs are under clinical studies for various new indications including genetic, blood and central nervous system disorders.

In 2008-2009, approximately 193 MAbs were under research and development. Approximately, 375 clinical trials are under process for these 193 MAbs.

![Figure 29: MAbs Market, Global, Pipeline Segmentation by Disease, 2009](image)

Source: GBI Research

5.2 MAbs Nomenclature

The nomenclature of MAbs is the name given to identify the generic, or nonproprietary, names to MAbs. This is widely used by all pharmaceutical and biotechnology companies as well as World Health Organization’s International Nonproprietary Names and the United States Adopted Names.

Affix for origin: The affix preceding -mab suffix is the animal origin of the monoclonal antibody. For human MAbs, the affix -u- and for humanized monoclonal antibody the affix is -zu-.
8 Global MAbs Market: Appendix

8.1 Related Reports
The Future of the Biosimilars - Market Forecasts to 2015 Key and Trends
RNA Therapeutics - Strong Potential for Unmet Needs in Pharma
The Future of the Oncology Therapeutics - Market Forecasts to 2015 and Key Trends
The Future of the Autoimmune Diseases Therapeutics - Market Forecasts to 2015 and Key Trends

8.2 Research Methodology
GBI Research’s dedicated Research and Analysis Teams consists of experienced professionals with a pedigree in marketing, market research, consulting background in the medical devices industry and advanced statistical expertise.

GBI Research adheres to the Codes of Practice of the Market Research Society (www.mrs.org.uk) and the Society of Competitive Intelligence Professionals (www.scip.org).

All GBI Research databases are continuously updated and revised. The following research methodology is followed for all databases and reports.

Figure 78: GBI Research Methodology

8.3 Geographical Scope
The report covers markets across the seven major geographies the US, the UK, Germany, France, Spain, Italy and Japan. In the report, wherever “global” is mentioned it refers to these seven geographies.

8.4 Coverage
The objective of updating GBI Research’s coverage is to ensure that it represents the most up to date vision of the industry possible.

Changes to the industry taxonomy are built based on extensive research of company, association and competitor sources.
Company coverage is based on three key factors: market capitalization, revenues and media attention/innovation/ market potential.

An exhaustive search of 56 member exchanges is conducted and companies are prioritized on the basis of their market capitalization;

The estimated revenues of all major companies, including private and governmental, are gathered and used to prioritize coverage; and

Companies which are making the news, or which are of particular interest due to their innovative approach are prioritized.

GBI Research aims to cover all major news events and deals in the medical industry, updated on a daily basis.

The coverage is further streamlined and strengthened with additional inputs from GBI Research’s Expert Panel (see below).

8.5 Secondary Research

The research process begins with exhaustive secondary research on internal and external sources being carried out to source qualitative and quantitative information relating to each market.

The secondary research sources that are typically referred to include, but are not limited to:

- Company websites, annual reports, financial reports, broker reports, investor presentations and SEC Filings;
- Industry trade journals, scientific journals and other technical literature;
- Internal and external proprietary databases;
- Relevant patent and regulatory databases;
- National government documents, statistical databases and market reports;
- Procedure registries; and
- News articles, press releases and web-casts specific to the companies operating in the market.

8.6 Primary Research

GBI Research conducts hundreds of primary interviews a year with industry participants and commentators in order to validate its data and analysis. A typical research interview fulfills the following functions:

It provides first-hand information on the market size, market trends, growth trends, competitive landscape, future outlook etc;

Helps in validating and strengthening the secondary research findings; and

Further develops the Analysis Team’s expertise and market understanding.

Primary research involves E-mail interactions, telephonic interviews as well as face-to-face interviews for each market, category, segment and sub-segment across geographies.

The participants who typically take part in such a process include, but are not limited to:

- Industry participants: CEOs, VPs, marketing/product managers, market intelligence managers and national sales managers;
- Hospital stores, laboratories, pharmacies, distributors and para-medics;
- Outside experts: Investment Bankers, Valuation Experts, Research Analysts specializing in specific medical equipment markets; and
- Key Opinion Leaders: Physicians and surgeons specializing in different therapeutic areas corresponding to different kinds of medical equipment.
8.7 Models

Where no hard data is available GBI Research uses modeling and estimates in order to produce comprehensive data sets. The following rigorous methodology is adopted:

Available hard data is cross referenced with the following data types to produce estimates:
- Demographic data: Population, split by segment;
- Macro-economic Indicators: GDP, Inflation Rate etc;
- Healthcare Indicators: Health expenditure, Physicians Base, healthcare infrastructure and facilities; and
- Selected epidemiological and procedure statistics.

Data is then cross checked by the expert panel. All data and assumptions relating to modeling are stored and are available to clients on request.

8.8 Forecasts

GBI Research uses proprietary forecast models. The following four factors are utilized in the forecast models:
- Historic growth rates;
- Macro indicators such as population trends and healthcare spending;
- Forecast epidemiological data; and
- Qualitative trend information and assumptions.

Data is then cross checked by the Expert Panel.

8.9 Expert Panels

GBI Research uses a panel of experts to cross verify its databases and forecasts.

GBI Research expert panel comprises of marketing managers, product specialists, international sales managers from medical device companies; academics from research universities, KOLs from hospitals, consultants from venture capital funds and distributors/suppliers of medical equipment and supplies etc.

Historic data and forecasts are relayed to GBI Research’s Expert Panel for feedback and adjusted in accordance with their feedback.

Details of the make up of the expert panel can be viewed through GBI Research.com, and are available to clients on request.

8.10 GBI Research Consulting

We hope that the data and analysis in this brief will help you make informed and imaginative business decisions. If you have further requirements, GBI Research's consulting team may be able to help you. GBI Research offers Tailor made analytical and advisory services to drive your key strategic decisions. For more information about GBI Research’s Consulting capabilities, please contact us directly at GBI Research: +1 646 395 5460 or email us at info@gbiresearch.com

8.11 Contact Us

If you have any queries about this report or would like further information, please contact at the below given telephone numbers or email address.

North America: +1 646 395 5460
Europe: +44 161 227 0669
Asia Pacific: +91 40 6616 6700
Email: info@gbiresearch.com
8.12 Disclaimer

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