China Genetic Engineering Drug Industry Report, 2011-2012

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STUDY GOAL AND OBJECTIVES

This report provides the industry executives with strategically significant competitor information, analysis, insight and projection on the competitive pattern and key companies in the industry, crucial to the development and implementation of effective business, marketing and R&D programs.

REPORT OBJECTIVES

- To establish a comprehensive, factual, annually updated and cost-effective information base on market size, competition patterns, market segments, goals and strategies of the leading players in the market, reviews and forecasts.
- To assist potential market entrants in evaluating prospective acquisition and joint venture candidates.
- To complement the organizations' internal competitor information gathering efforts with strategic analysis, data interpretation and insight.
- To suggest for concerned investors in line with the current development of this industry as well as the development tendency.
- To help company to succeed in a competitive market, and

METHODOLOGY

Both primary and secondary research methodologies were used in preparing this study. Initially, a comprehensive and exhaustive search of the literature on this industry was conducted. These sources included related books and journals, trade literature, marketing literature, other product/promotional literature, annual reports, security analyst reports, and other publications. Subsequently, telephone interviews or email correspondence was conducted with marketing executives etc. Other sources included related magazines, academics, and consulting companies.

INFORMATION SOURCES

The primary information sources include State Food and Drug Administration (SFDA), Southern Medicine and Economic Research Institution, National Institute for the Control of Pharmaceutical and Biological Products and Annual Reports of Listed Companies etc.

Abstract

China gets a late start in developing genetic engineering drug industry, but has achieved leapfrog advance. At present, China has at least one hundred enterprises involved in genetic engineering drugs. In recent years, the compound growth rate of genetic engineering drug market in China is as high as 49%, with an average gross margin of more than 80%. However, the technology strength and efficacy of locally produced genetic engineering drugs are relatively weak. In particular, the pegylated recombinant human granulocyte colony stimulating factor (PEG-rhG-CSF) for injection of CSPC Pharmaceutical Group Limited that approved for marketing in March 2012 is the only homemade long-acting protein product. Still, due to the impetus of huge market capacity as well as a package of preferential policies, many domestic enterprises, including GeneScience Pharmaceuticals, Amoytop and Anhui Anke Biotechnology, are accelerating the industrialized research of long acting protein drugs.

Monoclonal antibody is one of the most promising genetic engineering drugs. As of May 2012, SFDA approved the marketing of a total of 18 monoclonal antibody drugs. Among these drugs, nearly 60% are foreign brands including Roche, Merck and Novartis with the combined sales accounting for three fourths of the Chinese monoclonal antibody drug market. However, with the marketing of monoclonal antibody drugs made by companies such as Shanghai CP Guojian Pharmaceutical and Biotech Pharmaceutical, the market share of homemade monoclonal antibody industry is on the rise gradually.

In addition, recombinant human erythropoietin, recombinant human interferon, recombinant human growth hormone, recombinant human granulocyte-colony stimulating factor and recombinant human insulin are among the important genetic engineering drugs. As of late 2011, China had roughly 20 recombinant EPO manufacturers that approved for marketing of related products. In particular, as former EPO preparation exporters to China, enterprises including America-based Amgen and Germany-based Boehringer Mannheim GmbH have withdrawn from the Chinese market owning to low price competition. Presently, the Chinese EPO market is dominated by domestic manufacturers including 3SBio Inc. and DIAO Group. In 2011, the sales of 3SBio Inc. accounted for 42.7% in China's EPO market. As such, impacted by channel, price competition and other factors, recombinant human growth hormone and recombinant human granulocyte-colony stimulating factor markets are also dominated by domestic enterprises.

In the recombinant human interferon market, the high-performance long-acting interferon of Schering-Plough and Roche still maintained huge consumption in Chinese market in spite of the high prices. In recent years, the market share of imported long-acting interferon has remained at 60% or so in China.

Moreover, due to improving economic level and raising awareness of people, foreign-branded recombinant human insulin in Chinese market are predominant, occupying 90% market share in the corresponding period.

Although China lags behind in terms of the overall level of genetic engineering drugs, the industry has accumulated rich R&D and industrialization experience as well as capital reserves. Thus, with a host of genetic engineering drug patents to become due, Chinese enterprises, such as Walvax, are committed to the industrialization research of monoclonal antibody, long-acting recombinant protein drugs and other generic drugs with high technical barriers. On April 26th, 2012, Walvax announced to invest in Shanghai Fengmao in next four years to develop and produce genetic engineering generic drugs including rituximab, bevacizumab, adalimumab, panitumumab, denosumab and long-acting EPO.

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Table of contents

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Selected Charts

- Classification of Biopharmaceutical Products
- Classification of Genetic Engineering Drugs
- Sales of Amgen's Four Genetic Engineering Drugs, 2009-2011
- R&D Cost of Main Biopharmaceutical Enterprises in the World, 2009-2011
- Competition Pattern of Genetic Engineering Drugs in China, 2011
- Comparison between China, USA and Japan by Commercialization Schedule of Some Genetic Engineering Protein Drugs
- Expiration Date of Main Genetic Engineering Drug Patents in the World
- Monoclonal Antibody Drugs Approved for Marketing in China, As of 2012
- Sales of Monoclonal Antibody Drugs in China, 2008-2011
- Some Listed Companies Investing in Monoclonal Antibody Industry in China, 2009-2012
- Sales Volume and Value of EPO in China, 1999-2011
- Competition Pattern of EPO in China (by Sales Volume or Value), 2007-2011
- Market Size of rh-IFN in China, 2006-2011
- Market Share of Major rh-IFN Injection Enterprises in China by Sales, 2006-2008
- Market Capacity Forecast of rh-IFN for Hepatitis Therapy in China
- Comparison Between Long-acting IFN and Conventional IFN
- Market Share of Major rh-GH Enterprises in China, 2006-2008
- Market Capacity Forecast of rh-GH for Short Stature Therapy in China
- Market Prices of Common Insulin Products in China, 2010-2011
- Lot Release Volume and Its Growth Rate of Coagulation Factor VIII in China, 2008-2011 Market Share of rhG-CSF Enterprises in China, 2010
- Major Monoclonal Antibody Product Line under Research of Shanghai Lansheng Guojian Pharmaceutical
- Revenue and Net Income of Shanghai CP Guojian Pharmaceutical, 2008-2010
- Monoclonal Antibody Product Series under Research of Shanghai CP Guojian Pharmaceutical
- Under-research Monoclonal Antibody Projects of Beijing Biotech

Selected Charts

- Revenue and Profit of ANKE BIO, 2007-2011
- ANKE BIO's Revenue Breakdown by Industry, 2007-2012
- ANKE BIO's Revenue Percentage by Industry, 2007-2012
- ANKE BIO's Revenue Breakdown by Region, 2007-2011
- ANKE BIO's Revenue Percentage by Region, 2007-2011
- ANKE BIO's Gross Margin by Industry, 2007-2011
- ANKE BIO's Revenue from Top 5 Clients and % of Total Revenue, 2007-2011
- Name List and Revenue Contribution of ANKE BIO's Top 5 Clients, 2011
- ANKE BIO's Procurement from Top 5 Suppliers and % of Total Procurement, 2007-2011
- R&D Costs and % of Total Revenue of ANKE BIO, 2007-2011
- ANKE BIO's Revenue from Interferon and Growth Hormone, 2007-2011
- ANKE BIO's Gross Margin from Interferon and Growth Hormone, 2007-2011
- Revenue and Operating Income of GenSci, 2009-2011
- Research Schedule of GenSci's Genetic Engineering Drugs, As of 2011
- Revenue and Operating Income of SL Pharmaceutical, 2007-2012
- SL Pharmaceutical's Revenue and Procurement from Top5 Clients and Suppliers, 2008-2011
- SL Pharmaceutical's Revenue Breakdown by Products, 2008-2011
- SL Pharmaceutical's Revenue Percentage by Products, 2008-2011
- SL Pharmaceutical's Revenue Breakdown by Region, 2008-2011
- SL Pharmaceutical's Gross Margin by Products, 2008-2011
- R&D Costs and % of Total Revenue of SL Pharmaceutical, 2008-2011
- Revenue and Operating Income of Sihuan Bioengineering, 2008-2012
- Sihuan Bioengineering's Operating Revenue by Region, 2008-2011
- Sihuan Bioengineering's Revenue from Interleukin and EPO, 2008-2011
- Sihuan Bioengineering's Gross Margin from Interleukin and EPO, 2008-2011

Selected Charts

- Revenue and Profit of Beijing Four Rings, 2008-2011
- Revenue and Profit of Neptunus Interlong Bio-Technique, 2008-2012
- Neptunus Interlong Bio-Technique's Revenue Breakdown by Business, 2008-2011
- Products List of 3SBio Inc.
- Revenue and Profit of 3SBio Inc., 2007-2012
- 3SBio Inc.'s Revenue Breakdown by Product/Region, 2009-2012
- 3SBio Inc.'s Revenue Percentage by Products, 2009-2011
- 3SBio Inc.'s Revenue Percentage by Region, 2009-2012
- R&D Cost of 3SBio Inc. by Products, 2009-2011
- Research Schedule of 3SBio Inc. , As of Mar., 2012
- Revenue and Profit of THDB, 2008-2012
- THDB's Revenue Breakdown by Products, 2008-2011
- THDB's Revenue Percentage by Products, 2008-2011
- THDB's Revenue Breakdown by Region, 2008-2011
- THDB's Revenue Percentage by Region, 2008-2011
- THDB's Gross Margin by Products, 2008-2011
- THDB's Revenue from Top 5 Clients and % of Total Revenue, 2008-2011
- Name List and Revenue Contribution of THDB's Top 5 Clients, 2011
- Revenue and Gross Margin of THDB's Recombinant Human Insulin, 2008-2011
- Research Schedule of Amoytop Biotech's Long-acting Recombinant Protein Drugs, As of 2011

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