

KEY FINDINGS:

- The biopharmaceutical market is estimated to be worth \$78.8 billion in 2007 growing by 15% per annum, focusing on two key areas, monoclonal antibodies (\$31 billion) and biological active proteins (\$48 billion) and driven by improvements in manufacturing technologies and advances in biotechnology and drug delivery platforms.
- Most biopharmaceutical products, being large molecules, have hitherto been given by injection. Companies have focused on new technologies to optimize injectable delivery such as needle free devices, sustained/controlled release and long-acting subcutaneous implants. However, alternative routes of delivery are now being explored including transdermal drug delivery systems, (iontophoresis, micro needle array, electroporation), pulmonary delivery, oral delivery, nasal delivery and nanotechnology platforms.
- The generic sector of the pharmaceutical market has been evolving to keep abreast with changing market conditions, and a growing interest in developing biopharmaceuticals. Several leading biopharmaceutical companies generate sales in excess

of US\$1 billion per annum which has attracted the attention of generic specialists who are now embarking on the development of generic copies of biopharm products, referred to as “biosimilars”.

- The expertise required to choose, design, execute and monitor biopharmaceutical production processes is radically different from that involved in synthetic drug production and is the province of molecular biologists rather than pharmaceutical chemists. This has resulted in rapid advances in manufacturing processes and increased the need for outsourcing to access specialist technologies.
- The advent of medicines tailored to individual genotypes is brought a significant step closer by the link between genetic profiling and biopharm products with highly specific biological activities.
- The biopharmaceutical market sector is growing faster than pharmaceuticals overall and is set to represent 15% to 25% of all pharmaceuticals within five years, generating global sales in excess of US\$150 billion by 2020.

Introduction

“Over the last decade, biotech antibodies have provided some of the biggest breakthroughs in medicine. The list includes Avastin, Herceptin, Rituxan and Erbitux for cancer and Enbrel, Humira, and Remicade for immune and inflammatory disorders.”

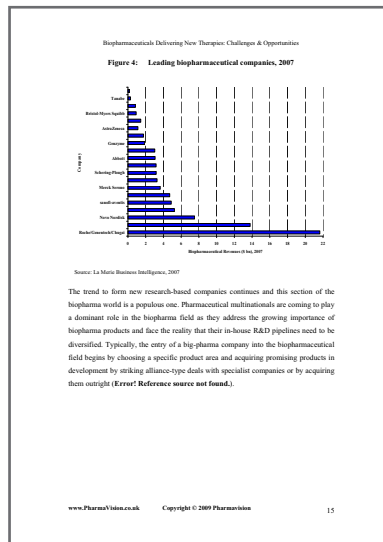
Sidney Taurel, Chairman and Chief Executive Officer Eli Lilly and Company

A biopharmaceutical is defined as a medical drug (proteins including antibodies, nucleic acids, DNA, RNA or antisense oligonucleotides) which is produced using biotechnology. In the late 1990s advances in manufacturing and processing revolutionized the production of biopharmaceuticals such as recombinant DNA technology and hybridoma technology. These technological advances have enabled the market place to open up and for smaller players to enter and capitalize on the growing need for targeted, personalized medicine.

During the 1960s and 1970s formulation began to assume greater importance. More recently still, the inconvenience of parenteral administration became a focus for attempts to minimize the burden and optimize treatment. Nowadays, any development programme for a new drug will include consideration of the optimal dosage form from the conception of a drug development project. A plethora of delivery platforms have evolved to meet market demands and overcome solubility and pharmacokinetic issues, and will have an important role to play in determining the dosage form that ultimately appears on the market.

The biopharm field represents a major opportunity for generic manufacturers with sufficient resources to withstand the relatively high development costs

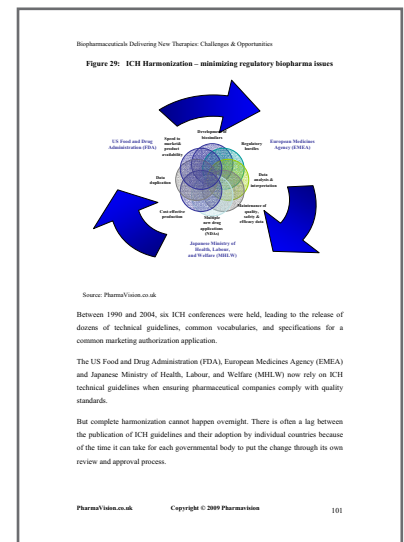
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and the technological demand. It is estimated that biosimilars, targeting the six leading biopharm products, could generate revenues in excess of \$2 billion within 2-3 years. However, there are considerable challenges facing companies developing and marketing biopharm products.

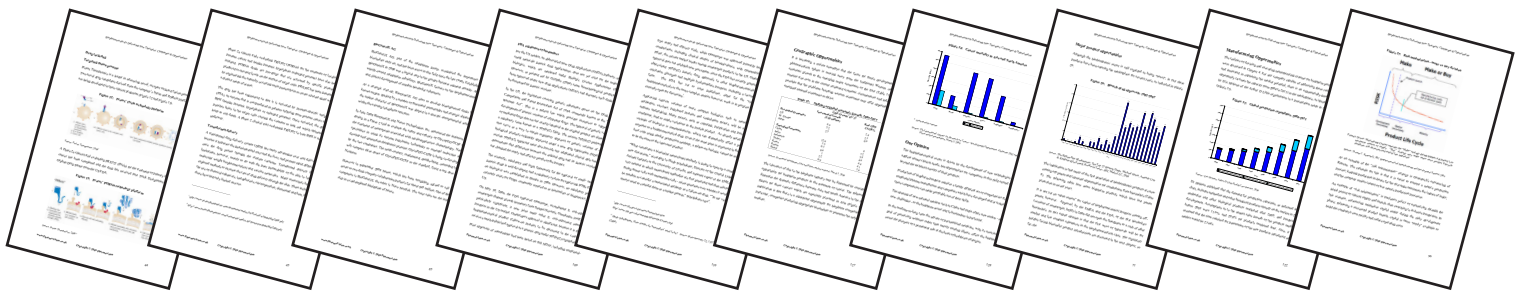
Manufacturing problems will remain a significant hurdle for companies entering this field; the regulation of innovator biopharm products continues to evolve and the harmonization of regulatory processes among the three main national regulatory agencies (the EU, the US and Japan) should make life simpler for biopharm companies seeking to establish a global presence for their products.

The biopharmaceutical market was estimated to be worth over \$78.8 billion in 2007 with antibodies representing around \$31 billion sales and protein



products generating almost \$48 billion. The biopharma market is growing at an annual rate of around 15% - far higher than pharmaceuticals (c. 6-7% per annum). By 2020 the market is forecast to be worth over \$150 billion driven by a shift in usage from conventional drugs to biopharma products, the relatively high cost of biopharma products, the launch of biosimilars and a new generation of bio-therapeutics.

Biotherapeutics represent 7.5 percent of all drugs on the market; they account for approximately 10 percent of the total expenditure for marketed drugs and their use is growing at more than 20 percent per year. Biotechnology drug candidates account for around 32 percent of all pipeline research programs. In addition, biological drugs are administered in life-saving or end-stage applications, 74 percent more than chemically derived pharmaceuticals.



EXPERTS FROM LEADING ORGANIZATIONS CONSULTED:

Bob Irving, PhD. Chief Operating Officer, Nanotechnology Victoria Ltd and CEO, Interstitial NS

Charles Potter, Founder and Chief Executive Officer, Glide Pharma

David Nowotnik, Senior Vice President of R&D, Access Pharmaceuticals, Inc.

Drew Hannaman, Vice President Research and Development, Ichor Medical Systems, Inc.

James Beesley, B.Sc., D.C. Senior Director, Investor Relations, Protox Therapeutics, Inc.

James Hamilton, President, Calando Pharmaceuticals, Inc.

Rianne Roukema, Corporate Communications, OctoPlus NV

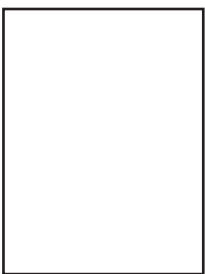
KEY QUESTIONS THIS REPORT ANSWERS:

- Which companies and academic institutes are actively involved in biopharmaceutical research?
- What are the key areas of therapeutic focus for biotherapeutics in the near- and long-term?
- What are the key obstacles companies and delivery technologist need to overcome to commercialize biotherapeutics?
- How will the delivery technologies drive the development of innovative biological agents in the future?
- Which delivery technologies and platforms are likely to win in the near-term and the long-term, and why?
- Where are the market opportunities now and in the future?
- What do we predict will be the value of the biotherapeutics by 2015 and 2020?

COMPANIES MENTIONED:

Abbott Laboratories, Acambis, Access Pharmaceuticals, Acusphere, Advanced BioScience Laboratories, Aegis Therapeutics, Affymax, Alkermes, ALZA Corporation, Amgen, Amylin, Aphios, Aradigm, Arius Research, AS Biotech AG, AstraZeneca, Aurigene, AVRA Labs, Bayer Schering, Bioceuticals, Biocon, Biogen Idec, BioGeneriX AG, BioPartners, BioSante Pharmaceuticals, Bristol-Myers Squibb, Calando Pharmaceuticals, Camurus, Cangene Corporation, Cenotcor, Chugai, CoGenesys, Controlled Therapeutics, CT Arzneimittel, Dr. Reddy's, Dragon Pharmaceuticals, Eisai, Elan Pharmaceuticals, Eli Lilly & Company, Emisphere Technologies, Enzon Pharmaceuticals, Flamel Technologies, GeneMedix, Genentech, Genexer Biotechnology Corporation, Genzyme, GlaxoSmithKline, Glide Pharma, GVK Bio, Hospira, ImClone, Inovio Biomedical Corporation, Intercell AG, Iomai Corporation, Johnson & Johnson, Kirin, Lonza, MacroGenics, MDRNA (formerly Nastech Pharmaceuticals), MedImmune (acquired by AstraZeneca), MedinCell S.A., Merck Serono, Mirus Bio Corporation (acquired by Roche), Modigene, Momenta Pharmaceuticals, Nanotechnology Victoria Ltd, Neose Technologies, Novartis, Novo Nordisk, Novopharm, OctoPlus NV, Oramed Pharmaceuticals, Orexo, Pfizer, Phage Biotechnology, Protox Therapeutics, Ranbaxy, Ratiopharm, Raven Biotechnologies, Roche, Sanmar Specialties, sanofi-aventis, Schering-Plough, Sciele Pharmaceuticals, Sequus, Serenex, SGX Pharmaceuticals, Shasun Chemicals, Shionogi, Shire Pharmaceuticals, Sirtis Pharmaceuticals, Stada Arzneimittel AG, Syngene, Talceris, Tanabe, Teva Pharmaceutical Industries Ltd, TheraJect, Titan Pharmaceuticals, TransPharma, UCB, VGX Pharmaceuticals, Vyteris, Wockhardt, Wyeth, Zenyaku Kogyu

About the author:



Dr Paul Evers is a market research consultant and writer, specializing in the pharmaceutical and other healthcare industries. He has researched and written detailed studies on a wide range of pharmaceutical

and medical market sectors including various aspects of drug delivery. Prior to becoming a

full-time consultant he worked as director of marketing for a major pharmaceutical company specializing in drug delivery technology. He studied medical sciences at the National University of Ireland and holds an honours degree in biological sciences and humanities from The Open University.

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