BACKGROUNDER

BIOPHARMACEUTICAL MARKET OVERVIEW

The rise of biologic drugs: sales to reach $239 billion by 2015

Millions of people now benefit from treatment with recombinant protein-based biologics or "large molecule" prescription drugs, which include antibodies and vaccines. In 1982, the U.S. Food and Drug Administration approved the first biologic drug, human insulin, produced in genetically modified bacteria. Today, there are more than 120 biologics on the market and hundreds more in development. The global market for biopharmaceuticals has grown from $8 billion in 1992 to $149 billion in 2010 and is expected to reach $239 billion by 2015, for a compound annual growth rate of 9.9% from 2010-2015[1].

More than 400 biotech drugs and vaccines targeting more than 200 diseases[2] are currently in clinical trials. Biologics accounted for 39% of the top 10 drugs sold globally in 2008, and are anticipated to increase to 79% of the top 10 drug sales by 2014[3].

Monoclonal antibodies (mAbs)

PlantForm's first three products will be monoclonal antibodies (mAbs). Monoclonal antibodies comprised 31.9% or $43 billion of the global biologics market in 2009. The mAb segment is expected to increase at the **fastest rate** within the total biologics market to reach $86 billion in sales by 2015, from $48 billion in 2010, a compound annual growth rate of 12.4%.

The emergence of biosimilars

Many early biologic drugs are now approaching patent protection expiry and are being targeted by biosimilar competition. PlantForm is positioning itself to be an extremely low-cost producer of biosimilar antibody drugs using its tobacco-plant-based biologic production system.

The market for biosimilars is virtually untapped. While the generic small molecule, chemical entity drugs sector currently accounts for 65% of total prescriptions dispensed around the world, the biosimilar industry is forecast to grow rapidly. A 2009 *Research and Markets* report states that $80-billion worth of biologic drugs will lose patent protection by 2013.

1 Biosimilars and Follow-On Biologics Report: The Global Outlook 2010-2025, *Visiongain Ltd., (2010)*
2 BIO's Guide to Biotechnology, Bio (2007)
3 Credit Suisse Report: Biosimilars 101, August 2009

Plant-based production

Plant-based production processes are emerging as highly cost-effective alternatives to the mammalian cell culture systems (e.g., Chinese hamster ovary cells) and bacterial systems (e.g., *E coli)* that today account for the vast majority of antibody and protein drug production. Mammalian and bacterial cell systems are typically extremely expensive: a regime of Herceptin® for breast cancer (produced using mammalian cell culture) costs approximately $40,000 per patient in Canada.

The potential for large-scale, low-cost agricultural production of valuable recombinant protein therapeutics is vast. The global market for botanical and plant-derived drugs is expected to reach $32 billion in 2013, with a five-year compound annual growth rate of 11%, according to the *BCC Research* market report, “Botanical and Plant-Derived Drugs: Global Markets.”

The regulatory environment

Biologic drug production, including monoclonal antibodies using recombinant technologies (as proposed by PlantForm), is regulated by:

- Health Canada's Biologics and Genetic Therapies Directorate (BGTD);
- The U.S. Food and Drug Administration’s Center for Biologics Evaluation and Research (FDA, CBER);
- The Committee for Proprietary Medicinal Products (CPMP) of the European Medicines Agency (EMEA); and
- Comparable agencies in other countries worldwide.

The process for establishing a standard specifically for regulatory approval of biosimilar drugs has been defined in Europe, PlantForm’s first market. In the U.S., the FDA issued draft guidelines for biosimilar drugs in early 2012. In Canada, the BGTD is developing a comprehensive regulatory framework for subsequent-entry biologics, and in 2010 released the finalized *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)*.

A number of biosimilar drugs have been approved to date in the U.S., Europe, Japan and Canada, some under new biosimilar regulations and others under standard regulations for innovator biologics.

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