

## INDUSTRY UPDATE ON PLANT-MADE PHARMACEUTICALS

Pharmaceuticals produced from biotech plants are a new application of biotechnology that turn plants into “factories” that produce therapeutic proteins used in biopharmaceuticals. Medicines produced from plants represent one of the brightest new hopes in medicine. While great strides have been made through biotechnology in the search for treatments and cures to the most formidable diseases, research and development of biotech drugs may be cut short due to capacity and cost issues. Plants may offer a cost-effective, sustainable, and faster source of medicines for patients, and provide access to new treatments which would otherwise be out of reach.

In the last year, progress in the plant-made pharmaceutical industry has advanced significantly – from the first regulatory approval of a plant-made animal vaccine to successful clinical trial results in developing countries, to identifying the potential of producing insulin from biotech safflower. Several companies have shown the effectiveness of plant-made pharmaceuticals in addressing the medical needs of large and growing patient populations. In January 2005, market research firm Frost & Sullivan predicted that the plant-made pharmaceutical market could realize revenues of \$98.2 billion by 2011.

### **First Federally Approved Plant-Made Vaccine**

In January 2006, the U.S. Department of Agriculture’s (USDA) Center for Veterinary Biologics (CVB) gave regulatory approval for the first plant-made vaccine to Dow AgroSciences’ Animal Health division and their Concert™ product, a vaccine to improve animal health. This first U.S. regulatory approval of a plant-made vaccine demonstrates the safety and efficacy of plant-made vaccines.

### **Child Health Study of Plant-Made Proteins in Electrolyte Replacement Solutions Demonstrates Success**

Every year, two million children die of complications from diarrhea, making it the second largest infectious killer of children under age five. With children in the United States, there are more than 1.5 million outpatient visits, 200,000 hospitalizations and 300 deaths per year due to acute diarrhea. It has been estimated that this is a multi-billion dollar burden for the healthcare system in the United States.

In the 1960s, health professionals found that rehydration using electrolyte solutions reduced annual deaths from greater than five million to two million. Modern research has demonstrated that breast-fed children have a significantly lower incidence of diarrhea and infections, leading Ventria Bioscience to begin research into the development of an electrolyte solution that contained the protective proteins found in breast milk.

Ventria has developed an electrolyte solution that includes Lactiva™ (lactoferrin) and Lysomin™ (lysozyme), two proteins naturally found in breast milk, which are produced in rice. The University of California at Davis worked with leading international institutions to conduct a Child Health Study using this product.

The randomized, double-blind study enrolled 140 children under 5 years of age who were suffering from acute diarrhea. Children who took the electrolyte solution which contained Lactiva™ and Lysomin™:

**“Using plants as factories to produce recombinant protein products is emerging as a cost-effective, high capability solution to the issue of production capacity.”**

*Phil Webster, research analyst  
Frost & Sullivan*

- Were sick for less time – on average, they were sick for 3.67 days, as compared to 5.21 days for children who consumed conventional electrolyte solution.
- Reached complete resolution of their diarrhea with much higher frequency than children receiving the electrolyte solution alone. 85.1 percent of children who consumed Lactiva™ and Lysomin™ electrolyte solution recovered, while only 69.2 percent of the control group recovered.
- Were less likely to relapse into another episode of diarrhea. The percentage of children who relapsed was lower in the Lactiva™ and Lysomin™ electrolyte solution group versus the control group.

### **Using Plants to Combat the Diabetes Epidemic**

In July 2006, Calgary-based SemBioSys announced that it can produce over one kilogram of insulin per acre of protein-producing biotech safflower. This is enough to supply 2,500 patients for one year of treatment each. With insulin demand projected to be 16,000 kilograms by 2012, SemBioSys' biotech safflower may be the only way to ensure adequate supply of insulin to continue to treat a growing diabetic patient population.

Affecting millions of people worldwide, diabetes has been growing at a disturbing and epidemic rate over the past decade. If left untreated, diabetes can lead to life-threatening complications, such as blindness, kidney disease, nerve disease, heart disease, amputations, and stroke. It is projected to affect over 370 million individuals by 2030. The increasing incidence of diabetes, combined with the adoption of alternative delivery technologies with low bioavailability will drive insulin demand from current levels (about 5,500 kilograms) to over an estimated 16,000 kilograms by 2012.

In addition to meeting patient supply needs, producing insulin in biotech safflower can reduce capital costs compared to existing insulin manufacturing by 70 percent and products costs by 40 percent.

### **Biotech Plants Address Drug Abuse**

Abuse of PCP and methamphetamine is increasing and there are currently no therapies available for treatment. According to the National Institute on Drug Abuse (NIDA), there are more than 400,000 people considered to be "hardcore" PCP and methamphetamine-users. California-based InterveXion Therapeutics is developing two forms of products for the treatment of PCP abuse, as well as in overcoming methamphetamine addiction. More than a decade of research has concluded that monoclonal antibodies (MABs), which can be found in both of InterveXion Therapeutic's products, absorb the toxins in the bloodstream to reduce the acute effects of overdose and can also be used in the chronic setting to help drug abusers overcome dependency.

### **PMP Research Continues**

For the millions of patients who suffer from cystic fibrosis, cancer, multiple sclerosis, AIDS, diabetes, and heart disease, plants that produce therapeutic proteins may be the only chance to obtain needed treatments. In addition to the companies above, other groups working on plant-made pharmaceuticals include: cystic fibrosis treatment from biotech corn (Meristem); treatment for ovarian cancer from biotech tobacco (Chlorogen); biotech tobacco to address dental caries, as well as the common cold, and hair loss (Planet Biotechnology); and the production of monoclonal antibodies from biotech duckweed (Biolex).