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Ausbiotech 2009 Newsletter

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AlcheraBio LLC (www.alcherabio.com) was established in the US state of New Jersey in 2001 to support the animal health industry. In 2008, AlcheraBio became a subsidiary of Argenta, a global formulation R&D and manufacturing company headquartered in New Zealand.

Our company is a full-service animal health consultancy and veterinary Contract Research Organization. We also work with biotechnology and life sciences companies to identify and develop potential animal health applications for their innovations and with animal health companies to uncover new platform technologies and compounds for their pipelines. We have experience with conventional and emerging technologies and have experience with the separate US regulatory authorities involved in evaluating and approving pharmaceuticals, biologics, and pesticides for use in animals. In addition, we help the investment community evaluate potential animal health applications of the technologies they're assessing.

Dr. Jane Eagleson, AlcheraBio president and Argenta head of client services, is representing AlcheraBio and Argenta at Ausbiotech 2009. To arrange a meeting with Dr. Eagleson or obtain additional information, phone her mobile at: 64 (0)21 278 0266 or email jane.eagleson@argenta.co.nz. You can also find information at www.argenta.co.nz and www.alcherabio.com.

Why Animal Health?

Many disease conditions in animals can resemble human disease. The basic biochemistry and physiology of animals and humans are similar, and, despite species differences, much research and development in biotechnology and life sciences is applicable to treatment in all species. Animals can also benefit from advances in areas such as diagnostics and delivery systems. During the past decade, many animal health companies have turned to strategic licensing or acquisitions from biotechnology and life sciences companies to take advantage of emerging technologies and bolster their pipelines.

What Are Some Examples of Animal Health Products or Technologies Derived from Biotechnology or Life Sciences?

In many instances these types of applications are in development and therefore proprietary, but here are a few examples. You may be surprised to see how many biotech "firsts" in the United States have been animal-health-related:

- *The first licensed DNA vaccine:* In 2005, The Centers for Disease Control and Prevention (CDC) in the US and Fort Dodge Animal Health announced the world's first licensed DNA vaccine. The vaccine protects horses from West Nile virus.
- *The first plant-based vaccine:* In 2006, Dow AgroSciences announced the first regulatory approval in the world for a plant-made vaccine. The company's Concert™ Plant-Cell-Produced vaccine production system was developed in collaboration with Washington University, Boyce Thompson Institute for Plant Research, Benchmark Biolabs, Inc., and The Biodesign Institute at Arizona State University. Dow AgroSciences has entered into a number of collaborations to develop animal-health vaccines based on its system.
- *The first licensed therapeutic DNA vaccine:* Collaboration among Merial Ltd., Memorial Sloan-Kettering Cancer Center, and the Animal Medical Center in New York produced the first therapeutic DNA vaccine, a vaccine for canine oral melanoma. The product received a conditional license from the USDA (US Department of Agriculture) in 2007. It was the first time that the US government approved a therapeutic vaccine for the treatment of cancer in humans or in animals.

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- *Regenerative medicine:* In 2004, Vet-Stem introduced the first veterinary stem cell service in the US. The company isolates stem and regenerative cells from an animal's own fat for therapeutic injection into injured tissue. According to the company's website equine veterinarians have successfully treated tendon, ligament, and joint injuries using Vet-Stem's fat stem cell therapy for horses. Companion animal veterinarians can use the Vet-Stem technology to treat arthritis, tendon and ligament injuries in dogs. Vet-Stem is actively investigating additional potential applications.
- *Human therapeutics produced in transgenic animals:* In February 2009 the US Food and Drug Administration issued its approval for Atryn® antithrombin, a biologic product for humans produced by genetically engineered (i.e., transgenic) animals. The regulatory pathway also involved a New Animal Drug Application (NADA) required for the recombinant technology used to develop the transgenic animals, in this case the goats that produce the recombinant antithrombin. The FDA Center for Veterinary Medicine approved GTC's NADA, which was the first of its kind to regulate genetically engineered animals. GTC Therapeutics has also announced a collaboration agreement with AgResearch Limited of New Zealand to develop transgenic founder animals to produce two follow-on biologics.

AlcheraBio Can Help You Assess and Develop or License Your Technology for Animal Health

If you haven't thought about animal health, it could be well worth considering. Under the right conditions, animal health applications can add value to biotechnology businesses. We will work with you to assess opportunities your company may offer, analyze the marketplace, identify critical issues, and define key success factors.

If you're already interested in animal health, we can conduct a preliminary assessment, develop an overall plan and timeline, perform a risk analysis, devise proof-of-concept or other key early stage experiments, define the regulatory approach for major markets, and build marketplace and financial models that can help you decide how to pursue your potential application(s).

If you're already working on a product, platform, or technology that has animal health applications we can be your development and commercialization company. For clients wishing to develop the applications themselves, we can provide contract research services, including but not limited to: developing protocols, interacting with regulatory agencies, conducting and managing pivotal studies, developing regulatory submissions, providing data entry and data management, and preparing final reports. For clients wishing to outlicense or partner their applications, we can identify potential partners or licensors, prepare the appropriate package, facilitate contacts in animal health, and put together presentations.

To learn more about AlcheraBio and meet the members of our staff, visit www.alcherabio.com.