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BIO 2009 Newsletter
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Opportunities for Biotechnology in Animal Health and Veterinary Medicine

AlcheraBio LLC (www.alcherabio.com) was established in 2001 to provide services and consulting for the animal health industry. The company was acquired in 2008 and is now a subsidiary of Argenta, which is a leader in animal health product manufacturing, formulations, and related services (see page 2).

We work with biotechnology and life sciences companies to identify potential animal health applications for their innovations and with animal health companies to uncover new platform technologies and compounds for their pipelines. We also work with the investment community to evaluate potential animal health applications of the technologies they're assessing.

*As full-service consultancy and Contract Research Organization, we offer our clients services required for assessing opportunities from technical and business standpoints, putting together development plans and protocols, designing proof-of-concept studies, interacting with regulatory agencies, conducting pivotal clinical studies, including data management, and completing and assembling regulatory submissions. Our Founder and Vice President – Clinical Development, Linda Rhodes, VMD, PhD, is the author of an industry report entitled **Biotechnology, Cloning, and Genetics: A revolution in the animal health industry?***



Katherine Moldave, AlcheraBio Cofounder and Vice President – Market Support, is attending BIO 2009. To arrange a meeting, please contact her on her cell phone at 732 429-7124 or call the AlcheraBio office at 732 205-0192.

If you haven't thought about animal health, it could be well worth considering. Many disease conditions in animals resemble human disease. Although there are species differences, the basic biochemistry and physiology of animals and humans are similar, and much research in biotechnology is applicable to treatment in all species. 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 of your technology, 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 the full spectrum of contract research services. 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.

See page 2 for some examples of biotechnology applications related to animals and animal health.

What are some examples of animal health products or technologies derived from biotechnology or life sciences companies?

In many instances, these types of applications are in development and therefore proprietary, but here are a few examples:

- *The first licensed DNA vaccine:* In 2005, The Centers for Disease Control and Prevention (CDC) and Fort Dodge Animal Health announced the world's first licensed DNA vaccine, a vaccine that protects horses from West Nile virus.
- *The first plant-based vaccine:* In 2006, Dow AgroSciences announced that it had received 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:* A collaboration among Meril Ltd., Memorial Sloan-Kettering Cancer Center, and the Animal Medical Center in New York produced the first therapeutic DNA vaccine, which is a vaccine for canine oral melanoma. The product received a conditional license from the USDA 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.
- *Regenerative medicine:* In 2004, Vet-Stem, Inc. 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 use the Vet-Stem technology to treat arthritis and tendon and ligament injuries in dogs.
- *Biological product produced by genetically engineered animals:* In February 2009 the Food and Drug Administration issued its first approval for Atryn® antithrombin, a biological human therapeutic produced by genetically engineered animals. This followed the release of the much anticipated FDA Center for Veterinary Medicine Final Guidance on Regulating Genetically Engineered Animals in January of this year. The product, manufactured by GTC Therapeutics, is a therapeutic protein derived from the milk of goats that have been genetically engineered by introducing a recombinant DNA construct into their genes with instructions for the goat to produce human antithrombin in its milk. Transgenic production enables the development of recombinant forms of proteins, such as antithrombin, that otherwise are not practical to develop using other technologies. Along with the approval of Atryn, the FDA's Center for Veterinary Medicine also approved GTC's New Animal Drug Application, the first of its kind to regulate genetically engineered animals. This is now required for a recombinant technology used to develop transgenic 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.



What Is Argenta?

AlcheraBio LLC is a subsidiary of Argenta, which is headquartered in New Zealand. The world's first Contract Development and Manufacturing Organization (CDMO) dedicated to animal health, Argenta offers formulation and analytical development services, and manufactures clinical trial material and commercial animal health products to cGMP. Argenta exports to more than 60 countries, including the US and European nations. For more information, see www.argenta.co.nz or contact Dr. Jane Eagleson, Argenta business development manager and AlcheraBio president at: 011 64 9 250 3192 (office) or email: jane.eagleson@argenta.co.nz.