



Aktiv-Dry LLC

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health



National Institutes of Health Commercialization Assistance Program
(NIH-CAP)

Company Profile

Industry Sector: Biotechnology specializing in inhalable powder formulation, manufacture, and delivery

Company Overview: Aktiv-Dry was founded in 2002 by Drs. Bob Sievers, Brian Quinn, and John Carpenter to commercialize certain technologies discovered at the University of Colorado. Its core proprietary technology uses supercritical carbon dioxide as a nebulizing agent in the production of extremely fine powders of high value compounds, usually pharmaceutical products. The powders may be engineered to consist of particles with dimensions of 1-5 microns and are suitable for delivering therapeutic agents deep into the alveolae through inhalation. To support its powder inhalation activities, the company has also developed an extremely inexpensive device for delivering dry powder measles vaccine to patients in developing countries. The measles vaccine project was funded by a \$20 million grant from the Gates Foundation and administered by the FNIH.

Target Market(s): Pharma and biotech companies seeking alternative product delivery.

Key Value Drivers

Technology: Carbon Dioxide Assisted Nebulization with a Bubble Dryer (CAN-BD) is Aktiv-Dry's core technology and, along with continuations and derivatives, has been patented in the U.S., Europe, China, Japan, and Australia. Altogether, the company's I.P. portfolio includes 5 domestic patents, 7 foreign patents, 1 domestic application, 1 foreign application, and trademarks. CAN-BD has successfully made respirable powders of a live attenuated measles vaccine, a siRNA that targets RSV, a HPV vaccine, a live attenuated influenza vaccine, several of the more common drugs for treating TB and XDRTB, and many other sensitive drug products. In addition to powder formulation technology, Aktiv-Dry has developed the PuffHaler, a single dose active DPI with a very low cost point, approximately 10¢ per administration.

Competitive Advantage: CAN-BD is a gentle process that is applicable to forming powders and drying the most thermally labile products, even proteins and live virus vaccines, without damaging the potency of the compound. In addition, CAN-BD is a continuous process that is readily integrated with existing manufacturing lines.

Plan & Strategy: Seeking a strategic partner for merger or acquisition.

Management

Leadership:

Brian Quinn, Ph.D, President and COO

Robert Sievers, Ph.D., CEO

Product Development Advisory Group:

Dr. Scott Winston, Director

Dr. Jose Luis Valdespino, Birmex

Dr. Ron Wolfe, Nektar

Dr. Julia Barrett, Biologics Consulting Group

Dr. Mark Papania, CDC

Dr. Alan Shaw, Vaxinnate

Dr. Frank Malinoski, MedImmune

Mr. Mike Ligotke, Genentech

Dr. Ana Maria Henao Restrepo, World Health Organization

Dr. Dan Carucci, United Nations Foundation

Dr. Paul Rota, CDC

Product Pipeline

Aktiv-Dry's inhalable measles vaccine has produced an immune response without adverse reactions in cotton rats and in rhesus macaques, and is scheduled for preclinical toxicity studies in July/August 2009. The PuffHaler was used to administer the vaccine powder in all of the animal tests. Phase 1 clinical trials are scheduled for October/November 2009.