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

Company Profile

Industry Sector: Biotechnology, Novel Immunotherapies and Vaccines

Company Overview: Apolmmune is developing novel immunotherapies and vaccines to fight disease. Our immunotherapy technology is capable of either activating a patient's immune system to fight cancer and infectious disease (i.e., tuberculosis, influenza), or suppressing a patient's immune system in instances of autoimmune disease. Our unique lead technology, ApoVax104, is a flexible vaccine platform technology that can be used to create many different disease-specific vaccines that have clinical value in a multitude of diseases representing many unmet clinical needs.

Target Market(s): The Company is focused on using the technology to treat cancer and infectious diseases with its initial market being cervical cancer. Human papillomavirus is the virus that causes cervical cancer, and although a preventative vaccine for HPV infection has been approved (Gardasil, Merck), a therapeutic treatment or vaccine to cure HPV infection and cervical cancer represent major advances in the treatment of these diseases.

Key Value Drivers

Technology*: ApoVax104 is a recombinant, subunit protein vaccine that can be combined with any antigen to create disease-specific vaccines. In preclinical studies, the vaccine has proven to be much more effective and less toxic than other vaccine components currently being tested in late stage clinical trials by large pharmaceutical companies.

Competitive Advantage: What sets ApoVax104 apart from other vaccines is that it not only activates the immune system, it overcomes strategies used by tumors and chronic infections to evade the immune system and survive in the body. ApoVax104 overcomes these evasion strategies by inhibiting the action of a specific set of immune cells called T regulatory cells which normally shut down immune defenses within the tumor microenvironment thereby allowing the tumor cells to evade the immune system.

Plan & Strategy: Apolmmune has scheduled a pre-Investigational New Drug application meeting with the FDA for May 7, 2009, and plans to have an IND submission by 4Q 2009 to begin a Phase I clinical trial with ApoVax104-HPV in women with recurrent cervical cancer at the James Graham Brown Cancer Center in Louisville, KY.

Management

Leadership:

Steven T. Downey - Chairman, President & CEO

Dr. Haval Shirwan, Ph.D. - Founder and Chief Scientific Officer

Dr. Rolf Huseby, Ph.D. - Vice President, Research and Development

Dr. Kathryn MacLeod, Ph.D. - Director, Research and Development

Board of Directors:

Steven T. Downey - Chairman, President & CEO

Dr. Haval Shirwan, Ph.D. - Founder and Chief Scientific Officer

George Emont - Managing Partner, Kentucky Seed Capital Fund, and Partner, Triathlon Medical Ventures

Steve Gailar - Managing Partner, Kentucky Seed Capital Fund, and President &

CEO, MetaCyte Business Lab

Regulatory Advisors:

Dr. Joy A. Cavagnaro, Ph.D. DABT, RAC - Leesburg, VA Summit Drug Development Services - Rockville, MD

Product Pipeline

