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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, Novel Immunotherapies and Vaccines

**Company Overview:** ApoImmune 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:** ApoImmune 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

