
Technology for the Next Generation of Vaccines

CORPORATE OVERVIEW

VaxInnate is a privately-held biotechnology company developing novel, proprietary vaccines for both pandemic and seasonal influenza. The company's breakthrough vaccines are based on its Toll-like receptor (TLR) technology platform, which dramatically improves vaccine immunogenicity and efficacy. Using the TLR technology, vaccines can be produced by simple, low-cost, highly-scalable recombinant DNA techniques, avoiding many of the challenges and pitfalls of egg-based or cell-culture influenza vaccine production. VaxInnate's technology has the potential to significantly improve the cost-effectiveness, manufacturing capacity, and potency of influenza vaccines – key issues facing the clinical and public health communities.

CORPORATE HISTORY

VaxInnate was founded by Ruslan Medzhitov and Richard Flavell, both of Yale University and Howard Hughes Medical Institute and leaders in the field of innate immunity. The company started in 2002 with a research team in New Haven, CT. In 2004, the company expanded and established a development team and corporate headquarters in Cranbury, NJ. The company currently has approximately 58 employees including 18 with doctoral degrees.

Currently, VaxInnate occupies approximately 30,000 square feet of laboratory and office space in Cranbury, NJ, and New Haven, CT. This includes molecular and cell biology labs, cell culture facilities, a protein pilot plant and analytical laboratory space.

VaxInnate has access to BSL-2 vivarium space through a collaborative research agreement with Yale University. VaxInnate also has a collaborative arrangement with an academic institution for access to high level biocontainment facilities (BSL-3 and -4). Since avian influenza requires BSL-3 or -4 facilities, depending on the strain in question, this access enables the company to conduct live virus challenges in animal models

INFLUENZA

Seasonal Influenza

Influenza is one of the most communicable diseases. The flu typically affects children and the elderly the hardest. Complications from flu cause more than 200,000 hospitalizations in the U.S. annually and lead to approximately 36,000 deaths in the U.S. in a typical flu season. Because of growing awareness of the value of influenza vaccine to prevent disease, the market for influenza vaccine is expected to grow to over \$3 billion by 2010.

The seasonality of influenza drives the annual vaccine formulation and manufacturing cycle. Using a worldwide reporting system, the CDC and the FDA

choose late in one winter the novel and hold-over strains that health care officials believe are most likely to predominate in the next winter's flu season. Manufacturers then race to produce the vaccine in time to be administered prior to the next flu season. Currently, it takes approximately six months from when the strains are chosen until the first flu vaccine reaches the market.

Pandemic Influenza

Novel influenza strains are widely generated in populations of domestic and wild fowl, pigs, humans and other animals. Most strains only infect animals. Of those that spread to humans, many are easily combated by a healthy person's immune system. Occasionally, however, an entirely new strain emerges that spreads from animals to humans. Because humans lack any previous exposure to and thus protection from these novel viruses, they may cause a pandemic involving widespread, sometimes severe disease. Influenza pandemics generally occur every thirty years. The last pandemic occurred in 1968/1 969.

A new, highly virulent strain of H5N1 bird flu has been circulating in domestic and wild birds in East Asia, and has the potential to be the source of one of the next human pandemics as humans have not developed immunity to this avian strain. So far, the mortality rate among confirmed cases of avian flu is greater than 50 percent.

VAXINNATE ADVANTAGES

Stronger response, improved production

Currently marketed influenza vaccines are based on a development, production and vaccination strategy that has not changed significantly in the past five decades. Due to the seasonal nature of the disease and the genetic instability of the virus, it is necessary to formulate a new influenza vaccine each year based on an epidemiological prediction of the strains most likely to be circulating in the human population in the next winter's flu season. Current vaccines are formulated with hemagglutinin (HA) as the viral antigen (the component of the virus, usually a protein, that serves as a target for an immune response). Due to slow development and production cycles, there is general concern that traditional vaccines may not consistently meet the demands of seasonal influenza or potential pandemic virus outbreaks.

The novel approach championed by VaxInnate is designed to meet those demands by drawing upon breakthroughs in our knowledge of the way the immune system works and taking advantage of efficient manufacturing technology. By leveraging both of the two primary mechanisms of immune defense, referred to as "innate" and "adaptive" responses, VaxInnate's proprietary TLR technology leads to a more effective vaccine against both variable antigens, and antigens that remain conserved from one strain of virus to the next. Because the vaccines can be produced in bacteria, they can be developed and manufactured at a large scale within a short period of time.

Efficient and cost-effective production method

VaxInnate's bacterial production method is more efficient and cost-effective than current flu vaccine production techniques. Traditional vaccines are generated by growing the virus in eggs, a process that takes several months. VaxInnate's approach is to grow the necessary proteins in a bacterial expression system, a method that has been proven in the production of other recombinant proteins and biopharmaceuticals.

The VaxInnate production method results in larger quantities of vaccine produced over shorter periods of time. Current levels of production of flu vaccine in the U.S. are still inadequate in the event of a pandemic. By producing a higher yield, more robust vaccine that does not rely on egg-based technology, we can reduce or eliminate many of the bottlenecks in the current flu vaccine production process. VaxInnate's production method yields greater efficiencies. Other methods, such as cell culture and egg-based systems, grow the whole virus, which must be harvested, purified and then inactivated. By contrast, VaxInnate very efficiently produces individual recombinant proteins, eliminating several steps in the production process.

PRODUCT PIPELINE

VaxInnate is developing vaccines to respond to urgent public health needs. The company's technology is broadly applicable for providing protection against and treatment for a wide range of diseases, including bacterial, viral, and parasitic infections. Current product development focuses on one of the most vexing and costly public health challenges – influenza.

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VaxInnate has a strong preclinical influenza pipeline, with programs targeting both seasonal and pandemic influenza:

- ***Flagellin.HuHA*** and ***flagellin.AvHA***: fusion proteins linking flagellin with the most immunoprotective domain of viral hemagglutinin (HA) – the globular head – derived from human and avian influenza virus, respectively.

VAXINNATE

Corporate Backgrounder

- ***Flagellin.HuM2e*** and ***flagellin.AvM2e***: fusion proteins linking flagellin with the M2 ectodomain (M2e) of the influenza A virus and avian influenza virus, respectively. M2 is the influenza virus ion channel that helps the virus change its pH when it has entered a cell, a critical step in the infectious process. M2e is a conserved segment of M2 projecting above the surface of the viral particle.

FINANCING

VaxInnate has raised more than \$64 million to date and is backed by well-known venture capital firms, including HealthCare Ventures, Oxford Bioscience Partners LLC, MedImmune Ventures, Inc., CHL Medical Partners, New Leaf Venture Partners, and Canaan Partners.

MANAGEMENT TEAM

VaxInnate's management team has deep experience in the development, formulation, regulatory approval, manufacturing and marketing of vaccines.

Alan R. Shaw, Ph.D. – *President and Chief Executive Officer*

15 years experience at Merck, most recently as Co-Head of Vaccine Development; Responsible for R&D of Varivax, ProQuad, RotaTeq, Gardasil and Zostavax

Robert S. Becker, Ph.D., MBA – *Vice President, Business Development*

15 years experience at Sanofi-Aventis, including as VP, Corporate Development at Sanofi Pasteur

Andrew Drechsler – *Chief Financial Officer*

Andrew Drechsler joined VaxInnate in June 2007, from Valera Pharmaceuticals, Inc. where he served as Chief Financial Officer. During his tenure at Valera, he was responsible for the company's initial public offering and the sale of the company to Indevus Pharmaceuticals. Mr. Drechsler served as Controller for a variety of tech companies, including i-STAT Corporation, HydraWEB Technologies, and BioMatrix. Prior to his corporate biotechnology experience, Mr. Drechsler worked for the accounting firm Coopers & Lybrand LLP. Mr. Drechsler graduated magna cum laude from Villanova University with a Bachelor of Science in Accountancy. Mr. Drechsler also obtained his qualification as a certified public accountant in the state of New Jersey.

Edward Arcuri – *Chief Operations Officer*

Dr. Arcuri joined VaxInnate in June 2007 from Emergent BioSolutions, Inc. where he served as Chief Operating Officer. At Emergent, Dr. Arcuri was directly responsible for all development, manufacture and project management activities. Prior to his role at Emergent, Dr. Arcuri held executive positions at MedImmune, Inc. where he was instrumental in the manufacture of RSV disease treatment (Synagis) and viral Flu prevention (FluMist). He has held a variety of executive, scientific and research positions at Aviron, Inc., North American Vaccine, Inc.,

SmithKline Beecham, Merck & Co., The Helicon Foundation, and Oak Ridge National Laboratory. Dr. Arcuri graduated with honors with a degree in Biology from the State University of New York at Albany, and he went on to earn both his M.S. degree and Ph.D. in Biology from Rensselaer Polytechnic Institute.

David Taylor, MD, – Chief Medical Officer

Dr. Taylor, Chief Medical Officer, joined VaxInnate in March 2007 from Salix Pharmaceuticals, where he served as Chief Medical Officer and VP, Medical Affairs. Prior to his role at Salix Pharmaceuticals, he served as Research Professor in the Department of International Health at Johns Hopkins School of Public Health. Dr. Taylor also brings to VaxInnate extensive vaccine research and infectious disease expertise gained through his 22 years of distinguished service with the U.S. military. During his career with the U.S. Public Health Service and U.S. Army, he served in a number of positions in the Division of Communicable Diseases and Immunology at the Walter Reed Army Institute of Research (WRAIR), including acting Division Director, Clinical Director, Department of Enteric Infections, as well as founder and first Chief of the Department of Clinical Trials. Dr. Taylor also served at the Armed Forces Research Institute of Medical Sciences in Bangkok, Thailand, and was Director of the Cholera Vaccine Project at the Naval Medical Research Institute detachment in Lima, Peru. He currently serves as Adjunct Professor of Preventative Medicine/Biometrics, Uniformed Services University of the Health Sciences and Adjunct Professor in International Health at Johns Hopkins University School of Public Health. He is a Diplomat of the National Board of Medical Examiners and American Board of Internal Medicine, a Fellow with the American College of Physicians and Infectious Diseases Society of America, and a member of the American Society of Microbiology. Dr. Taylor has authored more than 200 publications and received his medical degree from Harvard Medical School.

BOARD OF DIRECTORS

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Michael Lytton, J.D. – Oxford Bioscience Partners

Alan Shaw, Ph.D. – President and CEO, VaxInnate

Franklin Top, Jr., M.D. – MedImmune

Gregory Weinhoff, M.D. – CHL Medical Partners

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