

CORPORATE OVERVIEW

VaxInnate is a privately-held biotechnology company that is pioneering breakthrough technology for use in developing novel, proprietary vaccines. Now in clinical development, this novel technology has the potential to dramatically improve the potency, manufacturing capacity and cost-effectiveness of vaccines. No other vaccine technology in use or development today has these same potential capabilities

VaxInnate's lead product candidates are vaccines for both seasonal and pandemic influenza, including a promising universal vaccine candidate that could provide multi-year, cross-strain protection.

These vaccine candidates are based upon a proprietary Toll-Like Receptor (TLR) technology platform, which dramatically improves vaccine immunogenicity --the body's ability to make an immune response -- and efficacy. VaxInnate's influenza vaccine candidates are produced using the TLR technology together with a novel, proprietary, intellectual-property-protected method for making the key influenza vaccine component, hemagglutinin (HA), in a simple recombinant fermentation process.

Combining the TLR technology with the efficient production of HA means that vaccines can be produced with simple, low-cost, highly-scalable recombinant DNA techniques, avoiding the challenges and pitfalls of current egg-based or cell-culture-based influenza vaccine production.

CORPORATE HISTORY AND CURRENT FACILITIES

VaxInnate was established by Ruslan Medzhitov and Richard Flavell, internationally-recognized leaders in the field of innate immunity from Yale University and Howard Hughes Medical Institute. Formed in 2002 with a research team in New Haven, CT, VaxInnate grew with the establishment of corporate headquarters and a separate development team in the Princeton, NJ suburb of Cranbury.

Today, VaxInnate occupies 30,000 square feet of laboratory and office space in both locations, including molecular, cell biology and analytical laboratories, cell culture facilities and a protein pilot plant. Many of the company's 60 employees have doctoral degrees as well as extensive experience in the development, formulation, regulatory approval, manufacture and marketing of vaccines.

In addition to its own laboratories, VaxInnate has access to BSL-2 vivarium space through a collaborative research agreement with Yale University. VaxInnate also has a collaborative arrangement with another 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 under study, this access enables Vaxinnate to conduct

live virus challenges in animal models.

INFLUENZA

Seasonal Influenza

Influenza is a highly communicable disease, and typically has the severest impact on children and the elderly. Influenza complications lead to about 200,000 hospitalizations and 36,000 deaths in the United States alone during a typical influenza season. Due to growing awareness of the value of influenza vaccine in preventing disease, the market for influenza vaccines is projected to exceed \$3 billion by 2010.

The seasonal nature of influenza, and the virus' ability to mutate and still cause disease, makes it necessary to formulate an entirely new influenza vaccine annually. Seasonal influenza vaccine is based upon a prediction by the Centers for Disease Control (CDC, part of the U.S. government) and the World Health Organization (WHO) of the strains that are likeliest to circulate and cause disease during the next winter's influenza season.

Once the strains are identified, manufacturers race to produce the vaccine so it can be ready before the next influenza season hits. Currently, it takes about six months from the time when the influenza strains are chosen until the first flu vaccine reaches the marketplace. It can take even longer if the strains fail to grow well in eggs, the medium that has been used to produce influenza vaccine for a half century.

Current vaccines are formulated with hemagglutinin (HA) as the viral antigen, which is the protein component of the virus that serves as a target for an immune response. There is growing concern, however, that traditional influenza vaccines may not consistently meet the demands of seasonal influenza or potential pandemic virus outbreaks due to slow development and production cycles. These fears have been realized twice in just the past four years when annual influenza vaccine was in extremely short supply early in the season, the ideal time for vaccinating to prevent illness.

Pandemic Influenza

Novel influenza strains are widely generated in populations of domestic and wild fowl, pigs, and other animals. Fortunately, most strains infect only animals, while many of those that infect humans are easily combated by healthy immune systems.

Occasionally, however, an entirely new strain emerges that spreads from animals to humans. Because humans lack previous exposure to and protection from these novel viruses, a pandemic involving widespread, sometimes severe disease can result. Influenza pandemics generally occur every 30 years. The last pandemic occurred in 1968/1969, while the worst in memory was one that emerged in the closing days of World War I, causing millions of deaths worldwide.

A new, highly virulent strain of H5N1 avian or bird flu emerged within the last decade and has been circulating in the domestic and wild birds in East Asia. Experts agree that

VAXINNATE

Corporate Backgrounder

this strain has the potential to cause the next human pandemic, since humans have not developed immunity to this strain. To date, the mortality rate among confirmed human cases of avian influenza has been greater than 50 percent.

VAXINNATE ADVANTAGES

Stronger immune response, improved production

Currently marketed influenza vaccines are based on a development, production and vaccination strategy that has changed little in 50 years. Due to slow vaccine development and production cycles, there is growing concern that traditional influenza vaccines may not consistently meet the demands of seasonal influenza or potential pandemic virus outbreaks.

Current vaccines are formulated with hemagglutinin (HA) as the viral antigen, which is the protein component of the virus that serves as a target for an immune response. Currently licensed vaccines require a seed virus, which is a reassortant influenza virus that grows well in eggs (or cell culture) and produces high yields of the target HA protein. It takes several months to make the egg-adapted master seed from which stock seeds are derived and then distributed to vaccine producers. After receiving stock seeds, each manufacturer then must develop working seeds, the source for batches of intermediate bulk vaccines.

The novel approach championed by VaxInnate is designed to meet the demands for seasonal and/or pandemic influenza vaccine by drawing upon new understanding of the way the immune system works, and maximizing the value of efficient manufacturing technology.

By leveraging both of the two primary mechanisms of immune defense, known 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 are proteins that can be readily produced in bacteria, they can be developed and manufactured at a large scale in a short period of time. Eggs and cells are unnecessary media, since VaxInnate produces the target HA protein in bacteria using rapid, reliable, economical recombinant DNA techniques.

Cost-effective and time-saving

VaxInnate’s bacterial production method is both more efficient and cost-effective than current influenza vaccine production techniques. Traditional vaccines are generated by growing the virus in eggs in a laborious process that takes up to six months. There are no eggs or cells involved in the VaxInnate approach. Instead, VaxInnate grows the necessary proteins in a bacterial expression system, a proven method that is commonly used in the production of other recombinant proteins and biopharmaceuticals.

The VaxInnate production method yields larger quantities of vaccine produced in about half the time of egg- or cell-based production methods.

Experts agree that current levels of influenza vaccine production in the U.S. would be inadequate in the event of a pandemic. By producing a high-yield, more robust vaccine that does not rely on egg- or cell-based technology, VaxInnate reduces or eliminates many of the bottlenecks in the current influenza vaccine production process. Cell culture and egg-based systems grow the whole virus, which must be harvested, purified and then inactivated. By contrast, VaxInnate produces individual recombinant proteins, eliminating several steps in the production process.

PRODUCT PIPELINE

VaxInnate is developing vaccines that address urgent public health needs. The company's technology is broadly applicable for protecting against and treating a wide range of diseases, including bacterial, viral, and parasitic infections. While our current clinical development programs focus on one of the most vexing and costly public health challenges – influenza -- preclinical vaccine programs include Dengue, malaria, Japanese encephalitis, and other diseases.

VaxInnate has completed a Phase I clinical trial focused on a highly conserved influenza protein called M2 ectodomain. The first clinical trial of our HA program is expected to get underway in late 2008. In addition, we have a robust preclinical influenza vaccine 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.
- ***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 internationally-recognized 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 substantial experience in the development, formulation, regulatory approval, manufacturing and marketing of vaccines, having participated in the development, licensure and launch of more than 20 different vaccine products that are in wide use today.

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

Assumed leadership of VaxInnate in 2005 after 15 years of experience at Merck, most

VAXINNATE

Corporate Backgrounder

recently as Co-Head of Vaccine Development; Responsible for R&D of many Merck vaccines, including Varivax, ProQuad, RotaTeq, Gardasil and Zostavax; party to licensures of other Merck vaccines, including Comvax, Vaqta, and Pentavax.

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

Joined VaxInnate after 15 years of experience at Sanofi-Aventis, including as Sanofi Pasteur's VP, Corporate Development. Party to development and licensure of Adacel, Avaxim, Daptacel, Hexavax, Menactra, Pentacel, Quadricel, and others.

Andrew Drechsler – *Chief Financial Officer*

Moved to Vaxinnate after 15 years of experience in Finance roles of increasing responsibility, including CFO for Valera at their Initial Public Offering and the sale of the company to Indevus Pharmaceuticals; previously served in Finance positions with i-STAT, HydraWEB Technologies and Biomatrix. Licensed as a CPA in New Jersey.

David Taylor, MD – *Chief Medical Officer*

Joined the VaxInnate team from most recent role as CMO and VP, Medical Affairs for Salix Pharmaceuticals. Previously served in an academic position at Johns Hopkins, following more than 20 years with the U.S. Public Health Service and U.S. Army, where he participated in the development of enteric vaccines for cholera, typhoid, and Dukoral, among others.