

# COMPANY OVERVIEW

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## Welcome to TechnoVax

TechnoVax is a biotechnology company based in Westchester County (New York) that specializes in vaccine development. The company aims to begin clinical trials by Q4-2010.

Our unique and innovative Virus-Like Particle (VLP) technology is used to produce mass market vaccines for infectious diseases such as influenza, respiratory syncytial virus (RSV), para-influenza virus (PIV) and other diseases such as HIV and cancer.

***TechnoVax's patented platform technology is based on its unique virus-like particle (VLP) approach, and has the potential to completely transform the vaccine industry and redefine the marketplace.***

# Business Objectives

**TechnoVax has three initial complementary goals**

- **Improve our current base technology:**
  - Advance our primary vaccine candidates into human clinical;
  - Evolve and refine our proprietary VLP platform technology to support cost effective and large scale production;
  - Develop combination vaccines blending VLPs carrying antigens of different viral pathogens on their surfaces (multiple virus protection in one vaccine product.)
- **Expand our product pipeline**
  - Respiratory viral targets
  - HIV and cancer vaccines
  - Hemorrhagic fevers
- **Seek commercial partnerships**
  - At regional level;
  - Product centered;
  - Project oriented;

***By achieving these goals, TechnoVax will be extremely well positioned to generate new technologies and products for commercialization and out-licensing.***

## Senior Management Team

**Dr. Jose Galarza** (DVM, PhD) is the President and Founder of TechnoVax. He has more than 27 years of scientific experience in the field of virology and vaccine development and is currently an adjunct Associate Professor of Microbiology and Immunology at New York Medical College. Before founding TechnoVax, he was Principal Scientist and leader of the influenza subunit vaccine development program in the Vaccines Division of Wyeth Pharmaceuticals in Pearl River, New York. Prior to joining Wyeth Vaccines, Dr. Galarza held research positions at the University of California at Irvine, and the University of Utah Medical Center in Salt Lake City, Utah.

**Dr. George Martin** (PhD) is the Chief Technical Officer and co-founder of TechnoVax. He is Scientist Emeritus at the National Institutes of Health and former Senior Vice President for Scientific Affairs of Fibrogen, Inc. in San Francisco. Dr. Martin has been extensively honored and recognized for his scientific accomplishments and has published more than 350 research papers.

**Mr. Hector Munoz** (MBA) is the Vice President of Business Development and CFO of TechnoVax. He brings over 19 years of domestic and international corporate experience. Mr. Munoz has held senior management positions in Business Development, Corporate M&A and Trade Marketing with R.J. Reynolds Int'l and with JT Int'l, during which time he has orchestrated multi- million dollar corporate M&A projects, ranging from divestitures to international joint-ventures. Mr. Munoz also possesses extensive financial and commercial experience working in five languages.

## **Advisory Board**

**Dr. Doris Bucher, PhD**, is an Associate Professor in the Dept. of Microbiology and Immunology at New York Medical College, Valhalla, NY. Dr. Bucher has dedicated most of her research career to work on influenza viruses and influenza vaccine development. Her laboratory at New York Medical College (NYMC) is one of only three laboratories worldwide which produce high growth reassortant 'seed' viruses for the influenza vaccine. For the past six years (including 2009-2010), the NYMC H3N2 reassortants have been used either exclusively or for the bulk of world production of 400-450 million doses of influenza vaccine (inactivated). With the onset of the swine influenza in late April, her laboratory group began development of a seed virus for H1N1v (swine origin, 2009). This reassortant, NYMC X-179A, as well as NYMC X-181, have been used as the seed viruses for most of the swine flu vaccine (inactivated, egg based) produced world-wide. The clinical trials showed that a protective immune response was achieved with a single dose of the X-179A vaccine. It is estimated that 1-2 billion doses of 2009 H1N1 vaccine will be produced.

**Dr. Nathan Litman, MD**, is Professor of Pediatrics at the Albert Einstein College of Medicine, and Director of Pediatrics and Pediatric Infectious Diseases at the Children's Hospital at Montefiore. Dr. Litman has received numerous awards for teaching including from the pediatric house staff at Montefiore, from the Infectious Diseases fellows at Montefiore, from medical students at the Albert Einstein College of Medicine, and from the Pediatric Staff at Flushing Hospital; he has recently been named a "Master Teacher" by the Department of Pediatrics at Montefiore. Dr. Litman has a broad range of interests within the field of pediatric infectious diseases and is frequently consulted by pediatricians in practice. He has participated in clinical trials of several vaccines which are now part of the routine immunization schedule. He regularly is asked to give lectures to medical groups and hospitals throughout the region. Dr. Litman has been named several times in various lists of "Best Doctors in New York". Dr. Litman was one of the co-authors on the initial article describing AIDS in children, and the acquisition of Rocky Mountain Spotted Fever in an urban environment. He has authored chapters in textbooks on sexually transmitted diseases, mumps, actinomycosis, nocardiosis, and viral infections. He serves as a reviewer for several medical journals.

**Dr. Anjani Shah, PhD**, has a PhD in cell biology and experience in medical writing and public relations. Her unique background enables her to approach projects from a variety of perspectives - which is the key to effective communications. Prior to starting her own biomedical writing and consulting practice, she was Director of Scientific Affairs for Targent Pharmaceuticals, a start-up specialty pharmaceutical company specializing in cancer. At Targent she developed its website, co-wrote its business plan, corporate presentations, summaries about its product pipeline and helped research licensing opportunities. Before joining Targent, Dr. Shah worked at Noonan/Russo Communications, a public relations company where she developed media and investor relations programs and corporate materials for biotechnology companies. She writes for non-profits, biotech companies and industry publications such as Drug Discovery and Development. She also produces scientific conferences in the biotech/pharma industry for Cambridge Healthtech Institute. She earned her PhD from the Albert Einstein College of Medicine in the area of signal transduction. Her undergraduate degree is from Princeton University where she majored in biology and earned a certificate in the program of Science in Human Affairs.

## **Advisory Board (cont.)**

**Dr. Stephen Udem, MD, PhD,** is an internationally recognized virologist and vaccinologist, considered especially expert in the field of negative strand RNA viruses including such human respiratory disease pathogens as influenza. He previously was Vice President of Wyeth Vaccines Research and a member of the Wyeth Vaccine Business Unit's Senior Management Team charged with candidate identification, design, development, regulatory submission, intellectual property assessment, as well as U.S. and international product licensure. Thereafter, he served as Chief Scientific Officer and Senior Vice President of Vaccine Development of the International AIDS Vaccine Initiative before opting to start his own Vaccine R&D consultant/advisor practice. Prior to joining industry, Dr. Udem held senior academic positions at the Albert Einstein College of Medicine and the New Jersey Medical School. Dr. Udem's contributions have been extensively published in the scientific literature and many of his creative technology inventions have been patented. He received his undergraduate degree from the City College of New York and his Ph.D. and M.D. from the Albert Einstein College of Medicine.

**Dr. Raphael P. Viscidi, MD,** is a Full Professor of Pediatrics at Johns Hopkins University School of Medicine. He is board certified in Infectious Diseases. For over 25 years he has conducted clinical and laboratory research in Virology with an emphasis on viral pathogenesis, humoral immune responses to viruses and epidemiology of viral infections. His research has focused primarily on human papillomaviruses and polyomaviruses, but also on human immunodeficiency virus and coronaviruses. His laboratory has produced virus like particles for vaccine development and as reagents for antibody assays. He is the Virology Editor of the journal *Molecular and Cellular Probes*. He serves as a regular member of the National Institutes of Health Clinical Research and Field Studies of Infectious Diseases study section. He has published over 160 peer-reviewed scientific papers and written over 25 book chapters.

**Mr. Sohal Shah, BSc, A.C.A,** Mr. Shah currently holds a senior position at JP Morgan Chase and has previously worked with Price Waterhouse in London, Hong Kong and New York City as well as with Cazenove, Merrill Lynch, and ING Barings. He has also been involved in the many aspects of establishing and growing small companies. He holds a degree in Banking and International Finance from the City of London Business School.

**Mr. William B. Kerr, Esq.,** is a partner in the Kerr&Richards, LLP law firm located in New York city. His legal expertise spans across the following fields: Financial Services Litigation, Private Equity, Environmental, Corporate Governance, Election & Campaign Finance. He holds a BSc in Agricultural Economics from Cornell University and a Law Degree from the University of Pennsylvania, as well as post-graduate courses at the London School of Economics.

## Milestones

### **Achievements to Date:**

January 2004	Incorporation.
November 2005	TechnoVax was awarded \$1.0 million in funding from The National Institutes of Health (NIH / U.S. Department of Health and Human Services ) to support development of its influenza vaccine program.
July 2006	Immunization with a TechnoVax H5N1 VLP vaccine provided 100% protection to mice challenged with a lethal dose of the highly pathogenic H5N1 influenza virus (bird flu).
December 2006	TechnoVax completed the licensing of the core VLP technology from Wyeth.
2006-2007	TechnoVax filed 4 additional patents on vaccines for a variety of viral diseases.
July 2007	TechnoVax developed and tested in mice and ferrets, two VLP vaccine candidates designed to provide protection against the 1918 (H1N1) influenza virus and the potentially pandemic H7N7 strain. Results were promising.
2007-2009	Development of bivalent VLP vaccine technology.
2008-2009	Development of RSV, HIV, cancer candidates (discovery stage).
September 2009	TechnoVax won \$2.9 million in funding from The NIH (U.S. Department of Health and Human Services ) to further support its vaccine programs.
October 2009	Initiated exploration for establishing potential regional partnerships worldwide.

# TECHNOLOGIES

Technologies  
VLP Vaccine  
Manufacturing  
Market Opportunities  
Technovax vs. Competition  
Products Pipeline  
Intellectual Property and Portfolio

## Technologies

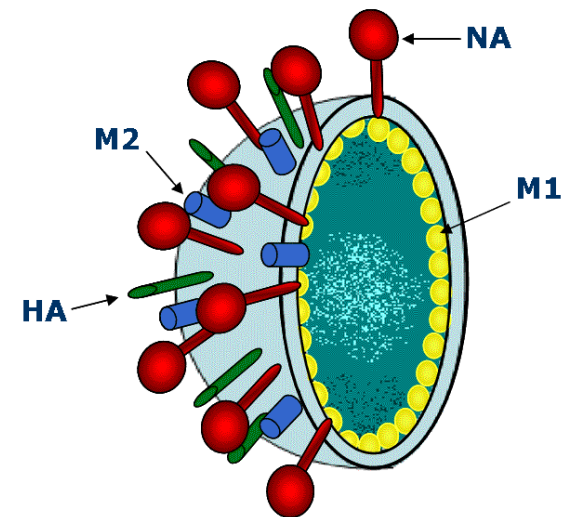
TechnoVax and its team of scientists have developed a new way to produce highly immunogenic, non-infectious monovalent and polyvalent virus-like particle (VLP) vaccines using a cell-based manufacturing system.

One of the most exciting aspects of the TechnoVax VLP technology lies in its versatility, which allows for the development of single, polyvalent or combination vaccines that carry the antigen (s) to protect against epidemic strains of respiratory viruses, emerging viruses such as avian influenza (distinct antigenic variants) SARS and other bioterrorism agents. Vaccines developed with TechnoVax's VLP technology also have the potential to be used as prophylactic or therapeutic treatments for HIV and cancer.

In the medium term TechnoVax plans to extend its technology platform to target many diseases where no vaccine is currently available.

### ***Virus-Like Particle (VLP) Technology***

***Expressing only 4 viral proteins together allows assembly and release of VLPs from cells***



***Resembles Virus but Lacks Nucleic Acid and Ability to Replicate***

Four viral structural proteins are sufficient for the formation of the VLP. As a vaccine the VLP induces a strong immune response and provides complete protection.

# VLP Vaccine

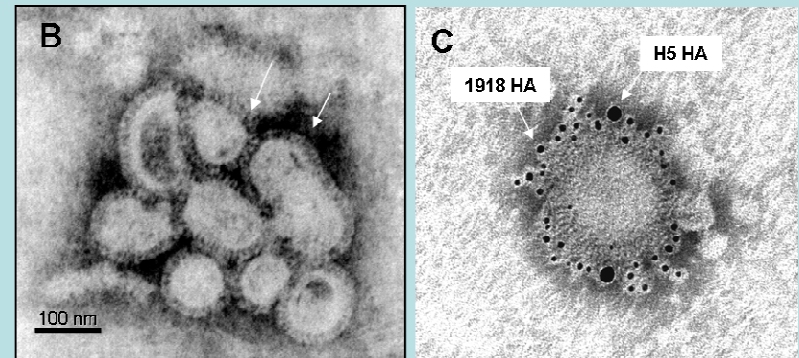
TechnoVax’s innovation on the core platform technology allows for the creation of polyvalent influenza VLP vaccines bearing protective antigens of two different influenza viruses on the surface of the same VLP. This is a significant advance over the current influenza vaccine production method which requires growing three different viruses in chicken eggs, chemical inactivation (killed vaccine) and blending in the final vaccine formulation.

Unlike the current influenza vaccine production process, polyvalent VLP vaccines are manufactured in a cell culture system and chemical inactivation is not required because the VLP vaccines are not infectious.

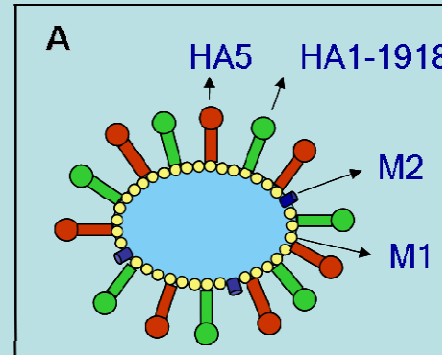
TechnoVax’s novel polyvalent VLP vaccines are produced in a single manufacturing step utilizing a new production process, reducing manufacturing time, steps and costs.

## **Polyvalent Influenza VLP Vaccine**

**To protect against multiple influenza virus strains**



*Negative Staining and Dual Immuno-gold Labeling EM of Polyvalent VLPs*



Polyvalent influenza virus-like particles carry on their surfaces two antigenically distinct HA molecules. Polyvalent VLP vaccines will protect against influenza viruses for which they carry antigens. A) Illustration of polyvalent VLP. B) Negative staining of polyvalent VLPs showing polymorphic influenza virus-like structures (arrows point to HA spikes). C) Dual immuno-gold labeling of VLPs with anti-1918 HA (5nm gold particles) and anti-HA5 (10nm gold particles) antibodies. The electron microscopy study was performed at the Bio-Imaging Center of Rockefeller University.

*Illustration of the Structure of a Polyvalent VLP*

# Manufacturing

## Production of Influenza Vaccine: Differences Between Current Process and VLP Technology

### Current Process

- Virus grown in embryonated chicken eggs
- Killed vaccine requires chemical inactivation
- Live attenuated vaccine requires extensive safety evaluation
- HPAI viruses (i.e. 1918, H5) kill the chicken embryo and prevent vaccine production
- Slow process when possible

### VLP Technology

- VLP produced in cultured cells
- VLPs are non-infectious, inactivation is not required
- Less safety concerns during production
- VLP for HPAI viruses can be produced safely
- VLP production is more rapid
- TechnoVax VLP production time is 3-4 months

### Robust Cell-based System for Large Scale Manufacturing

- VLP vaccines can be made in a ***continuous cell-culture system***, which is rapidly scalable for large volume manufacturing.
- VLP vaccines are ***purified from the culture medium*** and inactivation is not required, because VLP vaccines are not infectious.
- ***Fast and flexible system*** for rapid response to emerging pandemic or epidemic influenza virus strains.
- High yield, larger production capabilities, ***shorter production time and lower cost.***

## Market Opportunities

Annual vaccine sales worldwide are projected to reach about **\$18 billion and the vaccine market** is projected to increase 12% per year.

Introduction of **safe and efficacious novel vaccines** manufactured with the most cost-effective technology **will have significant commercial advantage** and will potentially dominate the marketplace.

### Potential Vaccine Targets Where VLP Technology Could Be Utilized

#### Primary Targets

- **Influenza A and B viruses**  
*Vaccine available, dated technology, Cumbersome manufacturing process*
- **Respiratory Syncytial Virus (RSV)**  
*No vaccine available*
- **Parainfluenza virus (PIV)**  
*No vaccine available*
- **Metapneumovirus**  
*No vaccine available*

#### Secondary Targets

- **Hepatitis C virus**  
*No vaccine available*
- **West Nile Virus**  
*No Available vaccine*
- **Coronavirus (SARS)**  
*No Vaccine available*
- **Viral Hemorrhagic Fevers: Dengue, Ebola, etc.**  
*No vaccine available*
- **Cancer Vaccine Targets**  
*No vaccine available*

## TechnoVax vs. Competition

### TechnoVax

Patented approach to create single and **multi-valent influenza VLP vaccines**

Patented scalable **mammalian cell-based system to continuously produce VLP** vaccine in shorter time and at reduced costs

Licensed system allows for **VLP vaccine development for other respiratory virus targets** (e.g. RSV, PIV and metapneumovirus) on co-exclusive bases with licensor, Wyeth.

**Additional patent applications protect the VLP system** for developing vaccines for respiratory viruses

Able to significantly **improve the technology**, Because we are the inventor of this VLP vaccine development system

### VLP Competition

One competitor that uses this VLP system for developing **only mono-valent influenza vaccines**

Competition uses the insect cell system, which requires **two steps and production is limited to 72hs**; then the process has to be repeated

**Competition not allowed to use** this VLP system for developing vaccines against the specified respiratory targets.

Further **preclude competition of using this VLP system to develop vaccine** for respiratory viruses ( RSV, PIV, metapneumovirus)

**Limit competition's ability** to utilize the VLP system

## Influenza VLP Technology for the Development of Other Targeted Vaccines

	Discovery	Preclinical	Phase I	Phase II	Phase III
<i>TVX001 - Seasonal Influenza</i>	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓	Q4-2010	Q3-2011	Q2-2012
<i>TVX002 - H1N1 (SW flu A)</i>	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓	Q4-2010	Q3-2011	Q2-2012
<i>TVX003 - H5N1</i>	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓	TBD		
<i>TVX004 - H1N1 (1918)</i>	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓	TBD		
<i>TVX005 - H7N7</i>	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓	TBD		
<i>TVX006 - Undisclosed Target</i>	✓ ✓ ✓ ✓	2010			
<i>TVX007 - Undisclosed Target</i>	✓ ✓ ✓ ✓	TBD			
<i>TVX008 - Undisclosed Target</i>	✓ ✓ ✓ ✓	TBD			
<i>TVX009 - Undisclosed Target</i>	✓ ✓ ✓	TBD			
<i>TVX010 - Undisclosed Target</i>	✓ ✓ ✓	TBD			
<i>TVX011 - Undisclosed Target</i>	✓ ✓	TBD			

## **Intellectual Property**

TechnoVax's intellectual property (IP) portfolio comprises issued U.S. and international patents licensed from Wyeth for all indications and fields of use plus pending patent applications filed by TechnoVax covering additional influenza vaccines such as 1918 flu, H7N7, H5N1 avian flu and further methods and compositions for multivalent VLP vaccines. These applications encompass the principal methods of virus-like particles (VLPs) formation and manufacturing, as well as the structural genes required for VLP assembly.

TechnoVax plans to file additional patent applications for new antigenic compositions of VLPs, as well as improved methods and compositions comprising VLPs having improved properties (e.g., enhanced intracellular formation and release, and increased immunogenicity.) Additionally, TechnoVax will develop a new biological method for VLP production that will translate into a more cost effective manufacturing system.

## **IP Portfolio**

- Influenza Virus-Like Particle (VLP) Compositions. Patent Pending
- Polyvalent Influenza Virus-Like Particle (VLP) Compositions. Patent Pending
- Respiratory Syncytial Virus (RSV)-Like Particle Vaccines Composed of Chimeric RSV/ Influenza Structural Proteins. Patent Pending
- Monovalent or Divalent Wild Type Respiratory Syncytial Virus (RSV)-Like Particle Vaccines. Patent Pending.
- Methods to Produce and Manufacture, Monovalent or Polyvalent Virus-Like Particles (VLPs) in Eukaryotic Cells to Be Used as Vaccines to Induce and Immune Response Affording Protection Against Viral Pathogens. Patent Pending.
- An HIV/AIDS Vaccine Based on Virus-Like Particles (VLPs) Exhibiting HIV Glycoproteins and Cellular Receptor and Co-receptor Which Interact, Create and Display Universal Conformation Antigenic Structures (UCAS) Able to Elicit Protective Immune Responses against the HIV Virus. Patent Pending
- License Agreement with Wyeth for the Basic VLP Technology

# MISCELANEOUS

Services  
Media  
Contact Us

## Services

TechnoVax Biological Division offers the following services for generating high quality reagents and biological products for research or diagnostic purposes.

### **Molecular Biology Services:**

- Cloning and expression
- Expression analysis
- Production of recombinant proteins in prokaryotic and eukaryotic systems
- Protein purification and characterization
- In vitro transcription/translation
- Transient and stable transfection of mammalian cells

### **Virology Services:**

- Virus production, purification and quantification
- Assays to measure antibody and virus neutralization activity
- Assays for assessing antiviral agent activity
- Antiviral and vaccine in-vivo efficacy studies

### **Immunology Services:**

- Generation of polyclonal and monoclonal antibodies
- Assay development

### **Construction of Recombinant Viral Services:**

- Vesicular stomatitis virus (VSV) recombinants
- Adenovirus vectors
- Adeno-associated virus vectors
- Vaccinia virus recombinants
- Baculovirus recombinants and vectors

*Inquire about construction of other viral vectors.*

## Media

### **Press Releases and Articles:**

- |            |  |
|------------|--|
| 10/20/2009 | TechnoVax Receives \$2.9 Million Grant for Flu and Influenza Virus-Like Particle (VLP) Vaccine Program   |
| 07/18/2007 | TechnoVax Reports on a VLP Vaccine Designed to Protect Against the Devastating 1918 Pandemic Influenza As Well As a Novel Bivalent VLP Vaccine Candidate |
| 12/11/2006 | TechnoVax Licenses Wyeth's Virus-Like Particle Vaccine Technology.   |
| 05/01/2006 | MIT- Technology Review: As it tests a new way of making vaccines, TechnoVax is targeting the deadly 1918 flu virus.                                      |
| 05/01/2006 | MIT- Technology Review: Catching the Flu: A Photo Essay.   |

### **Publications**

- |                     |   |
|---------------------|---|
| Viral Immunology    | A Novel Intranasal Virus-Like Particle (VLP) Vaccine Designed to Protect against the Pandemic 1918 Influenza A Virus (H1N1). 2007           |
|                     | Virus-Like Particle (VLP) Vaccine Conferred Complete Protection against a Lethal Influenza Virus Challenge. 2005                            |
| Journal of Virology | Formation of Wild-Type and Chimeric Influenza Virus-Like Particles following Simultaneous Expression of Only Four Structural Proteins. 2001 |

## Contact Us

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