

## Investor Page

### About ITI

Immunomic Therapeutics, Inc. (ITI) is a privately-held clinical stage biotechnology company headquartered in Lancaster, PA with lab facilities in Rockville, MD. ITI is developing next generation vaccines based on the patented LAMP Technology. Our LAMP-vax platform significantly increases the effectiveness of the immune response to nucleic acid vaccines while simplifying overall vaccine design and delivery, yielding safer, more cost-effective human and animal therapies. LAMP emerged from \$20 million of NIH-funded research conducted by distinguished scientist Dr. Tom August at the Johns Hopkins University School of Medicine. ITI has the exclusive worldwide license to the LAMP technology patent estate and is creating opportunities for ground-breaking next generation LAMP DNA vaccines, beginning with allergy, cancer and infectious disease.

### LAMP-Vax™ Vaccine Technology and Advantages

DNA vaccines represent the future of immunization, with lower costs and flexibility in design and application. FDA approval of these vaccines has historically been delayed due to difficulties achieving effective immune response. ITI's LAMP-vax™ vaccines solve the efficacy problem of DNA vaccines by enabling effective antigen presentation to the right part of the immune system. Alternative DNA vaccine methods emphasize presentation through a less effective generic pathway, MHC-I, on somatic cells (e.g. muscle cells). ITI's LAMP-vax vaccines harness the power of LAMP (Lysosomal Associated Membrane Protein), a naturally-occurring human protein and immune system potentiator that localizes in the lysosomal antigen processing pathway of dendritic cells, professional antigen presenting cells (APCs). APC's specific function is to effectively alert the rest of the immune system to foreign entities such as virus proteins or allergens. LAMP localizes to the same compartment as the Major Histocompatibility Complex Type II (MHC-II), whose primary function is to initiate a potent immune response through recruitment of the cytotoxic T-cells and CD4<sup>+</sup> helper T-cells necessary to produce immune system memory cells for true immunity.

LAMP-vax vaccines represent unprecedented scalability, flexibility and multiplexity. Because LAMP can be added to any nucleic acid vaccine or DNA construct, it can be used to treat allergies, infectious diseases, cancers, HIV and a host of other immune deficiencies. In addition, since the FDA has signaled that LAMP vaccines may have up to 6 different plasmids included in each formulation, multiple targets such as different pathogens of multiple allergens can to be targeted at once in a single vaccine. Thus, LAMP Vaccine Technology represents a disruptive, game-changing platform technology

with high potential for serial commercialization either by ITI directly or through selective sublicenses to biopharmaceutical companies around the world for exclusivity in their focused market segments.

LAMP-vax's advantage is highlighted when applied to allergy immunotherapy, an \$11B market and ITI's initial target. Conventional allergy desensitization aims to convert the allergen-specific IgE antibodies - normally produced in allergic patients' body on exposure to an allergen and responsible for allergic symptoms - to IgG antibodies. This results in elimination of allergic symptoms. The standard allergy therapeutic approach depends on directly administering trace amounts of allergen (e.g. peanut flower) to desensitize the person's immune system with frequent dosing over an extended treatment period that can last for years. Desensitization leaves the patient vulnerable to severe allergic responses, often making therapy impossible. LAMP-vax allergy vaccines can prevent and cure allergies through the same IgE → IgG conversion, without ever exposing patient to free allergen, providing unprecedented safety and making it possible to effectively treat problem allergies such as peanut allergy. Because there is no histamine produced, there is no allergic reaction. ITI is currently collaborating on a LAMP-vax vaccine for the treatment of peanut allergy with Dr. Hugh Sampson, a thought leader in the field of food allergies.

### **LAMP-Vax Technology – Clinical Product Strategy**

ITI's commercialization strategy for unlocking the potential of LAMP is capital efficient, focusing on applications within the \$11B allergy market. ITI's first product targets a potent allergy, Japanese Red Cedar (JRC) pollenosis, a large and growing problem for people living in Japan [see [Beauty & The Beast](#) book]. This efficient strategy represents the optimal path to FDA approval and commercial success, because it provides the quickest, most risk-averse approach to human clinical trials and meets a large, unmet market need. ITI has submitted its IND and is entering the clinic with its JRC-LAMP-vax™ vaccine for treating and preventing Japanese red cedar allergy. We are currently seeking a partner who will co-develop JRC-LAMP-vax by conducting parallel clinical trials in Japan.

In addition to products developed internally, The Geron Corporation (NASDAQ:GERN) entered into a license agreement with ITI for the incorporation of LAMP into its telomerase DNA vaccine (GRNVAC1) for treating metastatic cancers. GRNVAC1 recently completed a Phase II clinical study for Acute Myeloid Leukemia (AML) vaccine; results of the study released in December 2010 showed that 15 of 21 patients (mostly high risk) were in complete remission, some in this group for up to 36 months (the Standard of Care for AML is 8 months). This demonstrates that the LAMP platform holds the potential to enhance therapeutic efficacy of DNA vaccines in human and veterinary

applications. A complete report on the results of this study is currently available to potential investors under strict confidentiality.

### **Significant Historical Developments and Milestones to Date**

ITI has accomplished many key milestones since its inception and is now a well-positioned Company, from a capital and strategic standpoint:

- ITI signs exclusive, worldwide license to LAMP technology with **Johns Hopkins University**. ITI gains rights to all active LAMP-related intellectual property - September 2006.
- ITI grants sub-license to the **Geron Corporation** for the development of a LAMP-telomerase cancer vaccine. ITI receives upfront fee and milestone payments as well as royalties to the novel therapeutic vaccine once commercialized - October 2006.
- **ITI and Nature Pharmaceuticals agree to collaborate and cross-license vaccine technologies**. December 2006.
- ITI attracts investment from **Rathmann Family Foundation**, Montgomery Co. DED, Capital Genomix and Private Investors to raise important funding support – August 2007
- **Chimeric Vaccine Patent Issues** in Australia - June 2008.
- **ITI holds a Pre-IND Meeting with FDA** for its Japanese red cedar immunotherapeutic vaccine; the meeting held in March 2009, was successful and received the FDA's endorsement to proceed towards an IND filing in first quarter 2012.
- **Geron Announces GRNVAC1 Results from AML Study Meets Phase I/II Endpoints** with 15 of 21 patients receiving therapy to continue to be in remission, some for up to 2 years. December 2009 (updated May 2010).
- **ITI Selected as Frost & Sullivan Award Winner** for the 2010 Biotechnology Innovation of the Year Award in Vaccines. March 2010.
- **Life Sciences Greenhouse, M.A.I.N. & Trisiras Capital** closes on funding with immediate and future funding commitments of \$1.75 million. March 2010.
- **ITI Opens new facilities in Lancaster, PA** with offices at Liberty Place and a new laboratory at Franklin & Marshall College. March 2010.

- **ITI captures \$1 million in funding in Q4 2010** with commitments from the Life Sciences Greenhouse, significant angel participation and a Qualifying Therapeutic Development Grant. December 2010.
- **Chimeric Vaccine Patent Issued in Japan** providing key coverage for LAMP-vax formulation to 2022. January 2011
- **ITI signs collaborative animal health license with major biopharmaceutical company.** Dec 29 2011
- **ITI files IND for Japanese red cedar immunotherapeutic vaccine.** March 2012
- **ITI receives authorization from FDA to proceed with Phase I clinical study for Japanese red cedar immunotherapeutic vaccine.** April 2012
- **ITI closes series A round of investment \$2M.** April 2012

### **Management Team and Board of Directors**

The Company is led by Dr. William Hearl, an experienced biotech CEO and entrepreneur. **Dr. Hearl** is a pioneer in nucleic acid vaccine technology and is a holder of multiple patents in the area. He is also an experienced entrepreneur having founded Capital Genomix in 2000 and exiting that company with double-digit return to investors in 2006.

**Bernard Rudnick**, an established financier and business development executive is the CFO of the Company. Mr. Rudnick brings over 30 years of industry relevant experience and financial acumen to the executive team.

**Dr. Bruce Mackler** serves on the Board of ITI and as Vice President of Regulatory Affairs. Dr. Mackler is a recognized regulatory affairs expert with a long track record of supporting biotech corporate development and successfully working with the FDA to achieve product registration.

**Dr. Heiland** is Vice President of Research and Development at ITI and was one of the founding employees of the Company. Dr. Heiland is an experienced molecular biologist and holds multiple patents in the field of genomics. In addition, she is also a visiting scientist at Johns Hopkins University.

**Lisa Salley** is the Chief Operating Officer of ITI and brings over 24 years of corporate experience at major firms such as at DuPont, including senior executive positions at GE and Rohm & Haas. Ms. Salley is also the Senior Managing Partner of the Heritage Solutions Group (HSG), a business advisory firm.

The management is supported by an outstanding Board of Directors which is composed

of Dr. Hearl, Dr. Mackler and Dr. Ronald Thiboutot, Mr. Barry McDonald (Chairman) and Mr. James Wishart. Mr. McDonald and Mr. Wishart have each been CEO's of leading companies in the health and biotech fields and bring substantial experience and focus to the ITI Board. Dr. Thiboutot is a representative of the Life Sciences Greenhouse of Central PA and a former pharma executive in the vaccine field.

## **Strategy**

Immunomic therapeutics is executing a trifurcated business strategy.

First, the company has designed a clinical approach to allergy which it believes will: (1) demonstrate the immunogenicity of its LAMP-based vaccines; (2) reach multiple valuation milestones over an 18 month period culminating in a major distribution partnership with a global or Japanese biopharma company for Phase III development and market access of our JRC red cedar allergy vaccine; (3) establish proof-of-concept to support rapid development of multivalent vaccines for the major allergen classes including pollens, food and environmental targets (e.g., dust mite, pet dander).

Second is the development of joint partnerships for the licensing of non-core vaccine candidates. These would include both prophylactic and therapeutic vaccines for the government and military pandemic diseases and bioterrorism threats, veterinary applications and niche market diseases (often classified as Orphan Diseases).

Thirdly, after completing the first and second business initiatives, ITI intends to develop vaccines for which there already exists pre-clinical data in the areas of infectious disease and cancer. It is expected that this work will be done in collaboration with one or more major biopharmaceutical companies.

ITI further anticipates that the Company will sell substantially all or most of its business to its pharmaceutical partners.

## **Financial Summary**

Immunomic Therapeutics has operated a highly capital efficient business since its inception, relying primarily on operating revenue from licensing and collaborative deals. In mid-2011, Immunomic Therapeutics closed its debt financing round, successfully raising about \$2 million in short term, fully convertible to Common Stock debt. In order to meet the financial needs for clinical development of its first product, the Company successfully closed a Series A PPM offering in April 2012, raising an additional \$2 million. These funds, combined with the proceeds of an executed license with a large biopharmaceutical company, will provide ITI sufficient capital to operate the Company

and to complete Phase I and II Clinical Trials for JRC-LAMP-vax. The Company plans to secure a partner for the Japanese Red Cedar LAMP-Vax vaccine product to provide additional revenue in 2012 and 2013. The Management & Board have continuously worked to protect shareholder value by providing adequate resources and support for the Company to advance its business agenda while operating and planning in an economically prudent manner, will continue to do so in the future.