



Immunomic Therapeutics, Inc. Business Plan

Q3, 2011

313 W. Liberty St., Suite 342, Lancaster, PA 17603
9260 Medical Center Dr., Suite 100, Rockville, MD 20850
www.immunomix.com

Contact: Bill Hearl, CEO
bhearl@immunomix.com
717-327-1919 (office)
240-401-7496 (mobile)

or

Bernard Rudnick, CFO
bernie@immunomic.com
302-737-9252 (office)
302-981-9001 (mobile)

INTRODUCTION

The following business plan and technology overview is intended to provide an understanding of Immunomic Therapeutics' (ITI) strategy and rationale for developing high value – low risk nucleic acid vaccines based on LAMP Technology. ITI considers nucleic acid vaccines to be the future of vaccines and immunotherapy, much in same way that therapeutic antibodies approached the field of biologics only a decade ago.

Nucleic Acid vaccines (including DNA vaccines) have been under development for approximately 15 years and have shown signs of opportunity and promise to deal with many challenges in human health. Indeed, ITI's own LAMP Technology already has been incorporated in vaccines for cancer (prostate, AML, HPV), infectious diseases (influenza, HIV, dengue, West Nile, yellow fever & rabies) and allergy (dust mite).

Although there have been recent positive results, the DNA vaccine community generally remains confounded by the clinical trial process and by less than adequate immune responses. Nevertheless, there is active development of nucleic acid vaccines for the treatment of human diseases with over 40 ongoing phase I/II clinical trials. including candidate vaccines against human immunodeficiency virus (HIV-1), avian influenza infection (H5N1) and human papilloma virus (HPV). Experimental DNA vaccines have been effective in animal models and the first DNA vaccine targeting West Nile Virus in Equine was launched in 2008. A DNA “vaccine – like” product, Provenge®, was approved for use in treating cancer patients and works by activating an immune modulating protein, GM-CSF. While not technically a vaccine, it does qualify as a nucleic acid based immunotherapy and it does indicate the FDA acceptance of this class of therapeutics.

Why have DNA vaccines been slow to reach the human vaccine and therapeutic market? We believe that there are two primary causes for the delay in reaching the doctor's office: first, standard DNA vaccines result in the antigen being synthesized in the cytoplasm of somatic cells. This vaccine strategy is dependent upon using a **non-immune system cell** such as a muscle cell and expecting to successfully act as an immune cell. The presentation through the MHC-I pathway, while effective in attracting CD8+ cytotoxic T-cells to responds, is also competing with every other cell in the body which is also presenting markers through the MHC-I pathway. It weakly attracts helper T-cell CD4+ responses and is therefore creating weak antibody and memory responses, two key elements of a successful vaccine formulation. The second issue facing DNA vaccine development is that most of the work has **focused on applying the technology on diseases that present immense immunological challenges**. Diseases such as cancer, HIV and hepatitis C have evaded both traditional and non-conventional approaches and without a significant biological breakthrough may never be fully addressed through any type of vaccine. More recently, efforts have shifted to influenza, but again there is a concerted effort to focus on the complexities of pandemic influenza rather than annual, seasonal influenza. However, the recent Vical DNA-based Phase I study for their pandemic influenza vaccine demonstrated an immune response consistent with the development of protective antibodies and holds promise.

ITI's approach to commercializing DNA vaccines addresses these two shortcomings by incorporating our platform **LAMP-vax Technology** into vaccine design; this specifically addresses the problem of how antigens from DNA vaccines access the immune system. Vaccines using **LAMP-vax Technology** direct the immune target antigen to the **MHC-II** compartment **in professional antigen presenting cells**, resulting in a more complete and robust immune response. This response has now been documented in two human clinical trials with the cancer vaccine GRNVAC1, which has shown extraordinary promise in extending the lives of AML patients. The second problem – selecting a practical disease target – is addressed by focusing on allergy, a disease that is highly problematic, has enormous market potential, yet is not life threatening in most cases.

While we believe our LAMP-vax Technology platform can broadly offer a significant enhancement for nucleic acid (and protein) vaccines, our focus on allergy includes intense regulatory and clinical efforts to reach the market in less than 3 years. ITI's FDA strategy is designed to move rapidly from an initial clinical study addressing key safety and clinical design questions, into Phase III within 18 months of first dosing. Our study approach also incorporates exploration of alternate routes of administration (e.g. transdermal, sublingual or intranasal delivery) to supplement or replace traditional intramuscular delivery. We believe the alternate routes of delivery will facilitate acceptance. We further believe our approach, which minimizes the number of treatments, will be a key value driver, moving allergy immunotherapy into primary care, while maintaining profitable, reimbursable allergy vaccine products.



ABOUT ITI

Immunomic Therapeutics, Inc. (ITI) is a Delaware “C” corporation incorporated founded in 2005. The Company, which is privately held, was formed to commercialize LAMP Vaccine Technology. LAMP (Lysosome-Associated Membrane Protein) facilitates the presentation of antigens in nucleic vaccine formulations, resulting in an enhanced and effective immune response in humans.

LAMP Technology was invented and patented by Dr. J. Thomas August, M.D., Distinguished Professor at Johns Hopkins University; the LAMP patent estate was exclusively licensed (worldwide, all applications) by ITI from Johns Hopkins University in 2006. LAMP-based vaccines have been developed for a wide array of diseases and have been successfully applied in human clinical trials for prostate cancer and acute myeloid leukemia. This research has been supported by over \$20 million in government grants and has been the subject of over 70 research papers in life science literature. Recent publications have shown that LAMP vaccines can provide protection against rabies virus in dogs, against yellow fever in mice, prevent & cure dust mite allergies in mice, and are safe in humans and shown to be effective as an immunotherapy for treatment of certain cancers.

Immunomic Therapeutics will make money by selling vaccines to the human health market and by licensing the use of LAMP for a narrow selection of specific antigenic sequences and diseases. ITI is capital efficient and will continue to execute license and collaborative research agreements to drive revenue, further the commercial development of the LAMP Technology and formulate and commercialize its own nucleic acid based vaccines for human diseases. The Company has completed three funding transactions including sub-licenses to the Geron Corporation (telomerase in hyper-proliferative disease) and Nature Technology (research sale of vectors containing LAMP) for the commercial development of LAMP-based vaccines and has active collaborations with several laboratories. ITI has an experienced management team in place, expansion resources identified, and strong opportunities for multiple licenses to pharmaceutical and biotechnology companies active in vaccine development. The Company stands poised for rapid and attractive investor return through a merger and acquisition exit strategy or an IPO.

We are entering the estimated \$25+ billion vaccine market and specifically the nascent DNA Vaccine market. Currently estimated to be valued at about \$1.2 billion, the DNA Vaccine market is expected to show triple digit growth rate over the next 5 years. The Company’s allergy target market is significant; the immunotherapy market which generated about \$1.5 billion in (2010) revenue is dwarfed by a potential capture market of over \$10 billion for symptom treatments. Given our belief that our immunotherapeutic vaccines will have lasting, quite possibly permanent impact on reversing allergy with just a few treatments, we reasonably believe that our addressable market is over \$11 billion.

DNA vaccines, as a class, promise to perform much like the now \$50 billion therapeutic antibody market, which grew at annual growth rate of 54% over the last 10 years. The Company expects its initial product collaborations and licensing deals to lead to corporate revenues of at least \$5 million in 2012 and \$20 million in 2013.



EXECUTIVE SUMMARY

Immunomic Therapeutics, Inc. (ITI) is a clinical stage biotechnology company with exceptional patented science for application to vaccines and vaccine immunotherapy. The Company's core technology, LAMP-vax™, 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 vaccines have been validated in humans including the cancer vaccine, GRNVAC1, which was recently reported to reach its preliminary Phase II endpoints for safety and show promising efficacy results.

We have successfully completed pre-IND meetings with the FDA for two separate LAMP-based vaccines; we intend complete Phase I/II trials within the next twelve months for our allergy application following the protocols agreed upon by the Agency. Our R&D phase is complete and we will initiate a clinical allergy study in 2011 with patient dosing to begin in (about) Q4 11. This strategy brings an initial vaccine immunotherapy focus to allergy where there is both substantial clinical need and enormous market opportunity. We have both commercial and clinical validation for our breakthrough vaccine platform which has the potential to transform industry economics at a time when pandemic disease threats highlight the limitations of conventional vaccine science. We have achieved these goals in a cash efficient manner. Our external funding to date has been approximately \$2.7 M with substantial investment from the principals and cash flow from licensing revenues. We plan to exit the company upon the publication of Phase IIb data which is anticipated in Q4 of 2012.

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. In the initial Phase I/II trials for GRNVAC1, conducted in a group of prostate cancer patients with metastatic disease, the LAMP-hTERT vaccine showed no adverse safety effects in the study patients, and demonstrated an improved human immune response. GRNVAC1 is 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 **30 months** (median time to remission in AML patients receiving standard of care is 8 months). Patients in the high risk group (8) had a 1 year survival rate of >85% compared with <35% with standard of care and with 7/8 patients now in monitoring at 13 months survival with no disease. Clearly, 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 available under confidentiality and we expect publication of this data in 2011.

DNA-based vaccines are designed to take advantage of the cell's ability to synthesize protein using the coding sequence contained in the DNA. In the case of vaccines that include the sequence to LAMP (Lysosome-Associated Membrane Protein), the fusion protein (LAMP-vax™) produced - comprised of the combined sequences of the target antigen and of the full LAMP protein - remains localized within the cell. In dendritic cells (*professional* antigen presenting cells), the LAMP component directs LAMP-VAX to the critical intracellular compartment that normally functions to process foreign proteins; this intracellular processing of the antigen is essential in order to elicit an effective immune response to the pathogen or antigen. The LAMP-vax antigen fusion protein moves within the cell to the same key **MHC-II antigen-presenting compartment of the immune system** as do natural pathogen antigens; simply put, LAMP-mediated vaccines accesses the same immune pathway as a bacterial or a viral exposure. Since the MHC-II is the molecule that recognizes, binds to, and carries pieces of foreign proteins to the dendritic cell's surface for interaction with the immune system, vaccines that access this pathway activate immunity via helper T-cells. These cells then act to activate and regulate the immune response, inducing the formation of immune memory cells, antibody producing cells and cytotoxic T-cells - all functions critical for immunization against pathogens or allergens.

Immunomic Therapeutics **platform technology**, LAMP-vax Vaccines, enables the Company to pursue development of both therapeutic and prophylactic vaccines across a wide array of targets and applications. ITI intends to maximize application of LAMP Technology to support company growth and enhance investor value.



VALUE PROPOSITION

ITI's **LAMP_{vax}TM Technology** is the “missing link” that enhances the effectiveness of DNA vaccines. **It has the ability to make simple, inexpensive and effective DNA vaccinations a reality.** LAMP has been proven to direct the target of DNA-based vaccines to the MHC-II compartment within dendritic cells, resulting in a helper T-cell mediated immune response. The LAMP element is a platform technology that can be incorporated into virtually any existing DNA or RNA vaccine to produce a proven enhancement of the appropriate immune responses to the vaccine target. LAMP, already in Geron's human clinical trials with prostate and AML cancer patients, has been shown to be both safe and effective in humans in activating the immune system. The simple integration of the LAMP element into existing DNA or RNA vaccine constructs has shown evidence of major enhancement of the immune responses, increasing the likelihood of successful clinical trial outcomes. We believe that we and our partners will be successful taking the LAMP-based vaccines into the clinic and providing near-term liquidity to our shareholders through a strategic acquisition or IPO.

PRODUCTS IN DEVELOPMENT

Immunomic Therapeutics has identified the allergy immunotherapy market as its first application area for LAMP-*vax* Technology in order to take advantage of its highly advantageous clinical, regulatory and market attributes. By focusing on allergy, ITI has brought its technology to bear on a Quality of Life opportunity with low risk and low cost but very high reward. Following successful trials, the Company will be able to apply the LAMP platform to other attractive targets such as cancer and infectious diseases.

LAMP-VAX FOR JAPANESE RED CEDAR (JRC), & MULTIVALENT FORMULATIONS

Immunomic Therapeutics' LAMP_{vax} Allergy Vaccines are intended to demonstrate an effective and long-lasting solution to allergic rhinitis caused by Japanese red cedar or short ragweed pollen. The products will be plasmid DNA vaccines that will generate specific Th1 – IgG responses and in effect re-educate the immune system to recognize the allergenic proteins as antigens and thus mitigate the allergic response:

- **JRC LAMP-*vax*** is the Company's first allergy vaccine targeting Japanese red cedar which is an allergenic pollen in Japan with over 25 million severely affected. This vaccine has been designed and validated. ITI is seeking a Japanese corporate partner to develop this vaccine in Japan under favorable terms. In Texas, antigens of Japanese red cedar (Cry J1) are cross-reactive with the potent allergen mountain cedar (known as the “red menace”) and are recognized as a major regional health problem in the United States. ITI is now preparing to submit an IND (Investigational New Drug) notice with the FDA to conduct Phase I clinical studies on Japanese ex-patriots living in the US in controlled environmental chambers.
- **Multivalent Allergy LAMP-*vax*** is the Company's allergy vaccine targeting multiple allergy targets in a single formulation. This composition will include the leading weed allergen, short ragweed, and the number one tree allergen, birch. The formulation is likely to be supplemented with dust mite, the most prevalent environmental allergen and possibly one grass pollen. This vaccine will be used as a model for the FDA and is intended to develop a second generation formulation of a single vaccine targeted against grasses, weeds and trees. Such a vaccine (containing multiple plasmids with different allergens) will ultimately address all of the major outdoor allergies in a single therapy regimen.
- **ARA LAMP-*vax*** is ITI's food allergy vaccine for treating anaphylactic peanut allergy. Peanut allergy is one of the most well-known food allergies; its incidence is continually growing. The Company has enlisted the support of leading expert Dr. Hugh Sampson (Mt. Sinai) and is pursuing SBIR funding to support the development of this important application. Preliminary feedback is encouraging.



ADDITIONAL PRODUCTS IN DEVELOPMENT THROUGH COLLABORATION & LICENSE AGREEMENTS

In addition to the development of ITI's DNA vaccines, the Company has entered into agreements to advance the commercialization of two additional targets which are not in ITI's primary areas of focus:

- **GRNVAC1/2** is a LAMP – based vaccine being commercialized through a license agreement with the Geron Corporation (see www.geron.com for details). This vaccine has been used in two clinical studies (prostate cancer and AML) and we anticipate its further development by Geron. ITI will receive royalties and milestone payments from this product.
- **HIV LAMP-vax** is the Company's therapeutic anti-HIV vaccine. This vaccine has been designed, validated, evaluated in animal models and is now ready to enter the cGMP manufacturing phase. We are seeking a partner to commercialize this important therapeutic application.

MARKET

Nucleic acid vaccines have tremendous potential to revolutionize the world of vaccines with their favorable economics, physical stability and design flexibility. We plan to enter the growing vaccine market (over \$25 billion in 2010), targeting the nascent DNA vaccine segment with ITI's in-house vaccines for allergy. The vaccine market in general is experiencing rapid expansion with an AGR of 15-20% while the DNA vaccine segment is predicted to show triple digit growth over the next 5 year.

The vaccine market is now poised for major expansion, as evidenced by three new vaccines that are already having significant impact on the state of the market.: First, Gardasil, the new vaccine for HPV and cervical cancer, is predicted to be a multi-billion dollar product; second, strong forecasts have followed the announcement of Dendreon's therapeutic cancer vaccine; and third, Sanofi-Pasteur recently received approval for the first avian influenza vaccine, while Vical has announced a proof of concept Phase I/II influenza study and will be moving towards a Phase III. These new products, combined with recent merger and acquisition activity in the sector, portend a new and burgeoning market that could likely emulate the therapeutic antibody market segment. This segment emerged commercially in 1997 and grew to over \$50 billion by 2005, achieving an annual growth rate of 56%. With the approval of Vical's canine melanoma therapeutic DNA vaccine and some 50 human and animal DNA vaccines at various stages in the clinic, the vaccine market is on the cusp of a paradigm shift toward DNA therapeutics.

ITI's allergy focus addresses a significant opportunity in the allergy immunotherapy segment (**\$1.2 billion addressable market scalable to \$5-\$10B**) which is in addition to the large existing general vaccine market. This market currently represents the sales of marginally effective sublingual drop desensitization technology. If one includes symptom treating medication, the opportunity expands to at least \$11 billion.

We have and will continue to earn revenue through application and therapeutic-specific licenses and collaborations that provide us with milestone payments, supporting internal development without dilution. While initial and long term royalty revenues will come from partners, our internal development programs will enhance our enterprise value through the commercialization of our lead vaccines, targeting key allergy targets and in the future, infectious disease.

REGULATORY / FDA STRATEGY

ITI has held multiple successful pre-IND meetings (in 2008, 2009 & 2010) with the FDA, to confirm the preclinical protocols it filed in support of its first two IND's. One IND is part of our collaborative project for the clinical study of a LAMP-based therapeutic HIV vaccine and the second is for our allergy vaccine, JRC LAMP-vax. This project has enabled



the Company to establish procedures and protocols for the cGMP manufacture and qualification for its own future DNA vaccines, as well as to develop an early working relationship with the FDA. The Japanese red cedar LAMP-based vaccine project has been approved to proceed into pre-clinical manufacture and toxicology work in advance of the Phase I/II clinical study. ITI plans to use these FDA interactions to form the basis of developing an “IND pipeline” of LAMP-based vaccines. One major FDA position has been that ITI’s LAMP-based DNA vaccines can comprise 3-5 plasmids, each containing a different antigen; treated by the FDA as a single product for safety and efficacy studies; thus obviating separate studies on each plasmid.

ITI believes that with the systems established for the HIV and Japanese red cedar vaccines and early initiation of research studies to demonstrate a proof-of-concept in animals, it should be able to rapidly move its own allergy vaccine into human clinical studies starting in 2011. The Company expects to file an IND in September 2011 to support these efforts. The allergy vaccine FDA strategy is designed to leverage the safety data from its Phase I studies, rapidly progress through Phase II, and gain sufficient information to design a potentially successful pivotal Phase III. We anticipate that our Phase III study will be initiated within 18 months following Phase I.

Consistent with FDA guidance, ITI believes that its choice of vector, which has already been demonstrated to be safe in prior clinical trials, should reduce the need for extensive preclinical work. Additionally, published evidence from NIH, see Sheets et al. (2006) indicates that using the same vector with different nucleic acid antigen inserts does not change the safety characteristic of the vector; thus facilitating entry into early clinical trials with future vaccine candidates.

MANAGEMENT TEAM

The Company is led by Dr. Bill 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 significant return to investors in 2006 (approximately 10X). 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 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.

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. The Board also has three contributing observers, Mr. Bernard Rudnick, our CFO, Dr. Charles Grudzinskas, former Board member and industry expert, and Mr. Kal Vepuri, a noted investor and entrepreneur. The Board is also supported by distinguished attorney Winston Lowe who serves as Corporate Counsel. Dr. J. Thomas August, Distinguished Professor at Johns Hopkins University and scientific founder of ITI, Dr. Roscoe Moore Jr., former U.S. Asst. Surgeon General, noted business development executive and intellectual property expert, Dr. Tama Copeman, senior executive Ms. Lisa Salley and distinguished allergist Dr. Larry Weiner are also advisors to the Company.

SIGNIFICANT HISTORICAL DEVELOPMENTS

- 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 awarded **Maryland TEDCO grant to support LAMP** research in collaboration with the August Lab at Johns Hopkins University - December 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
- ITI holds a **successful pre-IND meeting with the FDA** and receives the “green light” to proceed with its planned pre-clinical studies for an IND application for a therapeutic HIV vaccine – April 2008.
- ITI signs collaborative research agreement with **Ichor Medical Systems, who has a premier electroporation vaccine delivery system** - May 2008.
- **Chimeric Vaccine Patent Issues** in Australia - June 2008.
- **ITI holds a Pre-IND Meeting with FDA** on Allergy 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 later this year or early in 2010.
- **ITI establishes mouse model for Red Cedar & validates LAMP-vax vectors for JRC as inducing an allergy neutralizing IgG response.** April 2009.
- **Immunomics submits SBIR for Safe Treatment of Peanut Allergy** to NIH NIAID utilizing LAMP Technology; grant receives support of Dr. H. Sampson at Mt. Sinai Hospital – December 2009.
- **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 enters into manufacturing agreement with the Waisman Institute** (University of Wisconsin) to manufacture cGMP-grade JRC-LAMP-vax (June 2010). Vaccine in manufacturing process (current).
- **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.
- **ITI enters into a CRO Agreement with BioReliance** to conduct pre-clinical analysis of JRC-LAMP-vax including both toxicology and biodistribution studies in rabbits to support IND filing, Dec 2010.



- **cGMP Manufacture of JRC-LAMP-*vax* completed** and is available for use in pre-clinical toxicology and biodistribution studies, January 2011.
- **Chimeric Vaccine Patent Issued in Japan** providing key coverage for LAMP-*vax* formulation to 2022. January 2011
- **Toxicology & Biodistribution Studies** have been initiated at BioReliance. January 2011

FINANCIAL

Immunomic Therapeutics has operated a highly capital efficient business, since its inception relying primarily on revenue from license and collaboration deals to operate the company. As ITI moves towards initiating its clinical trials, it will have increased expenses and cash requirements, although, we believe our plans to partner the Japanese red cedar vaccine will provide revenue in 2009 and 2010.

The company is seeking \$2 million in new investment capital to complete JRC-LAMP-*vax* commercialization, complete its short ragweed vaccine development and launch initiatives in other immunological areas – all enhancing value and return to investors. Approximately \$500,000 in new working capital will be used for business development in promoting and licensing the use of the LAMP-*vax* Technology to major biopharma companies globally.

Summary Financial Results / Projections

	2006-2008 Actual	2009	2010	2011	2012	2013
Revenue	\$550,000	\$30,000	\$0	\$300,000	\$10,000,000	\$35,000,000
Expenses	\$1,291,000	\$385,170	\$1,200,000	\$1,800,000	\$5,000,000	\$10,000,000
Grants	\$115,000	--	\$244,700	\$300,000	\$1,000,000	\$1,000,000
EBITDA	(\$742,000)	(\$355,170)	(\$955,300)	(\$600,000)	\$1,000,000	\$5,000,000



Immunomic Therapeutics, Inc. Business Plan

THE COMPANY

Immunomic Therapeutics, Inc. (ITI), which is privately held, was formed to commercialize LAMP Vaccine Technology. LAMP (Lysosome-Associated Membrane Protein) facilitates the presentation of antigens in nucleic vaccine formulations, resulting in an enhanced and effective immune response in humans. LAMP Technology was invented and patented by Dr. J. Thomas August, M.D., Distinguished Professor at Johns Hopkins University; the LAMP patent estate was exclusively licensed (worldwide, all applications) by ITI from Johns Hopkins University in 2006. LAMP-based vaccines have been developed for a wide array of diseases and have been successfully applied in human clinical trials for prostate cancer and acute myeloid leukemia. This research has been supported by over \$20 million in government research grants and has been the subject of over 70 research papers in the life science literature. Recent publications have shown that LAMP vaccines can provide protection against rabies virus in dogs, against yellow fever in mice and prevent & cure dust mite allergies in mice.

Immunomic Therapeutics has completed multiple transactions including sub-licenses to the Geron Corporation (telomerase in hyper-proliferative disease) and Nature Pharmaceuticals (research sale of vectors containing LAMP) for the commercial development of LAMP-based vaccines and has active collaborations with several laboratories. ITI has an experienced management team in place, expansion resources identified, and strong opportunities for multiple licenses to pharmaceutical and biotechnology companies active in vaccine development.

BUSINESS STRATEGY & MODEL

Immunomic Therapeutics is implementing a multi-faceted business strategy to maximize revenue potential for the LAMP Technology platform. 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 II development and market access of our 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).

The second arm of our business approach 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 disease and bioterrorism threats, veterinary applications and niche market diseases (often classified as Orphan Diseases).

Finally, after we have completed the first and second business initiatives, we intend to develop vaccines for which we have pre-clinical data in the areas of infectious disease and cancer. For this focus, we have the expectation that all work will be done in collaboration with one or more major biopharmaceutical company; we further anticipate that the Company will sell substantially all or most of our business to one of our pharmaceutical partners.

At the present time, we are in negotiation with significant allergy companies in regard to our Japanese Red Cedar program, with the veterinary vaccine arm of a top 5 pharmaceutical company, and with a division of a Fortune 200 company which focuses on vaccine development specifically through government contracts. We have a high degree of confidence in our ability to finalize acceptable partnerships in the allergy and veterinary vaccine spaces.

Our financial constructs for these partnerships vary; we have used a set of assumptions in our model which are derived from historical reference (our Geron agreement) in conjunction with our present negotiations with potential partners. We



assume that initial payments will vary with the size of the market opportunity and the comprehensiveness of our data. Consequently, we have arrived at the following set of assumptions which drive our business model:

	Preclinical excluding toxicity & biodistribution	Preclinical Including toxicity & biodistribution	Phase I Data	Phase IIB Data
Initial Payment	\$500,000*	\$1,000,000	\$2,500,000	\$35,000,000
Phase III Milestone Payments	\$500,000†	\$2,000,000	\$15,000,000	\$275,000,000
Royalty %	1.0%	2.5%	4%	8%

*†Historical precedence with Geron Corporation

CLINICAL STRATEGY & DEVELOPMENT

ITI has developed a DNA-LAMP based vaccine to the major allergens of Japanese Red Cedar CryJ1 (cross reactive with Mountain Cedar, Jun a1), & Cry J2, as a model program to establish in a clinical program immunogenicity, vaccination dose, dosing regimen and anamnestic response characteristics for DNA-LAMP base vaccines. ITI has recently executed a cGMP manufacturing agreement, organized animal safety studies and will file an Investigational new Drug (Biologic) application [IND] by October 2011. The Phase Ia study will assess the safety and immunoglobulin (IgG & IgE) responses to two doses of the DNA vaccine (4-6 immunizations) in 20 -36 adults (18 - 50 years old) with demonstrable allergic rhino conjunctivitis symptoms by their assessing the allergic reactions of immunized patients in an Allergen Challenge Chamber (ACC) pre-and-post vaccination. The Phase Ia study will try and validate the utility of pollen challenges in such chambers as a biomarker for quantifying therapeutic effects.

ITI will recruit Japanese expatriates, who naturally acquired sensitivity to Cry J1/J2 in Japan, where the incidence of allergy to Cry J1/J2 is 50-60%. At the conclusion of the 3-4 month Phase Ia, the patients will be rolled over into a long term follow-up (9-12 months) Phase Ib protocol to assess IgG levels over time, then revaccinated when these levels fall 40-50% from their peak and allergic symptoms to Cry J1/J2 assessed in the ACC chambers. ITI will seeks a Japanese pharmaceutical partner for the subsequent Phase III pivotal studies in Japan and US for FDA licensure of the vaccine for an Orphan Drug indication in adults and children; children will be assessed in a separate subsequent clinical study.

ITI believes that it can demonstrate the clinical utility of DNA-LAMP-allergen vaccines and address FDA's potential regulatory issues using the Cry J1/J2 model. Many of the R & D, manufacturing, preclinical and clinical issues addressed in the Cry J1/J2 model are directly applicable to development of other DNA-LAMP-allergen vaccines. The Development Phase of Cry J1/J2 vaccine as outlined below is now ongoing to generate sufficient research data to support the therapeutic rationale. ITI is now executing Agreements with a contract manufacturing to produce cGMP compliant product and negotiating with several Contract Laboratory Organizations to perform the two animal safety studies requested by FDA/CBER during its prior March 10, 2009 Pre-IND interaction. In the clinical area, ITI has started the development of a focused Phase Ia & Ib clinical protocol with its Medical Director, Dr. Larry Weiner, an immunologist-allergist with a substantial allergy practice. ITI is exploring the use of the Allergen Challenge Chamber, which is acceptable by FDA and EMEA, to generate supporting data to design a Phase III pivotal study protocol: dose, dosing regimen, anamnestic booster immunizations; the FDA/NIH is expected to hold a meeting in mid-2011 to explore the utility of using Allergen Challenge Chambers to conduct Phase III pivotal studies.



ITI is now negotiating with several Contract Laboratory Organizations to finalize the animal safety testing protocols that would supported the clinical studies protocol. ITI anticipates receiving a sufficient quantity of its investigational DNA-LAMP-allergen from its contract manufacturer by mid-June in order to begin dosing animals in July to meet the timetable for the end of year submission of IND. ITI is scheduling the production of the cGMP material from its contract manufacturer to use in clinical studies to be initiated in the 1st Quarter of 2011. ITI anticipates filing an IND application in the fourth quarter of 2011 and commencing a clinical trial shortly thereafter.

Projected Timeline to Complete Phase I/II

TASK	2010				2011				2012			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Pre-Clinical Validation	█											
cGMP Mfg		█										
Biodistribution					█							
Toxicology					█							
Milestone: IND Filed							◆					
Phase I Study							█					
Phase II Study										█		

PRODUCT RATIONALE

ITI has chosen to use the CryJ2 , a polygalacturonase molecule, [*Cryptomeria japonica*], which has a sequence identity with Cha o 2 from Japanese Red Cedar trees and is considered to be the major allergen for its initial safety evaluation. ITI recognizes that the United States market for Japanese red cedar vaccine is quite limited and it is likely to be viewed by FDA as an orphan disease [$<200,000$ patients per year]. For the purpose of clinical trials, however, the Company plans to access native Japanese and Japanese expatriates who were sensitized during their prior life in Japan. In addition, the CryJ2 confers cross-allergenicity among Taxodiaceae and Cupressaceae, as well a 40% identity with the polygalacturonase from tomatoes, which may provide ITI with additional clinical intended uses to extend the US market for a FDA licensed CryJ2 or a Cry J1/J2 vaccine. Following Phase I safety studies, Cry J1 allergen, a pectate lyase with cross reactivity to Mountain Cedar allergen Jun a1, will be incorporated into the vaccine formulation in a 1:1 ratio with Cry J2, creating the complete JRC-LAMP-vax formulation. ITI believes that after completion of Phase Ia & Ib, it will be able to license the Cry J1/J2 DNA-LAMP vaccine to a Japanese partner, who will fund further clinical development. ITI intends to retain the intellectual property rights to pursue FDA licensure in the US for the Cry J1/J2 vaccine, using both clinical data from a US site and from Japanese clinical Phase III data; ITI has the CryJ1 DNA-LAMP construct available to include in any licensing deal.

ITI is interested, based on the demonstration of the DNA-LAMP-Cry J1/J2 vaccine response, to develop a multivalent DNA-LAMP vaccine that uses 4-5 plasmid vectors in one product, each containing 1-2 allergens, in partnership with a partner. This product rationale is possible because FDA has allowed the use of 4-5 plasmids, containing different antigens, to be testing as a single product, substantially reducing preclinical and clinical testing costs, initiating plasmid development by 1st quarter of 2011 and entering Phase Ia & Ib clinicals within 9-12 months. ITI would develop separate adult and pediatric multivalent conifer vaccine products.

LOCATION AND ORGANIZATION

Immunomic Therapeutics maintains its corporate offices in Lancaster, PA and primary laboratories at 9620 Medical Center Drive in Rockville, MD. The Company also is opening a new laboratory in partnership with Franklin & Marshall College in Lancaster, PA.

ITI's management is led by Dr. William Hearl, an experienced biotech CEO and entrepreneur. Dr. Bruce F. Mackler (Ph.D. J.D.), who was a Professor of Immunology with over 100 publications and then an attorney representing biotech and drug companies before FDA for 27 years, is the Vice President of Regulatory Affairs and Development and is



directing the Company's strategy and interactions with the FDA. ITI has already had its first successful pre-IND meeting for a DNA vaccine and intends to file for the pre-IND meeting for allergy later this year. Dr. Teri Jones Heiland leads the Company's research program as its VP of R&D; in addition to her extensive professional experience at the NIH and within the industry, Dr. Heiland is a visiting scientist at Johns Hopkins University. Mr. Barry McDonald, a member of the Board of Directors, heads the Company's business development activities drawing on over 30 years of industry experience. In addition, Ms. Lisa Salley and Dr. Tama Copeman provide organizational and business leadership as strategic advisors to ITI.

INTELLECTUAL PROPERTY

ITI has exclusively licensed the LAMP technology from Johns Hopkins University and has subsequently developed a strong technology base and is developing a broad patent portfolio, which covers the allergy area. In preparing specific DNA vaccines, ITI would either use allergy nucleotide sequences in the public domain or license the use of proprietary allergens. Additionally, ITI has sublicensed the LAMP technology to Geron for use in two telomerase anti-cancer DNA based vaccines; the first such vaccine has shown good safety and efficacy in AML cancer patients.

TECHNOLOGY

INTRODUCTION

Lysosomal Associated Membrane Protein or "LAMP" is a protein that localizes in antigen presenting cells (APC) to the same compartment as the Major Histocompatibility Complex Type II (MHC-II). Work in the laboratory of Dr. J. Thomas August at Johns Hopkins University showed that when LAMP is combined with the sequence of a target antigen, the LAMP intracellular targeting sequence directs the antigen to the lysosome (MHC-II) antigen processing pathway resulting in a significantly enhanced immune response, particularly an IgG antibody response. ITI's LAMP-*vax* vaccine formulations utilize this intra-cellular trafficking function to access the MHC-II pathway and in the case of allergy vaccines, convert the immune system response from a Th2/ IgE allergen response to a Th1/ IgG antigen response with the concomitant elimination of allergy symptoms. This supports one of the mechanisms of action attributed to efficacious allergy vaccination, namely a re-orientation in TH1 and TH2 cell activity, possibly through induction of T-regulatory cells. (See Figure 3, page 17 below for diagram of immune system pathway). Thus, the ITI approach allergy vaccines involves attacking the problem using a traditional method – converting the immune response from an **IgE** mediated response to allergen to an **IgG** mediated response. LAMP-*vax* allergy vaccines introduce the allergen (antigen) to the immune system exclusively through the MHC-II / Th1 pathway which favors the generation of an IgG response and is accomplished without exposing the patient to free allergen as is required in conventional immunotherapy.

Allergy is a hypersensitivity disease characterized by the production of **IgE antibodies** against antigens (i.e., allergens) affecting more than 25% of the population. Allergens can enter the body through the respiratory tract, skin contact, ingestion, insect bite or injection of a drug. Thus, allergic patients can exhibit a variety of allergic manifestations including rhino-conjunctivitis, asthma, food allergy, skin reactions, and severe systemic reactions such as anaphylactic shock when they encounter the allergens against which they are sensitized. In contrast to non-allergic individuals who respond to allergens with production of IgG antibodies and a balanced T cell response, allergic patients produce allergen-specific IgE antibodies and show a preferential allergen-specific Th2 response. The class switch to IgE antibody production occurring during primary sensitization in allergic patients is driven by IL-4, which is a product of Th2 cells and other effector cells of the allergic immune response.

Treatment of allergy most often falls into two categories: avoidance and dosing with anti-histamines. A third alternative, **allergy immunotherapy** requires the patient to receive weekly injections small amounts of the offending allergens in order to help the immune system reeducate its response to the allergen. Most currently available approaches for allergy immunotherapy continue to elicit a predominately TH2-inducing T-cell response, producing IgE antibodies. This



mechanism requires a lengthy and frequent treatment regimen, oftentimes lasting several years and necessitating 100 or more shots. Consequently, patient compliance is a significant issue. Results from current immunotherapy vary widely and this course of treatment is not an option for those suffering from highly reactive allergies (e.g., peanut, penicillin).

There is increasing recognition of the potential benefit of genetic immunization as a method for both prophylactic and therapeutic treatment of the broad spectrum of protein allergens. The underlying rationale is that allergen protein encoded as a DNA vaccine will preferentially activate allergen-specific T-helper type 1 (Th1) responses with the production of interferons by antigen presenting cells (APC), natural killer cells (NK), and T cells, rather than the characteristic Th2-type responses, such as secretion of interleukin (IL) -4, -5, and -13, and the formation of immunoglobulin E (IgE) by B lymphocytes and the maturation and recruitment of eosinophils in late-phase reactions. It is believed that (a) the cellular trafficking properties of the allergen protein in transfected cells is one of the major determinants of the immune system response to the allergen, and that (b) a design of the allergen-encoded DNA vaccine that will facilitate trafficking into the MHC II processing and presentation pathway of APCs is critical for optimal and precise expression of Th1 immune responses.

There is no current consensus regarding the mechanism of successful allergy vaccination apart from the view that there is a modulation of the activity of T helper cells. One possibility is that there is a switch, changing cytokine profiles of allergen-specific T cells from a more TH2 like to a more TH1 like profile leading to down-regulation of the late-phase reaction, associated inflammation and reduction in IgE antibodies. Thus, switching to a TH1 response should increase the level of immune IgG, which bind circulating allergens, which is the main therapeutic paradigm for desensitization by allergists.

A further advantage of the LAMP-vax DNA vaccine approach using is the ability to develop formulations that target more than one allergen. The FDA has stated that formulations of up to six different plasmids are acceptable and we also have shown that we can successfully create plasmids that express up to four different antigens. This could be very valuable in meeting the needs of patients with multiple allergy indications.

Potential indications for LAMP^{vax} allergy vaccine immunotherapy include:

- Patients diagnosed with allergic rhinitis (hay fever), allergic conjunctivitis, urticaria, atopic dermatitis, or allergic bronchial asthma, particularly severe patients who have not responded to conventional desensitization protocols.
- Patients with severe symptoms, who have not responded to other forms of treatment – drugs and allergen avoidance methods
- Patients showing slow or no response to conventional immunotherapy
- Adults and children above age 6 years
- Patients with single or multiple allergen sensitivities.

DNA VACCINES: ADVANTAGES AND LIMITATIONS

An alternative to conventional vaccines is DNA vaccines, an expanding area of vaccine development with a growing portfolio of candidates entering clinical trials. With DNA vaccines the individual is not injected with the viral antigen, but with DNA sequence encoding the antigen. DNA vaccines are injected into patients either as “naked” DNA or DNA carried by a non-pathogenic virus vector. In either case, the DNA gains access to cells where the antigen protein is synthesized by normal cell mechanisms and presented to the immune system to stimulate the immune response to it. Because DNA can be synthesized to encode many different elements, there are many alternative ways to build a DNA vaccine.

As illustrated in the diagram below, nucleic acid is delivered to the cells either as DNA, RNA or as part of a specially modified virus that acts only as a carrier of the target DNA. It does not cause an infection because the DNA is selectively made to encode only the antigen(s) of the pathogen which evoke protective immune responses.

Once the nucleic acid is inside the cell, it uses the cell’s own biochemistry to make the antigenic protein(s) coded in the vaccine nucleic acid (the “red diamonds” inside the cell in step 2). The cell, then processes this antigenic protein, as it does all proteins, by digesting it into small pieces. A certain number of these pieces attach to specialized MHC proteins, and

move to the outside of the cell. (In the diagram, the grossly exaggerated piece of the protein is represented in orange.) The protein is now free to interact with the outside world, and in particular the immune system.

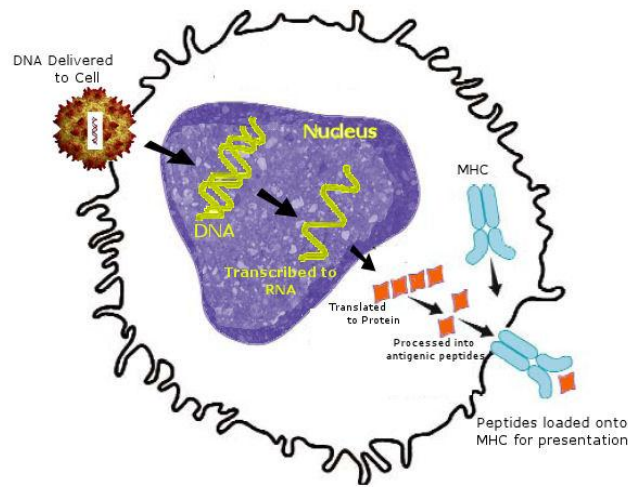


Figure 1: DNA Vaccines

Depending on the type of cell that received the DNA, the antigenic protein will follow either MHC I or MHC II presentation. Class I MHCs are found in all cells; the MHC-IIs are only found in specialized “antigen presenting cells” (APCs) such as dendritic cells (“DCs”).

DNA vaccines have several distinct advantages: ease of manipulation, use of a genetic technology, simplicity of manufacture, and chemical and biological stability. However, the majority of work to date has been performed using laboratory animals, through which these vaccines have been able to protect against tuberculosis, SARS, smallpox, and other intracellular pathogens. Further, the recent approval of Vical’s melanoma vaccine for dogs validates the commercialization of DNA vaccines for use in large mammals as well as their recent report on the immunization of humans against influenza antigens.

ITI’S LAMP TECHNOLOGY

LAMP Technology distinguishes itself from other vaccine approaches by specifically delivering antigen directly to the MHC-II compartment in professional antigen presenting cells. This is in contrast to non-LAMP DNA vaccines that process antigen in somatic cells (e.g. muscle cells) and presenting through the generic MHC-I pathway. In this manner, ITI’s LAMP vaccines directly access the immune system via helper T-cells while maintaining its ability to stimulate cellular immunity. This process has been shown in both animal model and human clinical subjects.

As previously noted, LAMP is a protein that localizes in antigen presenting cells (APC) to the same compartment as the Major Histocompatibility Complex Type II (MHC-II) and it has been proven that fusion proteins containing the LAMP targeting sequence will localize in the MHC-II+ lysosome in APC’s. This observation has important implications to the processing of antigens when used in DNA or RNA vaccinations. Shown in the left panel below is the process an APC follows when it encounters a foreign protein as it is delivered in a traditional vaccine. The protein is brought into the cell and processed in the endosome and then delivered to the MHC-II containing lysosome where the peptides bind the MHC-II molecule and are escorted to the surface of the cell for presentation to the immune system. This process activates the CD4+ Helper T-cell pathway leading to cytokine & antibody production as well as immunological memory.

In the center panel, the pathway of a DNA vaccine is shown. Once the DNA enters the cell (most often a muscle cell lacking MHC-II lysosomes), the protein is expressed in the cytoplasm and is directed to the proteasome where it is digested into peptides. These peptides find their way into the ER & Golgi where they bind the MHC-I protein for

presentation on the surface of the cell. This process activates CD8+ cells and the cytotoxic T-cell pathway. The CD4+ cells are not directly activated through this pathway and in muscle cells. When LAMP is included in the DNA vaccine construct, the resulting chimeric protein moves to the Golgi upon synthesis and the intracellular targeting sequence directs the antigenic protein to the MHC-II compartment in the cell. This results in a DNA vaccine directly activating the CD4+ pathway while maintaining the CD8+ cytotoxic T-cell response. LAMP nucleic acid vaccines induce both humoral and cellular immune responses; this response has been observed in mice, rats, monkeys and humans.

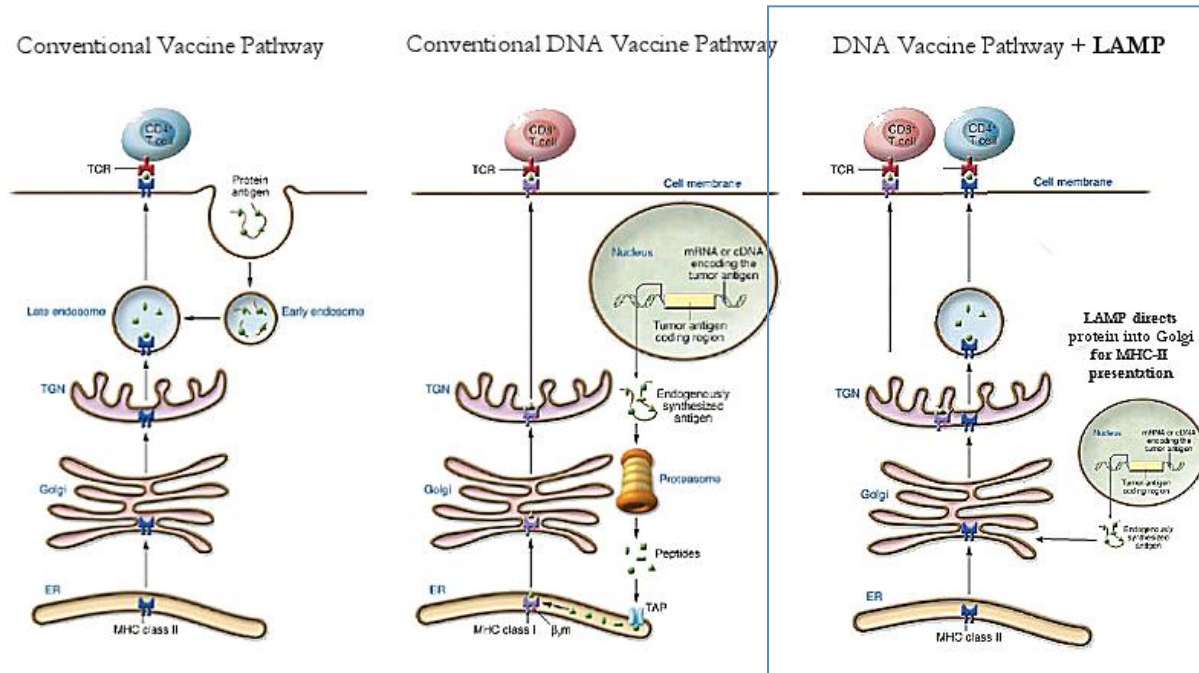


Figure 2. Presentation of Antigens on the surface of Cells

LAMP-vax DNA Vaccines As Immunotherapy For Allergy

The underlying rationale is that allergen proteins encoded in a LAMP-vax DNA vaccine will preferentially activate allergen-specific T-helper type 1 (Th1) cellular responses with the production of interferons by antigen presenting cells (APC), natural killer cells (NK), and T cells, rather than the characteristic Th2-type responses, such as secretion of interleukin (IL) -4, -5, and -13, and the formation of immunoglobulin E (IgE) by B lymphocytes and the maturation and recruitment of eosinophils in late-phase reactions. It has been demonstrated that LAMP-encoded allergen- DNA vaccine that will facilitate trafficking into the MHC II processing and presentation pathway of APCs is critical for optimal and precise expression of Th1 immune responses.

In the case of allergy, treatment with LAMP-vax vaccines convert the immune system response from an IgE allergen response to an IgG antigen response with the concomitant elimination of allergy symptoms. This conversion of the patient antibody responses from IgE to IgG is the principle therapeutic paradigm that allergist try to achieve with either sublingual exposure or intradermal injections of allergens during desensitization therapy; thus, we are not changing the current allergy therapeutic paradigm.

As shown in the figure below, the ITI approach to allergy immunotherapy involves attacking the problem using a traditional method – converting the immune response from an **IgE** mediated response to allergen to an **IgG** mediated response. LAMP-vax Allergy vaccines introduce the allergen (antigen) to the immune system through the MHC-II / Th1 pathway which favors the generation of an IgG response (see diagram below).

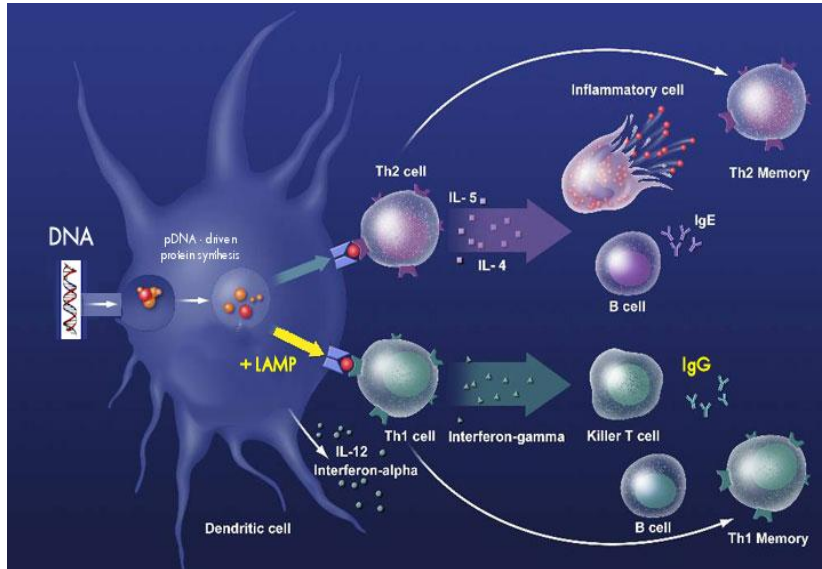


Figure 3. The Allergy Cascade and LAMP DNA Vaccination. DNA vaccines which utilize LAMP intracellular targeting result in immune system presentation that favors Th1 / IgG and Interferon- γ as opposed to Th2 / IgE & IL-4. (figure based on graphic from dynavax.com).

COMPETITIVE ADVANTAGES

A KEY SAFETY ADVANTAGE – NO FREE ALLERGEN IS PRESENT IN THE THERAPY

The structure of the LAMP-allergen chimera offers a unique safety feature that is not present in any other allergy vaccine formulation: the allergen is isolated in a specific cellular compartment (i.e., the lysosome) and is “encased” in LAMP. The diagram to the right shows the lysosome in a cell expressing allergen. The allergen is anchored in the lysosome with the tail of LAMP and then is linked to the remaining sequence of LAMP. Work with dust mite allergen showed that the LAMP sequence eliminates circulating free allergen; thus, allows patient exposure to allergens without the fear of atopic reactions during sensitization therapy with DNA-based vaccines.

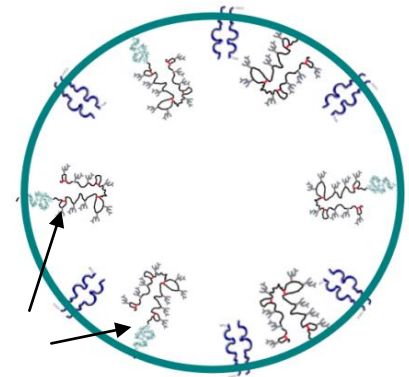


Figure 4. The LAMP Fusion Protein (*arrows*) is membrane-bound.

“PLUG & PLAY” VACCINE DESIGN FOR RAPID PRODUCT LINE DEVELOPMENT

The design of the LAMP-*vax* allergy vaccines utilizes a standard plasmid backbone that includes the LAMP elements. The target allergen is inserted into this plasmid easily at a multi-cloning site and then validated for proper expression characteristics. This process routinely requires about 30 days in design and development and an additional 30 days for validation of the construct. Thus, any given target can be developed into a working vaccine candidate (or component of a multi-vector formulation) within a business quarter and with limited expense. This versatility will enable ITI to not only expand its product line to address all the key allergic targets quickly, it will also make it possible to respond to emerging market demands in an extremely timely manner. It is important to note that the FDA has stated that it accepts safety data on DNA vaccines from earlier clinical studies as well as multi-vector formulations as a single vaccine entity.

PROVEN PERFORMANCE & SAFETY IN THE CLINIC

The LAMP-*vax* platform has been incorporated into clinical studies: patients at high risk with AML were given the cancer immunotherapy vaccine, GRNVAC1 in a Phase II study sponsored by our licensee, the Geron Corporation. In this study,



15 of 21 patients have been in extended complete remission for up to 30 months (as of May 2010). These patients have shown that not only is the LAMP formulation is safe with some patients receiving up to 30 injections of therapy, but also that LAMP-mediated education of the immune system does occur and does so primarily through helper T-cells. This study supports the earlier Phase I study in prostate cancer patients which also revealed a strong interferon-gamma response and a boost-able memory capability.

MULTIPLEXING ALLERGENS & MULTIPLE DELIVERY OPTIONS ADDRESS MARKET CONCERNS

LAMP-*vax* allergy vaccines can be configured to address important market concerns for allergy immunotherapy. One key issue is the ability to include more than one target allergen in a given formulation. We currently know that the FDA is accepting of a vaccine formulation that includes 6 different plasmids configured as a blend. Using this configuration, it is possible to deliver 6 – 12 different allergens in a single treatment. This has strong advantages over the approach using sublingual drops which deliver only 1 antigen at a time. Further, although the current proposed study will initially use an intramuscular injection for our safety studies, we believe the vaccine is well suited for intranasal delivery making home therapy possible (as with sublingual drops).

LAMP-VAX ALLERGY VACCINES IN DEVELOPMENT

JRC LAMP-*vax* is the Company's first allergy vaccine targeting Japanese red cedar which is a highly problematic allergenic pollen in Japan with over 25 million affected. This vaccine has been designed and validated. Animal studies to show immuno-reactivity are currently underway. ITI is seeking a **corporate** partner to develop this vaccine in Japan under favorable terms. In Texas, antigens of Japanese red cedar (Cry J1 / J2) induce occupational allergic asthma in saw mill employees providing a orphan drug populations of patients available for immediate clinical study of allergens that are directly relevant to the patients in Japan. ITI is now preparing to submit a pre-IND meeting request for occupational allergic asthma to conduct a Phase I safety study in workers in Texas saw mills processing cedar trees and to file an Orphan Drug Designation, both of which could be transferred to potential Japanese partner. The cedar allergen found in the saw mills shares allergic epitopes with Japanese red cedar, the target of our vaccine formulation.

Multivalent LAMP-*vax* is the Company's allergy vaccine targeting conifer/ tree pollens & short ragweed / weed pollens for development as multivalent formulations and is intended for the North American and European markets. These vaccines will be used as a model for the FDA and is intended to develop a second generation of formulations of a single vaccine targeted against grasses, weeds and trees. Such a vaccine (containing multiple plasmids with different allergens) will ultimately address all of the major outdoor allergies in a single therapy regimen.

MARKET OPPORTUNITY

ITI believes its technology can be a market driver in that a single DNA LAMP-based vaccine can incorporate multiple allergen targets given the FDA's acceptance that DNA vaccines can be composed of up to six plasmids in a single product. This broadens the commercial potential for the technology and the product family. The Company sees the LAMP technology as complementary to ongoing vaccine commercial initiatives.

As evidenced by Pfizer's purchase of PowderMed in 2006, pharmaceutical companies are making a stronger push into field of vaccine development. A confluence of events, including the concern about pandemic flu, the threat of bioterrorism, and worries about seasonal flu, have created an opportunity for those companies that can access new technology to rapidly produce vaccines in large quantities. Partly as a result of the improved understanding of immune-system function, the field is undergoing a renaissance, whereby the development of the prophylactic vaccine is giving way to vaccines that can treat previously untreatable infectious diseases, cancer, allergy, influenza and the like. Internationally, strategic players and financial backers are following this trend. In 2006, Danish allergy vaccine company ALK-Abello introduced a tablet vaccine



in Germany for grass pollen allergy. Other Danish companies are focusing on vaccines against smallpox, HIV, breast, prostate and other cancers, and TB.¹

At the same time, investors are betting that biotech startups will foster the next great advances in the field. For example, Kleiner Perkins Caufield & Byers' new pandemic and biodefense fund invested \$6 million in Juvaris BioTherapeutics, targeted to the company's influenza vaccine development. Clarus Ventures led a \$35.7M first round investment in seasonal and pandemic influenza vaccine developer Variation Biotechnologies of Ottawa, Canada. New Leaf Venture Partners led a \$40M third-round financing for Cranbury, New Jersey vaccine manufacturer Vaxinnate.²

Vaccines represent an estimated \$15 billion annual revenues in 2007 (Company reports) and include candidates for infectious diseases, such as measles, mumps, rubella, diphtheria, pertussis, varicella, Haemophilus influenza type b, polio, hepatitis A and B, meningitis and relatively new to the pediatric market, rotavirus and pneumococcal disease. New global health threats such as the bird flu and pandemic flu plus concerns over bioterrorism agents (e.g., anthrax), have brought increased energies, funds, and new players into the vaccine marketplace.

Currently marketed products are prophylactic vaccines designed with antigen-bearing constructs for stimulating the body's immune system to mount a response to a specific antigen. In recent years, new techniques have enabled the industry to create recombinant proteins as specific antigens or couple traditional antigens with novel immuno-stimulants (adjuvants).

ALLERGY VACCINE MARKET AND COMPETITION

Over 150 million individuals are affected by allergic rhinitis in the U.S. and Europe, driving a large pharmaceutical market for anti-histamines and related drugs. However, there is an emerging demand and opportunity to provide a more long term solution to allergy through treatment with vaccines. Approaches to create tolerance (desensitization) to an allergen have traditionally required a lengthy course of therapy, requiring multiple and weekly or bi-weekly shots over a period of one or two years. Successful results are not guaranteed.

World-wide market leader for immunotherapy (desensitizing allergy shots) is Denmark-based AKL-Abello with 2007 revenues of \$320 million. The company's history dates back to 1923 when the first allergen extracts were produced in a pharmacy at the Copenhagen University Hospital. In the early 1990's, AKL-Abello was the first company to launch a sublingual immunotherapy [under-the-tongue drops] in a single dose container. By the end of 2007, the company had over 40 different allergen types and mixes including different strains of pollen and dust mites. This administration allows patients to treat themselves to avoid doctor visits. The company made history in 2006 when it launched the first registered (in ECM) allergy tablet to address grass pollen allergy (GRAZAX™). The GRAZAX tablet is a fast dissolving, once a day immunotherapy for home treatment. The company has an extensive pipeline with products in tablet form for asthma, grass pollen, ragweed hayfever, tree pollen (birch), and dust mites in various phases of clinical trials in the US for both children and adults; and it continues to develop products for subcutaneous administration. The company prides itself as the technical leader in the immunotherapy field with basic research and scientific publications a significant corporate effort. AKL-Abello is publicly traded in Denmark and is profitable (pre-tax EBT \$50 million) (company reports).

Stallergenes was created within the Institute Merieux in 1962, subsequently merged with the allergy division of the Institute Pasteur. Today, it is public and listed on the Eurolist, with annual revenues for 2007 were \$231 million. Although it sells globally, about 50% of its business is in France with most of its remaining business in the ECM. Close behind AKL-Abello in product innovation, Stallergenes launched sublingual allergen administration in 1994 and has a number of clinical studies ongoing for allergy immunotherapy in tablet form for grasses, dust mites and birch pollen (company reports).

Trailing these two market leaders is Allergy Therapeutics (UK), a public UK-based company that had 2007 product revenues of about \$50 million. The company originates from the CL Bencard Foundation, a specialty allergy company, bought by the Beecham Group in 1949. With vaccines for grass pollen and ragweed allergies marketed for the UK and Canadian markets in 1972 and 1975 respectively, the company launched a sublingual allergy desensitizing vaccine in 1994. In 1998, Allergy Therapeutics was created via a management buyout from SmithKline Beecham. In mid-2007, the company's Phase III study for grass was placed on clinical hold by the FDA due to a rare adverse event. This clinical hold

¹ Breakthrough for Danish vaccine companies, Copenhagen Capacity, June 12, 2006

² Brian Gormley, Vaccine market draws venture capital interest, International Herald Tribune, January 17, 2007



has compromised the company's progress for a ragweed allergy product for the US market as well. Allergy Therapeutics is developing a vaccine for Japanese Cedar, the product is in pre-clinical phase. (company reports)

Curologic is a Phase II development company based in Denmark which in-licenses projects for further advancement. In early 2008, the company announced that it will cease its development of oral immunotherapy projects internally. In late December 2007, the company had announced the results of its Phase III ragweed allergy study which showed that the dose tested was not efficacious. And after a thorough assessment of those data and the results of other studies in grass and house dust mite allergies which utilized the same technological approach, the company decided to stop developing the product line. The company's future plans are unclear.

Cytos, based in Switzerland, is commercializing the Immunodrug™ therapeutic vaccine platform, technology based on synthetic immunostimulatory DNA sequences targeting dendritic cells. The company has two allergy products in Phase II studies, vaccines house dust mite and cat allergy. The Immunodrug™ technical approach is not dissimilar from ITT's as the Immunodrug is designed to shift the immune system to produce a non-allergic immune response to an allergen. The company's other immunotherapies include treatment for malignant melanoma, nicotine addiction (now partnered with Novartis), and hypertension. Cytos is publicly traded and has no product revenues.

Cytos Biotechnology's CYT003-QbG10 is an immunotherapeutic product candidate currently in development for the treatment of allergic diseases. This allergy product has previously shown strong efficacy in conjunction with a specific allergen in patients with house dust mite allergy. The vaccine uses an empty virus filled with DNA and attached to a protein from the dust mite excrement in order to trigger a response from the immune system. This boosts the activity of the immune system which tries to suppress that allergic reaction.

Recent trials have suggested that CYT003-QbG10 might work as a general allergy therapy. The therapy works by distracting the overactive immune system which is thought to be the cause of most allergic reactions. Patients receive a molecular "decoy" which makes their body behave as if it is under attack by a bacterium. Distracted, it stops reacting to otherwise harmless allergens. The company recently announced that 80 volunteers with either house dust mite or cat dander allergy who received a six-shot course of CYT003-QbG10 had experienced a 61 per cent reduction in symptoms, twice that seen in volunteers who received a placebo. Cytos will now start a trial of the mono-therapy in 300 people with dust-mite allergy later this year and another trial in people with hay fever next year. Still, larger studies are needed to determine the long-term effectiveness and safety of the series of shots.

Dynavax Technologies Corporation is a biopharmaceutical company that discovers, develops and focuses on commercializing Toll-like Receptor 9 (TLR9) agonist-based products to treat and prevent infectious diseases, allergies, cancer and chronic inflammatory diseases using approaches that alter immune system responses. Dynavax's TLR9 agonists are based on immuno-stimulatory sequences (ISS), which are short deoxyribonucleic acid (DNA) sequences that enhance the ability of the immune system to fight disease and control chronic inflammation. The Company's product candidates include TOLAMBA, a ragweed allergy therapy and HEPLISAV, a hepatitis B vaccine. Dynavax is also engaged in programs to develop an influenza vaccine.

Recently, TOLAMBA was shown to fail in clinical trials and will no longer be funded. Consistent with the results of earlier trials, TOLAMBA showed a trend toward a reduction of the symptoms of ragweed allergic individuals relative to placebo, although statistical significance was not achieved. The current trial displayed an unexpectedly high degree of variability in the data set possibly due to the subjective nature of symptom scoring used to assess efficacy. A similar effect was observed in previous TOLAMBA clinical trials. It was concluded that this problem may be difficult to overcome in future clinical studies. It is still uncertain as to whether Dynavax will continue with the development of their peanut and cat allergy therapies.

Dynavax's TOLAMBA anti-allergy vaccine is based on immuno-stimulatory DNA sequences linked to the major allergen of ragweed. In this technical approach, the vaccine attempts to inhibit and suppress the immune response responsibility for the inflammation associated with an allergic response. This product failed to achieve its primary clinical endpoint in a 2006 Phase II study; today this product is partnered with Deerfield Management in a second ragweed Phase II study. Data from this current study is expected in mid-2008. This vaccine is positioned to be administered in conjunction with conventional allergy shots or using prescription or OTC medications. The company has peanut and cat allergy vaccine in pre-clinical

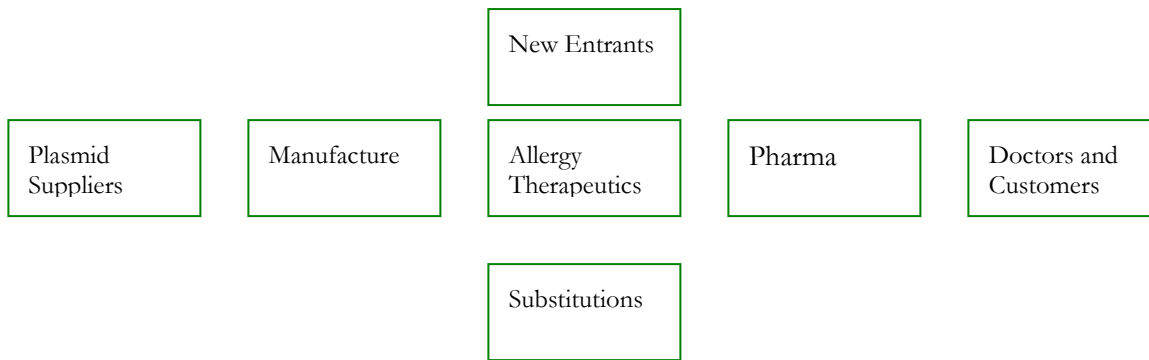


development. The company is publicly traded (Nasdaq:DVAX) and has development partnerships with Merck and AstraZenca and has no product sales.

COMPETITIVE LANDSCAPE ANALYSIS

ITI is positioned strongly in the emerging allergy therapeutics market. The established players in this market have a low-efficacy value proposition. ITI has a differentiated value proposition through the LAMP DNA vaccine technology and a several year lead in commercialization. LAMP is a platform technology with potentially very broad application throughout the allergy, infectious disease and other market segments. ITI’s intellectual property strategy integrates the platform nature of the LAMP technology with the Allergy Therapeutics and other market segments. The competitive landscape is constantly changing and this assessment is expected to change over time.

The competitive landscape from an Allergy Therapeutics perspective can arise from the supply and customer sides, potential new entrants and substitute products, in addition to competition directly within the space. An assessment of the value chain, potential new entrants and substitutions to the DNA vaccine approach is summarized below. The value chain is defined as Plasmid Suppliers, Manufacturers, Allergy Therapeutics, Pharma, Doctors, and End-Use Customers.



An assessment in each of these categories relative to ITI is summarized below. (+) Indicates a perceived positive for ITI. (-) Indicates a perceived negative for ITI. Key companies are also listed.

Suppliers – Plasmids

- (+) Supplier based business model prohibits entry into therapeutics, allows attractive in-licensing
- (+) ITI has in-house expertise in the form of trade secrets for plasmid construction
- (+) ITI can continuously monitor R&D in the plasmid space and adopt FDA approved plasmids
- (+) Plasmid suppliers often lack expertise and facilities to scale up manufacturing
- (+/-) Most DNA vaccine companies use in-house expertise

<u>Company</u>	<u>Technology</u>	<u>Business Focus</u>
Immunomix	LAMP	Allergy, license to other verticals
Nature Tech	LAMP-plasmid	Plasmid supplier
Gene Art	Plasmids	Plasmid R&D potential

Suppliers – Manufacturing

- (+) Lack scientific expertise, resources to enter therapeutic market
- (+) Manufacturers may be willing to subsidize manufacturing in exchange for down-stream product royalties
- (-) Control the manufacturing process for ITI’s therapeutics, including:
 - Bringing manufacturing to scale in a timely fashion
 - FDA compliance / potential for contaminants



- Can pass through higher material costs
- Could have joint rights to new inventions related to manufacturing ITI's therapies

<u>Company</u>	<u>Business Focus</u>
Cobra (now Reciphram Biologics)	Manufacturing, DNA/plasmid capabilities
Nature Tech (see above)	DNA Plasmids, cGLP manufacturing
Aldevron	Manufacturing, DNA/plasmid capabilities
VGX	Therapeutics/Manufacturing, DNA/plasmid capabilities
Althea	Manufacturing, DNA/plasmid capabilities
Waisman	Manufacturing, DNA/plasmid capabilities

Allergy Therapeutics

- (+) Established players have low-efficacy value proposition
- (-) Easy delivery methods
- (-) Well understood by doctors and patients; incumbent advantage
- (-) Offers a diverse offering for numerous allergy conditions
- (+) ITI offers a differentiated product

<u>Company</u>	<u>Technology</u>	<u>Business Focus</u>
Immunomics	LAMP	Allergy, license to other verticals
AKL Abello	Allergen extracts	Allergy. Over \$ 320 MM revenue
Allergy Therapeutics	Allergen extracts	Allergy. Over \$ 50 MM revenue
Stallergenes	Allergen extracts	Allergy. France and Euro focus.
Greer	Allergen extracts	Allergy. US focus.
Circassia	T-cell epitopes	Allergy
Biomay	Allergen extracts & therapeutics	Allergy. Euro focus.

Threat of New Entrants (from potential competitors like Vical, VGX and Phadia)

- (-) Could fund entry through current revenue.
- (-) Well capitalized with established core competencies and IP
- (-) Low barrier to minor improvements with slightly higher efficacy
- (+) High barrier to entry into LAMP based DNA vaccine

<u>Company</u>	<u>Technology</u>	<u>Business Focus</u>
Weiner/VGX	IL-15	HIV
Dynavax	Immunostimulatory DNA	Ragweed. First phase II failed.
ImVision	Peptide therapy	Allergy
VaxOnco (Pharmexa)	Peptide Therapy	Cancer, infectious diseases
Phadia		Diagnostics. Deciding strategy
Cytos	Immunostimulatory DNA	Nicotine, hypertension, melanoma, allergy
Vical	plasmids and lipids	Influenza, cancer, HIV, CMV, SARS

Threat of Substitutions

- (+) Technological approaches currently not very effective
- (+/-) All new technologies must be approved by FDA, including ITI
includes: MAT technology, protein therapies (oral, sublingual, injection), DNA vaccines, herbal supplements, adjuvants.

<u>Company</u>	<u>Technology</u>	<u>Business Focus</u>
----------------	-------------------	-----------------------



Dynavax	Immunostimulatory DNA	Ragweed. First phase II failed.
ImVision	Peptide therapy	Allergy
VaxOnco (Pharmexa)	Peptide therapy	Cancer, infectious diseases
Geron	Telomerase	Cancer
Herbal	boost immune system	minor infections

Customers – Pharma

- (-) Pharma has value chain strength through capital.
- (+) Pharma has a large number of patents expiring and they are actively seeking technology
- (+/-) Pharma prefers technologies with continual revenue streams in large markets. Allergy is an established large market.

<u>Company</u>	<u>Markets</u>	<u>Allergy Products</u>
Sanofi-Aventis	Fully integrated, Vaccines	
Merck	Fully integrated, Vaccines	
Pfizer	Fully integrated	
Roche	Fully integrated	
Novartis	Fully integrated	

Allergy Doctors/ GPs

- (+) Prescribe based off on efficacy, safety, and administration of therapy
- (+/-) Prescribe also based on of reimbursement from insurance companies.

End Customer

- (+) Will ask for most effective therapy
- (+) Price insensitive at higher rates of efficacy
- (-) Concern about the image of “DNA”

MANAGEMENT & ADVISORS

The Company’s entrepreneurial drive and energy is derived from the dynamic leadership of its Chief Executive, Dr. William Hearl, an executive with over 20 years of experience in biotechnology and an active supporter of Maryland start-up companies. The organization is supported by co-founder and Johns Hopkins Distinguished Professor, Dr. J. Thomas August, inventor of the LAMP technology.

LEADERSHIP

- Dr. William G. Hearl, Founder & Chief Executive Officer, Board of Directors
- Dr. Bruce F. Mackler, Vice President for Regulatory Affairs
- Mr. Bernard C. Rudnick, Chief Financial Officer
- Dr. Teri Jones Heiland, Vice President, Research & Development
- Dr. Lisa Salley, Operations

William Hearl, Ph.D.

Dr. Bill Hearl, the founder of ITI, is an experienced and successful scientific businessman and entrepreneur. He worked closely with Dr. Tom August, Capital Genomix and Johns Hopkins University to capture the LAMP technology for ITI and start operations in 2006. His extensive experience in intellectual property management and business development led to the speedy sub-license of the LAMP technology to Geron within 30 days of initiating operations.



Dr. Hearl is also the founder of Capital Genomix (CGI), a Maryland-based biomarker and drug discovery company and served as its first CEO from inception in 2000 until late 2002 when he assumed the role of Chief Scientific Officer. Dr. Hearl raised seed and Series A & B funding for CGI (~\$5 million in cash/debt) and acquired the Dynex Technologies division of Thermo in a leveraged acquisition deal. (Dynex was subsequently divested yielding a 10-fold return to the Company). He is also responsible for the acquisition and development of the core technologies of Capital Genomix: GeneSystem320 was licensed exclusively from MD Anderson Cancer Center and the ImmunoMouse was invented by Dr. Hearl.

He also has an established record of scientific productivity over his 20 years of work in the biotech industry. He started his career as a bench scientist at Electro-Nucleonics and developed blood based diagnostics for HIV, HTLV-I and Hepatitis C. He later worked at Life Technologies (LTI, now Invitrogen) and directed the Immunodetection Group. His lab developed a number of innovative antibody based detection kits and reagents. He moved into scientific management when he became the Director of R&D at Kirkegaard & Perry Laboratories in 1994. Dr. Hearl has a Ph.D. in biochemistry from the University of Tennessee (Oak Ridge, Knoxville) and a B.S. from East Tennessee State University

Bruce F. Mackler, Ph.D., J.D.

Dr. Mackler's 27 years of FDA legal/regulatory experience in biomedical products includes biologics, drugs, medical and in vitro diagnostic devices, manufactured by traditional and biotechnology processes (recombinant proteins, genomics, allergens, active and passive vaccines, cell and gene therapy). Dr. Mackler has advised financial groups on integrated FDA, technical and business issues, when performing due diligence assessments on biomedical opportunities prior to their making initial investments and during bridging. These due diligence activities integrate his business acumen from working in sales/manufacturing in a family textile business, owning and managing several bioservice businesses and being an university/NIH researcher for 15 years, prior to his 27 years in a FDA legal/regulatory practice with premier law firms. He has founded biomedical companies, established and implemented their regulatory strategies and also assisted in securing early stage funding.

Dr Mackler has a Ph.D. and M.S. in the area of Immunology/Microbiology and has authored more than 100 published scientific papers and abstracts in immunology, immunopathology, allergy and diseases, as well as numerous additional articles and briefing papers on FDA and FDA-related legal and regulatory issues. Dr. Mackler has advised clients and venture capital groups on FDA regulatory approval strategies for their portfolio companies, regulatory/quality problems regarding establishing manufacturing facilities and how to effectively initiate product development and interact with FDA. Dr. Mackler has experience drafting and evaluating numerous FDA regulatory documents (e.g., INDs/NDAs, DMFs, and BLAs, Accelerated and Fast Track Approvals, Orphan Drug Designation applications. He has, as a U.S. agent, held IDEs/INDs and secured Treatment-INDs with substantial cost reimbursement, and has written successful Orphan Drug Development/SBIR grants and Designation applications; therefore, he is familiar with the nuances of these regulatory procedures. Dr. Mackler received his J.D. from the South Texas College of Law (magna cum laude, 1979), his Ph.D. (Immunology/Microbiology) from the University of Oregon Medical School (1970), his M.S. (Immunology/Microbiology) from the Pennsylvania State University (1965), and his B.A. (Biology) from Temple University (1964).

Bernard C. Rudnick

Bernard C. Rudnick is Founder and Executive Vice President of KSR Associates, LLC. He has 35 years of experience in executive-level strategy, finance, and management. He has held positions of CEO, COO, President, and Executive Vice President in a number of companies, and has been instrumental as a financial advisor to many more. He founded West Consumer Electronics, a business with revenues exceeding \$60 million that achieved market leadership under his control. Mr. Rudnick has substantial experience investing and guiding investments in entrepreneurial companies and has led or co-lead capital formation totaling over \$270 million in the past several years. He is a founding member and principal of Diamond State Ventures, and has served on many corporate, charitable and governmental boards throughout his career. He has assumed multiple interim management positions while guiding companies through transition. Examples of this include interim CFO of AudioAudit and CEO of CA Technology Inc. Mr. Rudnick earned his BS in Biochemistry from Pennsylvania State University and was conferred a postgraduate degree in administration at Northwood University. His



educational development work has included presentations to the Wharton Executive MBA alumni group as well as guest lectures at Weidner University.

Teri Jones Heiland, Ph.D.

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. Prior to assuming the post as Vice President at ITI, Dr. Heiland led multiple research teams at Capital Genomix developing and validating GeneSystem320 and applying this technology to identify biomarkers associated with cancer. She has also worked closely with the development of the ImmunoMouse and is an expert in molecular biology and genomic analysis. Prior to joining Capital Genomix, Dr. Heiland worked as a senior scientist in R&D at Kirkegaard & Perry Labs (KPL) where she spent four years as a project leader on development and commercialization of six major kits and she was responsible for the utilization of GS320 with both cytokine and HIV model systems. She has facilitated the optimization of the GS320 assay and has been involved in work involving eukaryotic gene regulation since 1989. She has expertise in the fields of signal transduction, amphibian development, and gene regulation. Dr. Heiland is primary author on a number of publications that utilized extensive work with mRNA and cDNA and assays such as RT-PCR, RNase Protection Assays, Northern Blotting, and library cloning and screening. Dr. Heiland obtained her Ph.D. in molecular biology at the University of Missouri-Columbia in 1993. Dr Heiland also currently has an appointment at Johns Hopkins University as a Visiting Scientist.

Lisa Salley

Lisa Salley is the Chief Operating Officer of Immunomic Therapeutics and brings a broad background of management experience to the company. Ms. Salley is also the Senior Managing Partner of the Heritage Solutions Group (HSG), a business advisory firm. Just prior to starting HSG, Lisa was an award winning entrepreneur. She is founder of Heritage Capital Services which has focused on financing in emerging and underserved urban markets. She spent over 24 years in corporate America, including senior executive positions at GE and Rohm & Haas and experiences at DuPont. Her corporate appointments spanned from Materials Nuclear Engineer to Chief Strategy & Growth Officer. Her past experience includes doubling the size of a specialty chemical business within 5 years – including defining segment priorities and the roadmap to ensure global coordination and global execution of strategy – as well as leading the business development, design, and execution of the go-to-market strategy for a \$13B market expansion opportunity in a highly regulated financial services market. Earlier career experiences included worldwide leadership for overall growth and management of a \$100M specialty chemical product line in an over-capacity market with double digit price erosion and 70% of sales outside the US. Results included 18% increased revenue, +3% price realization, on-time delivery rates at 99%, introduction of the first new product in 5 years, and launch of Asia-based operations.

Lisa has been repeatedly recognized for leadership and execution abilities. She is most well known for innovation, profitable growth, and execution. Further, she is a Six Sigma certified Master Black Belt and has a BS in Metallurgical Engineering & Materials Science from Carnegie Mellon and an MS in Industrial and Management Engineering from Rensselaer Polytechnic Institute

BOARD OF DIRECTORS

- Dr. William G. Hearl (see bio above)
- W. Barry McDonald (Chairman)
- James W. Wishart
- Dr. Bruce F. Mackler (see bio above)
- Dr. Ronald P. Thiboutot
- Dr. Charles V. Grudzinkas (observer)
- Mr. Bernie Rudnick (observer, see bio above)
- Mr. Kal Vepuri (observer)

W. Barry McDonald



In over 30 years in healthcare, Mr. McDonald has held executive management positions with U.S., European and Japanese health care companies that include venture-funded start-ups, mid-size independent companies and subsidiaries of international health care conglomerates. His experience encompasses a broad range of human diagnostics and biotechnology products, services and markets worldwide. Among his management experiences and capabilities are general management skills, acquisition, divestiture, corporate alliance expertise, technology assessments, strategic planning, and development of supply chain delivery and service networks to global health care markets and sectors.

Prior to joining The Sage Group, Mr. McDonald was President and CEO of MAST/Hitachi and simultaneously headed an executive staff within Hitachi Chemical corporate, which was responsible for new technology assessments, acquisitions, and business development activities for Hitachi Chemical's life sciences business worldwide. Previously, he was with Hycor Biomedical, as Senior Vice-President of Sales, Marketing and Business Development, where he was instrumental in establishing a new strategic direction for the company, and developing its global distribution network and in acquiring two companies, which expanded Hycor's business globally. Mr. McDonald's entrepreneurial experience was gained as President and CEO of Photest Diagnostics, a company concentrating on novel, homogeneous fluorescent immunoassays for the point-of-care (POC) market. As a venture capital backed emerging company, he was responsible for the turnaround in Photest, commercialization of its technology, and its ultimate sale to a European corporation.

Mr. McDonald's technical and scientific competencies were developed through academic degree programs and medical school experiences. His broad health care business expertise has been augmented through participation in international strategic management schools in France, Japan, and in the United States at Wharton Business School and Columbia University. Mr. McDonald's academic experiences include an M.D./Ph.D. program at the University of Kentucky, Albert Chandler Medical School, an M.S. in Microbiology and Genetics and a B.S. in Biochemistry and pre-med from The University of Southern Mississippi.

Dr. Ronald P. Thiboutot

Ronald P. Thiboutot, Ph.D., is Senior Vice President of Science and Technology for the Life Sciences Greenhouse of Central Pennsylvania. His responsibilities include identifying promising new areas of technology, reviewing science and business opportunities, and investing in seed stage opportunities. Dr. Thiboutot is managing director of the LSGPA Tech Fund. In this capacity, Dr. Thiboutot oversees technical due diligence of the funded companies and provides technical and business mentoring to funded applicants. Dr. Thiboutot sits on six corporate and economic development boards and provides interim CEO services for selected start-ups as required.

Prior to joining the Life Sciences Greenhouse, Dr. Thiboutot was President of RT Consultants, Inc. which provided technical, equipment procurement, and facility design consulting services to the US and EU pharmaceutical industry. Among his other employers were Wyeth Pharmaceuticals, where he was the Plant Director of the vaccine manufacturing facility located in Marietta, PA; Bristol-Myers Squibb, where he worked in the international technology transfer division; and Baxter Travenol. Dr. Thiboutot holds a Bachelor of Science, Masters of Science, and Ph.D. from the Massachusetts College of Pharmacy, and has been active in numerous U.S. and International pharmaceutical trade organizations during his 25 years in the pharmaceutical industry.

James W. Wishart

James W. Wishart has been the President, CEO and a Director of Capital Genomix since 2002. Prior to 2002, Mr. Wishart was the founder of Odyssey Diagnostics Inc., and has served as the CEO of Odyssey Diagnostics Inc. since its inception in 2001. During 2002, he facilitated the merger of Odyssey Diagnostics, Inc. and Capital Genomix, Inc. From 1997 to 2001, he served as the President and CEO of DYNEX Technologies, Inc., which was a wholly owned subsidiary of Thermo Electron Corp., a \$5.4 billion public company (TMO). From 1993 to 1997, Mr. Wishart served as the President and CEO of Spectra-Tech, Inc., a subsidiary of Thermo Optek Corp., a \$250 million public company (TOC), and a worldwide leader in the development, manufacturing and marketing of FTIR microscopes, accessories and software for the analytical instrumentation market. Mr. Wishart received his BS degree from Geneva College and has served on several Boards of Directors, including those of Thermo BioAnalysis, Ltd., DYNEX Technologies, Inc., Spectra-Tech, Inc., and S.P. Japan, Inc. Board of Directors.



Charles V. Grudzinskas, Ph.D.

Dr. Charles Grudzinskas is a Co-Founder and Principal in NDA Partners, LLC, an organization that delivers value through a unique combination of premier drug development expertise, strategic advice and proven clinical development and management practices that lead to rapid, efficient, effective and economical development and commercialization. Dr. Grudzinskas is a consultant to the Center for Drug Development Science (CDDS) at Georgetown University Medical Center and to MdBio, an organization that is dedicated to assisting bioscience companies become successful in Maryland. Dr. Grudzinskas also consults on the strategy and tactics of drug development, regulatory strategies and program management, working across the full range of emerging and mature companies and is called upon frequently to assist both large and small companies prepare for FDA meetings.

SCIENTIFIC FOUNDER

J. Thomas August, M.D.

Dr. J. Thomas August is a Distinguished Professor at the Department of pharmacology at Johns Hopkins University School of Medicine and is the inventor of the LAMP Technology. Dr. August started his career with a medical degree from Stanford University and trained in medicine as the resident house physician to Sir Stanley Davidson at the University of Edinburgh. His early academic appointments included Assistant Professor of Medicine, Stanford University School of Medicine; Associate Professor of Medicine assigned to Microbiology, New York University School of Medicine and Chairman, Department of Molecular Biology and Director, Division of Biological Sciences, Albert Einstein College of Medicine.

In 1976 Dr. August was appointed Director of Pharmacology and Experimental Therapeutics at Johns Hopkins University School of Medicine. The focus of August research at Johns Hopkins included the use of monoclonal antibodies to identify cellular proteins including discovery in 1980 of a family of lysosome associated membrane proteins (and). Several laboratories with antibodies to LAMP showed its colocalization with the major histocompatibility class II (MHC-II) proteins that acts to deliver the antigenic peptide units of proteins to helper T cells. This finding prompted the development of DNA vaccines encoding antigen proteins as LAMP chimeras areas in order to target and enhance the delivery of the antigens to the helper T cell pathway. This research continues novel epitope-based vaccines to several viral pathogens including HIV, dengue, influenza, West Nile and others. Dr. August honors include appointments as a Markley Scholar in Medical Sciences; Fellow, John Simon Guggenheim Memorial Foundation; Fellow, Balliol College at Oxford University, Adjunct Professor of Medicine, National University of Singapore and an R37 NIAID Merit Award for HIV vaccine research.

ADVISORY BOARD

- Dr. Roscoe Moore
- Dr. Larry Weiner
- Dr. Tama Copeman
- Mr. Robert Rager

Roscoe M. Moore, JR., D.V.M., Ph.D., D.Sc.

*Former Assistant United States Surgeon General and
Rear Admiral, United States Public Health Service (Retired)*

Until his retirement in December 2003, Dr. Roscoe M. Moore, Jr. served with the United States Department of Health and Human Services (HHS) and was for the last twelve years of his career the principal person responsible for development support within the Office of the Secretary, HHS, with primary emphasis on Continental Africa and other less developed countries of the world (e.g., Indonesia, Malaysia, and Vietnam). He was the principal liaison person between the HHS and



Ministries of Health in Africa with regard to the development of infrastructure and technical support for the delivery of preventive and curative health needs for the continent. Dr. Moore received his undergraduate and Doctor of Veterinary Medicine degrees from Tuskegee Institute; his Master of Public Health degree in Epidemiology from the University of Michigan; and his Doctor of Philosophy degree in Epidemiology from the Johns Hopkins University. He was awarded the Honorary Doctor of Science degree in recognition of his distinguished public health career by Tuskegee University.

Dr. Moore was a career officer within the Commissioned Corps of the United States Public Health Service (USPHS) entering with the U.S. National Institutes of Health and rising to the rank of Assistant United States Surgeon General (Rear Admiral, USPHS) within the Office of the Secretary, HHS. He was selected as Chief Veterinary Medical Officer, USPHS by Surgeon General C. Everett Koop. Dr. Moore served as an Epidemic Intelligence Service Officer with the U.S. Centers for Disease Control and Prevention. Dr. Moore has conducted clinical research on infectious diseases such as Venezuelan equine encephalitis, tuberculosis, listeriosis, psittacosis, human Orf, malaria, and HIV/AIDS. He has carried out epidemiological research on a number of chronic and molecular diseases, for example, lead toxicosis, occupational and environmental cancers, and sickle cell disease. He has evaluated the safety and effectiveness of medical devices, and conducted relevant epidemiological research on the utilization experience and human health effects of medical devices and radiation. Dr. Moore has written or co-authored over 100 publications covering a broad range of public health issues.

Dr. Tama Copeman

Dr. Tama Copeman is the founder of Alcyone*7, a technology and business development advisory company focusing on physical and life sciences. Tama has contributed to numerous early stage companies through Alcyone*7, and as an advisory board member to Mid Atlantic Diamond Ventures and the Ben Franklin Technology Partners technical advisory committee. She has 33 years experience in business development, strategy and risk, general management and operations, ventures and equity investments, international partnerships, technology and product development, intellectual property strategy and competitive analysis, and research-facility management. Over the years, Tama has taken many products to market and has managed product portfolios supporting businesses with total revenue of about \$ 1 billion and intellectual property valued in excess of \$ 200 MM. Earlier, Dr. Copeman developed computational molecular models and simulated complex chemical and physical systems. Dr. Copeman has MS., and Ph.D. degrees in Chemical Engineering from Lehigh University and has completed Executive Education courses at Stanford, MIT, and the University of Chicago.

Robert Rager

Mr. Robert Rager is Founder and President of Practical Memory Institute, LTD, a bio-behavioral health company developing proprietary programs for human memory fitness from NIH funded research. A former chemist in GE's Plastics Business Division, Mr. Rager was named a General Electric Presidential Exchange Executive serving for one year in the USDA's Foreign Agricultural Service establishing the first 6 Foreign Agricultural Trade Offices in Asia, Eastern Europe and Western Europe. Mr. Rager has over 30 years of business and venture management experience with specialization in marketing and sales with companies including General Electric, Project Software & Development, Inc., Potomac Industries, Ltd., Compact Disc Incorporated and Practical Memory Institute, LTD. Mr. Rager earned a BA in Chemistry from Hunter College of the City University of New York, holds patents in computer diskette storage devices and is founding Publisher of the international journal, Cognitive Technology[®]. With 15 years of experience in successfully applying for Small Business Innovation Research (SBIR) grant awards, Mr. Rager has served as Principal Investigator of more than a dozen SBIR grants awarded by various NIH Institutes leading to commercialization of The Memory Works[®] series of memory fitness products for consumer and clinical use. Mr. Rager is a registered NIH consultant for reviewing SBIR grant proposals.

LEGAL

General Council, Mr. Winston Lowe III esq, Lowe & Savage LLC



COMPANY OPERATIONS

Our corporate headquarters are located in Lancaster, PA at Liberty Place. The business address is 313 W. Liberty St., Suite 343, Lancaster, PA 17603.

The company's molecular biology and mouse laboratory is located in Rockville at 9620 Medical Center Drive right across from the Shady Grove Johns Hopkins Campus. The company also has plans to open a research laboratory at Franklin & Marshall College.

CAPITALIZATION & OWNERSHIP

ITI is a privately-held C corporation chartered in the State of Maryland. The Company has issued approximately 3,750,000 shares of Common Stock as of the date of this Plan. Management and Johns Hopkins University are the major shareholders of the Company.

FINANCIAL OVERVIEW

THE PROJECTIONS COVERED IN THE FINANCIAL PLAN AND PROJECTIONS ATTACHED HERETO ARE SUBJECT TO RISKS AND UNCERTAINTIES WHICH COULD CAUSE ACTUAL RESULTS TO DIFFER MATERIALLY FROM THOSE PROJECTED AND DO NOT CONSTITUTE A REPRESENTATION OR WARRANTY OF PERFORMANCE BY ANY PARTY HERETO.

REVENUE

ITI expects to derive the major source of future income from the sale and/or license of in-house developed vaccines that have advanced into Phase II or Phase III clinical trials.

In addition, revenue will come from three primary sources:

- License of LAMP to entities developing vaccines, vaccine platforms and from collaborative research agreements linked to the commercialization of LAMP vaccines developed by ITI.
- Grant revenue from SBIR grants, private foundations and state funding.
- Sales of plasmids and reagents to life science researchers.

EXPENSES

ITI has the unique position of being independent of any major facility or laboratory requirement. Since the development of LAMP vaccines has been extensively funded through government grants and supported by researchers around the globe (estimated at greater than \$20 million), ITI is not obligated to do additional research to validate the LAMP technology. ITI's main R&D emphasis is in conducting pre-clinical work in support of the JRC LAMP-*vax* Investigational New Drug application with the FDA. The pre-clinical and clinical work will be conducted at the Rockville laboratory and through contracts with other laboratories under a CRADA or to a CRO. The Company intends to focus its use of cash resources on its clinical trial program for LAMP-*vax* allergy immunotherapy products.

In addition to revenue generating activities, ITI is building value through:

- Internal Development. We are continuing to develop technology internally and are seeking corporate partnerships to develop ITI-designed products for allergy, in particular Japanese red cedar and short ragweed.



- Vaccine Development Partnerships. We are actively pursuing out-license agreements with pharmaceutical and biopharmaceutical customers.
 - Technology Promotion. ITI is focused on promoting LAMP technology to companies already active in the DNA vaccine field. Targeted customers include Vical, Inovio, Oxford BioMedica, Pfizer (following its acquisition of PowderMed, Colera and Wyeth), Chiron/Novartis, Merck and CSL.
 - Cancer Vaccine Clinical Trials. We are actively pursuing out-license agreements with pharmaceutical and biopharmaceutical working in DNA cancer vaccines and HIV.
- Opportunistically In-license or Acquire Complementary Technologies. We believe that in-licensing or acquiring technologies that complement our capabilities will enable us to expand our technology offering more rapidly and enhance our state-of-the-art discovery capabilities. We will continue to evaluate disease-related genes and antibodies housed at leading academic institutions for potential use in our internal drug discovery efforts.

USE OF FUNDS

Immunomic Therapeutics is actively pursuing investment funding in order to accelerate our product development programs. We intend to use the net proceeds from these activities for the development and expansion of our vaccine and immunotherapy business, including:

- Conduct pre-clinical, Phase I and Phase II clinical trials to evaluate the proprietary vaccine constructs for LAMP-allergy.
- Recruit R&D team to support development of allergy vaccines.
- Working Capital.
- Business, Grant and License Development.

PROJECTED FINANCIAL RESULTS

ITI's proforma income statement is available upon request. The Company expects revenue to show significant increases in 2011 and beyond as vaccines in Phase II / III development attract pharmaceutical partners for final development and distribution.

FINANCIAL PLAN ASSUMPTIONS

- The Company will receive sufficient funding to support expanded business development by Oct 2010.
- Initial clinical study data will be sufficient to drive the partnering of at least one proprietary vaccine formulation by late 2011.
- The Company will secure one or more grants to support vaccine development, particularly for the development of food allergy, infectious disease, HIV or bioterrorism targets.
- The Company will align with one or more delivery companies (e.g. Vical, Inovio, Ichor) and receive funds for collaborative research projects.



SUMMARY

Immunomic Therapeutics, Inc. is a Mid-Atlantic-based biotechnology/biopharmaceutical company that is employing a business development strategy to commercially develop DNA vaccines based on the LAMP Technology. The Company has completed two significant sub-license agreements: (1) with the Geron Corporation; the technology is in Phase II clinical trials as a formulation of LAMP-hTert known as GRNVAC1; and (2) with Nature Pharmaceuticals for the research application development of the Company's LAMP platform. ITI plans to seek additional sub-licenses and collaborative research agreements with other pharmaceutical and biotechnology companies active in DNA vaccine development as the initial, business development stage of the business strategy. The Company plans to further vaccine design and development in-house targeting allergy (red cedar and short ragweed) as initial candidates for DNA vaccine design. ITI envisions a merger and/or acquisition exit strategy with significant return to our shareholders.