



Immunomic Therapeutics, Inc.

Executive Summary

Q3, 2011

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ABOUT ITI

Immunomic Therapeutics, Inc. (ITI) is a Maryland “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, acute myeloid leukemia and melanoma. 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. LAMP vaccines have been found to be safe in humans and have shown to be an effective form of 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 \$10 million by 2012.

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 to 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 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 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™ 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 undergoing a 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, 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 Technology 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

- **Dr. Hugh Sampson Agrees to Join Scientific Advisory Board.** Dr. Sampson, the leading U.S. food allergy expert has agreed to Join the ITT's SAB and provide guidance on developing applications for peanut and other food allergies. May 2011
- **Toxicology & Biodistribution Studies** have been completed at BioReliance; preliminary data shows favorable safety and biodistribution data to support IND submission. June 2011
- **Mr. Yuri Radziewsky to Join ITI Business Advisory Team.** CEO of world leading marketing communications firm, GlobalWorks, has agreed to join the ITI Business Advisory Board and provide important guidance on developing ITT's marketing strategy. June 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 2012 and 2013.

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 bio-pharmaceutical companies globally. The Company will also consider accepting investments of up to \$6 million in appropriately structured deals.

Summary Financial Results / Projections

	2006-2008 Actual	2009	2010	2011	2012	2013
Revenue	\$550,000	\$30,000	\$0	\$150,000	\$4,600,000	\$15,500,000
Expenses	\$1,291,000	\$385,170	\$1,511,200	\$1,869,000	\$7,100,000	\$14,200,000
Grants	\$115,000	--	--	\$244,000	\$1,000,000	\$1,000,000
EBITDA	(\$742,000)	(\$355,170)	(\$1,511,200)	(\$1,475,000)	(\$1,500,000)	\$2,300,000

ABOUT DNA VACCINES & THE LAMP ADVANTAGE

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.