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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D. C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended December 31, 2015

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____.

Commission file number 000-27239

TAPIMMUNE INC.
(Exact name of registrant as specified in its charter)

Nevada	000-27239	45-4497941
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

50 N. Laura Street, Suite 2500
Jacksonville, FL **32202**
(Address of principal executive offices) **(Zip Code)**

904-516-5436
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, Par Value $0. 001
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 of Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232. 405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by checkmark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (do not check if a smaller reporting company)	Smaller reporting company	☒

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant computed by reference to the price at which the registrant's common equity was last sold, as of June 30, 2015 (the last day of the registrant's most recently completed second fiscal quarter) was approximately $36,517,000.

The registrant had 70,990,762 shares of common stock outstanding as of April 1, 2016.

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NOTE REGARDING REVERSE STOCK SPLIT

On February 18, 2014, we filed Certificate of Change Pursuant to NRS 78. 209 with the Secretary of State of the State of Nevada to effect a reverse split of our common stock at a ratio of one for one hundred. All historical share and per share amounts reflected in this report have been adjusted to reflect the resulting reverse stock split.

FORWARD LOOKING STATEMENTS

This annual report contains forward-looking statements that involve risks and uncertainties. Any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expect”, “plan”, “intend”, “anticipate”, “believe”, “estimate”, “predict”, “potential” or “continue”, the negative of such terms or other comparable terminology. In evaluating these statements, you should consider various factors, including the assumptions, risks and uncertainties outlined in this annual report. Any of these items may cause our actual results to differ materially from any forward-looking statement made in this annual report. Forward-looking statements in this annual report include, statements as to:

- the discovery, development, formulation, manufacturing and commercialization of our compounds, our drug candidates;
- conducting clinical trials internally, with collaborators, or with clinical research organizations;
- our collaboration and strategic relationship strategy; anticipated benefits and disadvantages of entering into such agreements;
- our licensing, investment and commercialization strategies;
- the regulatory approval process, including obtaining U. S. Food and Drug Administration and other international health authorities approval for our products in the United States and abroad;
- the safety, effectiveness and potential benefits and indications of our drug candidates and other compounds under development;
- the timing and size of our clinical trials; the compounds expected to enter clinical trials; timing of clinical trial results;
- our ability to manage expansion of our drug discovery and development operations;
- future required expertise relating to clinical trials, manufacturing, sales and marketing;
- obtaining and terminating licenses to products, drug candidates or technology, or other intellectual property rights;
- the receipt from or payments pursuant to collaboration or license agreements resulting from milestones or royalties;
- plans to develop and commercialize products on our own;
- plans to use third party manufacturers;
- expected expenses and expenditure levels; expected uses of cash; expected revenues and sources of revenues;
- the adequacy of our capital resources to continue operations;
- the need to raise additional capital;
- our expectations regarding competition;
- our investments, including anticipated expenditures, losses and expenses;
- our patent prosecution and maintenance efforts; and

While these forward-looking statements, and any assumptions upon which they are based, are made in good faith and reflect our current judgment regarding future events, our actual results will likely vary, sometimes materially, from any estimates, predictions, projections, assumptions or other future performance suggested herein. Some of the risks and assumptions include:

- our ability to obtain additional capital when needed;
- fluctuations in net cash provided and used by operating, financing and investing activities;
- our limited operating history;
- our history of operating losses;
- our ability to discover, develop, formulate, manufacture and commercialize our drug candidates;
- the risk of unanticipated delays in, or discontinuations of, research and development efforts;
- the risk that previous preclinical testing or clinical trial results are not necessarily indicative of future clinical trial results;
- risks relating to the conduct of our clinical trials;
- changing regulatory requirements and administrative practice;
- the risk of adverse safety findings;
- the risk that results of our clinical trials do not support submission of a marketing approval application for our drug candidates;
- the risk of significant delays or costs in obtaining regulatory approvals;
- risks relating to our reliance on third party manufacturers, collaborators, and clinical research organizations;
- risks relating to the development of new products and their use by us and our current and potential collaborators;
- risks relating to our inability to control the development of out-licensed compounds or drug candidates;
- risks relating to our collaborators' ability to develop and commercialize drug candidates;
- costs associated with prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights;
- our ability to maintain or obtain adequate product liability and other insurance coverage;
- the risk that our drug candidates may not obtain or maintain regulatory approval;
- the impact of technological advances and competition, including potential generic competition;
- our ability to compete against third parties with greater resources than ours;
- risks relating to changes in pricing and reimbursements in the markets in which we may compete;
- competition to develop and commercialize similar drug products;
- our ability to obtain and maintain patent protection and freedom to operate for our discoveries and to continue to be effective in expanding our patent coverage;

- the impact of changing laws on our patent portfolio;
- developments in and expenses relating to litigation;
- our ability to in-license drug candidates or other technology;
- fluctuations in net cash provided and used by operating, financing and investing activities;
- the competitive environment in which we operate;
- our dependence on key personnel;
- conflicts of interest of our directors and officers;
- our ability to fully implement our business plan;
- our ability to effectively manage our growth; and
- other regulatory, legislative and judicial developments.

Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by federal securities laws, we undertake no obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

In this report all references to (i) "TapImmune" "we," "us," "our" or the "Company" mean TapImmune Inc. ; (ii) "SEC" refers to the Securities and Exchange Commission; (iii) "Securities Act" refers to the United States *Securities Act of 1933*, as amended; (iv) "Exchange Act" refers to the United States *Securities Exchange Act of 1934*, as amended; and (v) all dollar amounts refer to United States dollars unless otherwise indicated.

Calculation of Aggregate Market Value of Non-Affiliate Shares

For purposes of calculating the aggregate market value of shares of our common stock held by non-affiliates as set forth on the cover page of this annual report on Form 10-K, we have assumed that all outstanding shares are held by non-affiliates, except for shares held by each of our executive officers, directors and 5% or greater stockholders. In the case of 5% or greater stockholders, we have not deemed such stockholders to be affiliates unless there are facts and circumstances which would indicate that such stockholders exercise any control over our company. These assumptions should not be deemed to constitute an admission that all executive officers, directors and 5% or greater stockholders are, in fact, affiliates of our company, or that there are no other persons who may be deemed to be affiliates of our company. Further information concerning shareholdings of our executive officers, directors and principal stockholders is incorporated by reference in Part III, Item 12 of this annual report on Form 10-K.

AVAILABLE INFORMATION

TapImmune Inc. files annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"). You may read and copy documents referred to in this Annual Report on Form 10-K that have been filed with the SEC at the SEC's Public Reference Room, 450 Fifth Street, N. W. , Washington, D. C. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. You can also obtain copies of our SEC filings by going to the SEC's website at http://www. sec. gov.

PART I

ITEM 1. BUSINESS

Company Overview

We are an Immuno-Oncology Company specializing in the development of innovative peptide and gene-based immunotherapeutics and vaccines for the treatment of cancer. These immunotherapy platforms also have application in infectious disease. We combine a set of proprietary and exclusively licensed technologies including peptide antigen technologies and DNA expression technologies that improve the ability of the cellular immune system to recognize and destroy diseased cells.

Our Cancer Vaccines

In contrast to standard therapies for cancer treatment including surgery, radiation therapy and chemotherapy that imprecisely target cancer cells and normal cells, we are developing vaccines that precisely target candidate breast cancer(s), colorectal cancer(s), ovarian cancer(s) and non-small cell lung cancer(s). We are currently developing three core technology platforms:

(1) an exclusively licensed vaccine for the treatment of HER2/neu+ breast cancer that over-expresses Human Epidermal Growth Factor receptor 2 (HER2/neu),

(2) an exclusively licensed vaccine for treating breast and ovarian cancers that over-express Folate Receptor Alpha, and

(3) a wholly owned DNA expression vaccine technology (Polystart) for further treating various cancers or infectious disease.

To enhance shareholder value and taking into account development timelines, we plan to focus on advancing our clinical programs including our Folate Receptor Alpha program for breast and ovarian and our HER2/neu peptide antigen program into Phase II clinical trials. In parallel, we plan to complete the preclinical development of our Polystart technology as an integral component of our prime-and-boost vaccine methodology.

Products and Technology in Development

Product/Candidate	Description	Application	Status
HER2/neu+ Breast Cancer Vaccine TPIV 100/110	Peptide Vaccine	Treatment of HER2/neu+ Breast Cancer	Phase I trial completed Phase II to start in 2016
Folate Receptor Alpha Vaccine TPIV 200	Peptide Vaccine Peptide Vaccine + Checkpoint inhibitor	Treatment of Folate Alpha Breast and Ovarian Cancer	Phase I trial completed Multiple Phase II trials to start in 2016 Phase II trial to start in 2016
PolyStart	DNA expression technology	Broad Application to “Prime” and “Boost”	Preclinical

Clinical

For perspective, we note that clinical trials to support new drug applications are typically conducted in three sequential phases, although the phases may overlap. During Phase I there is an initial introduction of the therapeutic candidate into healthy human subjects or patients. For an immunotherapeutic/vaccine in particular, Phase I studies are generally conducted in cancer patients that have previously received one or another current standard of care and include the measurement of cellular immune responses. Phase II usually involves studies in a more focused patient population in order to carefully assess clinical activity of the drug in specific targeted indications, dosage tolerance (*i. e.* , dose escalation) and optimal dosage, while continuing to identify possible adverse effects and safety risks. If the therapeutic candidate is found to be potentially effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to further demonstrate clinical efficacy and to further test for safety within an expanded patient population at geographically dispersed clinical trial sites.

Human Clinical Trials – HER2/neu+ Breast Cancer – Mayo Foundation

On June 1, 2010, we signed an exclusive licensing option agreement with the Mayo Foundation for Medical Education and Research ("Mayo Foundation"), Rochester MN for clinical development of a new HER2/neu+ breast cancer vaccine technology. An IND for Phase I human clinical trial on the HER2/neu+ cancer vaccine in collaboration with the Mayo Foundation was allowed by the FDA in July, 2011 and the Mayo IRB approved the trial on May 4, 2012. Patients had histologically confirmed Stage II-III Her2/neu+ breast cancer and had completed systematic therapy at least 90 days prior to treatment and were without evidence of disease. Patient dosing has been completed and final safety analysis on all the patients treated has been completed. The vaccine was well tolerated with mild adverse affects. In addition, 19 out of 20 evaluable patients showed robust T-cell immune responses to the antigens in the vaccine composition. These results provide the rationale for advancement into Phase II in 2016**.** An additional secondary endpoint incorporated into this Phase I Trial will be a two year follow on recording time to disease recurrence in the participating breast cancer patients.

We have the exclusive option to license this technology from the Mayo Foundation upon the completion of Phase I. For Phase I(b)/II studies, we plan to add a Class I peptide, licensed from the Mayo Foundation (April 16, 2012), to the four Class II peptides. Management believes that the combination of Class I and Class II HER2/neu+ antigens, gives us the leading HER2/neu+ vaccine platform. As the folate receptor alpha vaccine is our lead product, our plans are now initiating formulation studies to progress the HER2/neu+ vaccine towards a Phase II Clinical Trial at the end of 2016.

Human Clinical Trials – Folate Alpha Breast and Ovarian Cancer – Mayo Foundation

On July 27, 2015, we exercised our option agreement with Mayo Foundation with the signing of a worldwide exclusive license agreement to commercialize a proprietary folate receptor alpha vaccine technology for all cancer indications. As part of this agreement, the IND from the folate receptor alpha Phase I trial was transferred from Mayo Foundation to us for amendment for Phase II Clinical Trials on our lead product.

Folate Receptor Alpha ("FRa") is overexpressed in over 80% of breast cancers and in addition, over 95% of ovarian cancers, for which the only treatment options are surgery and chemotherapy, leaving a very important and urgent clinical need for a new therapeutic. Time to recurrence is relatively short for this type of cancer and survival prognosis is extremely poor after recurrence. In the United States alone, there are approximately 30,000 ovarian cancer patients and 40,000 triple negative breast cancer patients newly diagnosed every year.

We have completed a 22 patient Phase I clinical trial for the Folate Receptor Alpha Vaccine. Twenty-two patients with breast or ovarian cancer who had undergone standard surgery and adjuvant treatment were treated with 1 cycle of cyclophosphamide (given days 1-7 and 15-22 of 28). Following this, patients were vaccinated intradermally at 3 sites with a mixture of the 5 FRa peptides on day 1 of a 28 day cycle for a maximum of 6 vaccination cycles. The vaccine is well tolerated and safe and 20 out of 21 evaluable patients showed positive immune responses providing a strong rationale rational for progressing to Phase II trials. Further, the data showed that 16 out of 16 patients in the observation stage still showed immune responses. We have developed a commercial quality lyophilized formulation of the vaccine in a single vial for reconstitution and injection. GMP manufacturing of initial batch for initial Phase II trials has been completed.

On September 15, 2015, we announced that our collaborators at the Mayo Foundation had been awarded a grant of $13.3 million from the U. S. Department of Defense. This grant, commencing September 15, 2015, will cover the costs for a 280 patient Phase II Clinical Trial of Folate Receptor Alpha Vaccine in patients with Triple Negative Breast Cancer. We will work closely with Mayo Foundation on this clinical trial by providing clinical and manufacturing expertise as well as providing GMP vaccine formulations. These vaccine formulations are being developed for multiple Phase II clinical programs in triple negative breast and ovarian cancer in combination with other immunotherapeutics.

On December 9, 2015, we announced that we received Orphan Drug Designation from the U. S. Food & Drug Administration's Office of Orphan Products Development (OOPD) for our cancer vaccine TPIV 200 in the treatment of ovarian cancer. The TPIV 200 ovarian cancer clinical program will now receive benefits including tax credits on clinical research and 7-year market exclusivity upon receiving marketing approval. TPIV 200 is a multi-epitope peptide vaccine that targets Folate Receptor Alpha which is overexpressed in multiple cancers including over 90% of ovarian cancer cells.

Preclinical

Polystart

In parallel with the above completed Phase I clinical trials and upcoming Phase II trials, we plan to complete preclinical development of the Polystart technology as an integral component of our “Prime” and “Boost” vaccine methodology. Unlike other vaccine technologies that narrowly address the initiation of an immune response, our (“Prime” and “Boost”) approach broadly stimulates the cellular immune system by enhancing the function of killer T-cells and helper T-cells. Our peptide immunotherapeutic approach may be coupled with our recently developed in-house Polystart nucleic acid-based technology designed to enhance T-cell antigen presentation on the surface of appropriate populations of presenting cells. Our Polystart technology directs the translation and subsequent endogenous natural processing of antigenic T-cell epitopes contained within a poly-antigen array(s) at four times the level of conventional comparator systems, thereby providing a greater signal/propensity to attract and directly interact with a patient’s T-cells. Accordingly, elevated levels of target specific cell surface presented T-cell antigen(s) are correspondingly expected to more effectively engage, activate and expand antigen specific killer T-cell population(s) that can then seek out and destroy target cells (e. g. , cancer cells). Moreover, our versatile Polystart technology is designed to express either Class I killer or Class II helper T-cell antigenic epitopes. Our nucleic acid-based systems can also incorporate “TAP” which stands for Transporter associated with Antigen Presentation. The nucleic acid-based platform may also represent a second stand-alone vaccine technology.

Our Polystart technology was invented in-house and is therefore not subject to any licensing fees or downstream royalty payments. The Polystart technology composition can be administered in the form of a plasmid DNA or incorporated into a viral delivery system (RNA or DNA). The Polystart technology comprises two portions, one supporting high level of expression and the other a T-cell peptide antigen array (“PAA”). The antigens making up the PAA are naturally processed inside a patient’s own cells where they are then presented on the cell surface visible for T-cell recognition, activation and expansion. We have confirmed that the Polystart/PAA technology works in preclinical studies in context with a smallpox vaccine candidate. However, it is important to understand that this is a platform technology which can be adapted to essentially any T-cell peptide antigen targeted indication, including HER2/neu. The Polystart technology combined with our peptide-based technology is an ideal opportunity for developing an effective prime plus boost vaccination methodology. We plan to incorporate the pre-clinical development of Polystart as a boost strategy for HER2/neu+ breast cancer, colorectal cancer, ovarian cancer and triple negative breast cancer. We have converted the previously filed U. S. Provisional Patent Application on Polystart into a full Patent Application, and will extend technology constructs as boost strategies for the current clinical programs in breast and ovarian cancer.

Management believes that the comprehensive scientific underpinnings of the overall approach, to elicit the production of both helper T- cells and killer T-cells, will provide us with highly competitive product candidates for the treatment of HER2/neu positive breast cancer, colorectal cancer, ovarian cancer and triple negative breast cancer.

Our Infectious Disease Program

Regarding our programs for the development of vaccines aimed at viral pandemics/biodefense, our collaborations with the Mayo Foundation progressed to a point where the immunogenicity of novel smallpox antigens in mice treated with both antigens and TAP expression vectors was shown to be encouraging. However, due the resources required to complete primate studies and the focusing of our current resources in the oncology field, we have decided not to dedicate resources to develop a smallpox product. We plan to pursue non-dilutive grant funding for these programs in collaboration with other interested vaccine developers and strategic corporate partnerships. The use of non-dilutive grant funding to progress this area allows us to focus the majority of our internal resources on HER2/neu+ breast, ovarian and triple negative cancers.

Mayo Foundation for Medical Education and Research Relationships

As part of our business strategy, we establish business relationships, including collaborative arrangements with other companies and medical research institutions to assist in the clinical development of certain of our drugs and drug candidates and to provide support for our research programs.

Below is a brief description of our significant business relationships and collaborations and related license agreements with Mayo Foundation that expand our pipeline and provide us with certain rights to existing and potential new products and technologies.

On May 26, 2010 we signed a Technology Option Agreement with the Mayo Foundation, Rochester, MN, for the evaluation of HER2/neu peptide epitopes as antigens for a breast cancer vaccine. The agreement grants us an exclusive worldwide option to become the exclusive licensee of the technology after completion of Phase I clinical trials.

Following approval of the IND by the FDA in July, 2011, TapImmune and the Mayo Foundation executed a Sponsored Research Agreement for the clinical trial.

On July 24, 2010, we signed a Research and Technology License Option Agreement with the Mayo Foundation, Rochester, MN, to evaluate novel smallpox peptide antigens. This agreement grants us an exclusive worldwide option to become the exclusive licensee of the smallpox vaccine technology after research studies have been completed under the terms of the agreement. This project was completed in Q4, 2014 and while the project successfully identified several peptide antigens as the potential components for a new vaccine, we decided not to proceed into primate studies to devote resources to its oncology clinical programs. As a result we did not exercise our Option to license this technology.

Mayo HER2/neu License

On April 13, 2012, we entered into a Patent & Know-How Agreement with the Mayo Foundation, Rochester, MN, to license a proprietary MHC Class I HER2/neu antigen technology. Under the terms of this agreement, we acquired from Mayo Foundation (i) an exclusive worldwide license to use the patent rights related to US patent application numbered 61600480 (titled “Methods and materials for generating CD8+ T-cells having the ability to recognize cancer cells expressing a Her2/neu polypeptide”) to make products in the prophylactic and therapeutic field (the “HER2/neu Licensed Products”) and (ii) a non-exclusive license to use certain of Mayo Foundation’s know-how to make the HER2/neu Licensed Products. We may sublicense the technology with the approval of Mayo Foundation, which approval may not unreasonably withheld.

In connection with the grant of the licenses, we are to (i) make an upfront license payment of $100,000 to Mayo Foundation followed by an additional $150,000 in license payments over a 12 month period, (ii) reimburse Mayo Foundation for documented patent expenses incurred to date by Mayo Foundation in connection with the license, (iii) pay an annual license fees, (iv) make milestone payments and (iv) pay royalties of gross annual sales. In addition, we are required to pay Mayo Foundation a fee if we fail to initiate a Phase I clinical trial of a HER2/neu Licensed Product within five years and if we fail initiate a Phase II clinical trial of a HER2/neu Licensed Product within eight years.

Mayo Folate Receptor Alpha License

On July 21, 2015, we entered into a License and Assignment Agreement with Mayo Foundation (“Mayo Foundation License”) pursuant to which we acquired certain intellectual property rights from the Mayo Foundation for the development and commercialization of certain products, methods and processes property relating to a folate receptor alpha immunotherapeutic vaccine comprised of a set of unique peptide epitopes targeting breast, lung and ovarian cancer. The Mayo Foundation License resulted from our exercise of an option that we acquired from Ayer Special Situations Fund I, LP (“Ayer”) that was issued pursuant to a Technology Option Agreement that Ayer entered into with the Mayo Foundation on March 18, 2014.

The Mayo Foundation granted us a license (with a right to sublicense) on a worldwide basis to make, sell and use products for therapeutic use against breast, ovarian, lung and other cancers that express folate receptor alpha. This license is an exclusive license for products that are based on the intellectual property and non-exclusive for products that are based on Mayo Foundation know–how and materials. The intellectual property that is being licensed includes (i) U. S. patent application numbers 12/303,054 and 13/202,236, (ii) U. S. patent number 8,486,412 and 8,858,952 and provisionals, (iii) divisionals including 13/917,410 and (iv) continuations including 14/484,057 (“Patent Rights”).

Under the Mayo Foundation License, and subject to certain exceptions, we are responsible for, among other things, developing the technology under the Patent Rights to bring Licensed Products (as defined in the Mayo Foundation License) to market and costs of filing, prosecution and maintenance of the Patent Rights. Mayo Foundation has sole control over the protection, defense, enforcement, maintenance abandonment and other handling of the Know-How (as defined in the Mayo Foundation License) and Materials (as defined in the Mayo Foundation License).

The Mayo Foundation granted this license in exchange for an initial upfront payment of $350,000, which was made on July 21, 2015. Upon the payment of the initial upfront payment, the Mayo Foundation assigned to us IND # 14546, and we assumed all responsibility and liability for this investigative new drug application. In addition to the initial upfront payment, we are to pay additional upfront payments, an annual license maintenance fee, milestone fees and royalty fees (which will be subject to a minimum annual royalty fee once royalty fees are due).

We have agreed to indemnify and hold Mayo Foundation harmless from any damages caused as a result of (i) the practice or exercise of any rights and assignments granted by the Mayo Foundation License by or on behalf of us or any sublicensee; (ii) research, development, design, manufacture, distribution, use, sale, importation, exportation or other disposition of Licensed Products; and (iii) our or any sublicensee's act or omission, including negligence or willful misconduct.

The term of this agreement runs from July 21, 2015 until the date of our last obligation to make payments under this agreement, provided that the Mayo Foundation may terminate this agreement if, among other matters, (i) 30 days after providing us with notice of a material breach of this agreement, we fail to cure such breach, (ii) 90 days after providing us with written notice, we fail to meet either of the following diligence events (a) initiate a Phase II clinical trial for a Licensed Product prior to the 2nd anniversary of the Mayo Foundation License and, once initiated, keep current on all of our Phase II funding obligations and (b) initiate a Phase IIB or III clinical trial for a Licensed Product prior to the 5th anniversary of the Mayo Foundation License, (iii) we fail to make a sale of a Licensed Product by July 21, 2025 and (iv) we cease to conduct business in the normal event of operations or become insolvent or bankrupt. We may voluntarily terminate the Mayo Foundation License at any time upon written notice to Mayo Foundation.

General

Company History

We were incorporated under the laws of the State of Nevada in 1991. We have one wholly owned subsidiary named GeneMax Pharmaceuticals Inc. ("GeneMax Pharmaceuticals"). We currently trade on the OTC Bulletin Board ("OTCQX") under the symbol "TPIV" and on the Frankfurt and Berlin Stock Exchanges under the symbol "GX1A". The listing on the Berlin Stock Exchange was done without our knowledge and consent.

We operated offices and laboratories at 1551 Eastlake Avenue, Seattle until July 1, 2015. This enabled us to effectively leverage world-class resources made available to us and manage our cash flow. Our small core team has allowed us to establish in-house technical expertise in molecular biology (expression vector development) to underpin our current and future development projects, and to optimally work with external collaborators/oncologists. It has also allowed us to make significant progress in the refinement and focus of clinical programs to take advantage of new antigens, the emerging field of vaccinomics and vaccine development strategies. In addition, it has allowed us to start generating new intellectual property (IP), adding to the core TAP IP and antigen specific IP from the Mayo Foundation for which we have either licensed outright or have exclusive options to license.

In July 2015 we moved our Corporate Headquarters to 50 North Laura Street, Jacksonville, FL 32202 to be in closer proximity to our collaborators at Mayo Clinic, Jacksonville, FL and our Strategic and Medical Advisors who live in Florida. We lease a single office at Eastlake Avenue, Seattle, for the purposes of continuing to develop and patent our PolyStart technology.

Over the past year, we have, in a challenging financing climate, raised sufficient working capital to fund and progress our operations and significantly restructured our balance sheet and capital structure. We believe that we continue to make progress with the resources available to us. With the start of clinical programs and our focus on securing non-dilutive financing from a number of sources, management is confident that our current pathway will secure longer term capital to finance and accelerate our activities. The strength of our science and development approaches is becoming more widely appreciated, particularly as our clinical program generates data and as we embrace additional collaborations with leading institutions and corporations.

While the pathway to successful product development takes time and significant resources, we believe that we have put in place the technical and corporate fundamentals for success. The strength of our product pipeline gives us a unique opportunity to make a major contribution to global health care.

The Immunotherapy Industry for Cancer

Management believes that there is a critical need for more effective cancer therapies. Given the unmet need in the treatment of metastatic cancer combined with our process for harnessing the body's own immune system to treat certain cancers, we believe that we are positioned to be a leading contributor to solving this problem. The immuno-oncology landscape includes the use of monoclonal antibodies, adoptive T-cell therapies, checkpoint inhibitors and in vivo T-cell vaccines. We believe that our use of peptide antigens that can stimulate both T-killer cells and T-helper cells together with the use of our PolyStart expression vector as a "boost" strategy can give us a competitive edge in the in vivo T-cell vaccine sector.

In addition, we continue to pursue the development of an approach which can allow the cellular immune system to make tumor cells more visible to the immune system. Many cancers are not very "immunogenic", meaning that the cancers are not able to induce an immune response because they no longer express sufficient levels of key proteins on their cell surface, known as Major Histocompatability Class I or MHC Class I proteins. In healthy cells, these proteins provide the information to the immune system that defines whether the cell is healthy or, in the case of cancer or viral infection, abnormal. If the MHC Class I proteins signal that the cells are abnormal, then the immune system's T-cells are activated to attack and kill the infected or malignant cell.

In many solid tumors and in metastatic cells, antigen presentation is often impaired thus presenting a weakened signal to which the cellular immune system can respond. Management believes that although a number of cancer therapies have been developed that stimulate the immune system, these approaches have often proven ineffective because the cancers remain invisible to the immune system due to this problem. A strategic vision of TapImmune is to broadly stimulate the cellular immune system while additionally improving antigen presentation. We believe that the use of our PolyStart expression vector for improved expression of antigens and TAP can improve the immune system's response to a variety of cancers.

In addition to our focus on the cancer vaccines, with adequate funding, we will also pursue the development of prophylactic vaccines against infectious microbes by partnering with other vaccine developers in the infectious disease market.

TapImmune's Target Market and Strategy

We will focus our product development in oncology, both alone and with corporate partners and/or collaborators, including the Mayo Foundation for HER2/neu+ Breast Cancer, Folate Alpha Ovarian and Breast cancer. The diversity of cancer types and their overall prevalence create a large need for new and improved treatments. Management believes that there is a significant market opportunity for a cancer treatment that utilizes the highly specific defense mechanisms of the immune system to attack cancers. The goal of our management is to ultimately have the FDA approve our cancer vaccines so that we can secure a portion of this market.

Management also believes that our Polystart expression vector approach will provide a flexible and unique platform for the creation of new vaccines that can rapidly respond to emerging viral threats/bioterrorism in addition to enhancing the efficacy of current vaccines in the treatment of infectious disease. If successful, this platform technology would be a significant advance in vaccine development and it will be a key business development strategy to pursue additional partnerships and joint research and/or development ventures with vaccine manufacturers and pharmaceutical companies to bring new and improved vaccines to market. In addition to a broad range of oncological treatments, this strategy includes the development of vaccines for pandemic diseases and for bioterrorism threats. Management believes that our adjuvant will increase the potency of many of the currently available vaccines and lead to the creation of better, more effective new vaccines, thereby allowing us to participate in this large market through novel new products and in combination with existing vaccines.

Our business strategy in cancer is to take products through Phase II clinical trials and then partner with pharmaceutical marketing organizations ahead of Phase III trials. In the infectious disease/biodefense area our business strategy is to seek joint research and development partnerships on our infectious disease platform with companies seeking to expand their product portfolios.

The global markets for cancer immunotherapy is estimated to grow to in excess of $80 billion by 2020 according to ResearchandMarkets. com (http://www.researchandmarkets. com/research/qjhgbh/global_and_usa). The market for infectious disease vacccines is estimated at roughly $30 billion worldwide, with the U. S. contributing approximately $20 billion. Importantly, there still exist significant development opportunities in the global vaccine market, as there are more than 300 infectious diseases yet effective prophylactic therapies for only approximately 15% of these (Source: The Life Sciences Report's "Vaccine Therapies Hold Promise for Investors: Stephen Dunn," April 12, 2012). Management believes that ultimately our combined technology platform(s) have the potential to develop more effective new vaccines, thereby allowing us to participate in this large market through novel new products and in combination with existing vaccines.

Research and Development Efforts

We direct our research and development efforts towards the advancement of immunotherapeutic and prophylactic vaccine products for the treatment of cancer, using our combined proprietary technologies, relevant killer plus helper T-cell peptide antigens, and Polystart nucleic acid-based expression system(s) expressing antigens and TAP. We have focused our efforts initially on the development of a therapeutic vaccine for applications in cancer treatment, while concomitantly demonstrating the breadth of our combined technology platform for the development of prophylactic vaccines. Our product development efforts are opportunistically designed to consider combinations with approved and emerging products in both cancer therapeutics and prophylactic vaccines against microbes. This approach allows us to pursue our own internal product development while positioning us to enter into multiple partnerships and licensing agreements. We have made significant progress in the development of a nucleic acid-based (Co-linear Polystart) technology which directs the enhanced synthesis of a linear peptide antigen array comprising multiple proprietary T-cell epitopes (CD4 and CD8). In addition, the technology also directs the synthesis of the protein TAP1 associated with the transport of MHC Class I epitopes to the surface of cells. The expression or functioning of this protein is often lowered in tumor cells or virally infected cells and its replacement can enhance antigen presentation. Recent work on this novel expression vector platform has demonstrated that T-cells recognize cell surface presented T-cell peptide epitopes confirming that multiple individual peptides are effectively and functional processed from a linear peptide antigen array and that this leads to peptide specific T-cell killing.

Intellectual Property and Patents

Patents and other proprietary rights are vital to our business operations. We protect our technology through various United States and foreign patent filings, and maintain trade secrets that we own. Our policy is to seek appropriate patent protection both in the United States and abroad for our proprietary technologies and products. An enforceable patent with appropriate claim coverage can provide an advantage over competitors who may seek to employ similar approaches to develop therapeutics, and so the future commercial success of products, and therefore our future success, will be in part dependent on our intellectual property strategy. The information provided in this section should be reviewed in the context of Item 1A, "Risk Factors".

We require each of our employees, consultants and advisors to execute a confidentiality agreement upon the commencement of any employment, consulting or advisory relationship with us. Each agreement provides that all confidential information developed or made known to the individual during the course of the relationship will be kept confidential and not be disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions conceived of by an employee shall be our exclusive property.

There can be no assurance that our patents, and any patents that may be issued to us in the future, will afford protection against competitors with similar technology. In addition, no assurances can be given that the patents issued to us will not be infringed upon or designed around by others or that others will not obtain patents that we would need to license or design around. If the courts uphold existing or future patents containing broad claims over technology used by us, the holders of such patents could require us to obtain licenses to use such technology. Patent coverage may also vary from country to country based on the scope of available patent protection. There are also opportunities to obtain an extension of patent coverage for a product in certain countries, which adds further complexity to the determination of patent life.

Patents

We currently own a number of issued and pending patents covering composition of matter of PolyStart and TAP. In addition, a number of issued and pending patents cover the HER2/neu and Folate Receptor Alpha peptides in our Option to License or License Agreements from the Mayo Foundation.

The following table sets forth information as of March 4, 2016 regarding each pending United States patent application or enforceable issued United States patent currently held or licensed:

Patent No. / Pending Application Publication No.	Patent Expiration	Title	Ownership	Jurisdiction Where Granted/Filed
Peptide Based Vaccine (Folate Alpha Breast and Ovarian Cancer)				
8,486,412	2029	Immunity To Folate Receptors	Exclusive License	USA
9,243,033	2029	Immunity To Folate Receptors	Exclusive License	USA
Peptide Based Vaccine (HER2/neu+ Breast Cancer)				
2015/0231218	N/A; not yet granted	Methods And Materials For Generating CD8+ T Cells Having The Ability To Recognize Cancer Cells Expressing A HER2/Neu Polypeptide	Exclusive License Option	USA
Nucleic Acid Based Vaccine (PolyStart)				
2015/0258186	Notice of Allowance Issued; Will Issue As Patent Upon Paying Issue Fee; Expected Patent Term Is Through 2035	Nucleic Acid Molecule Vaccine Compositions And Uses Thereof	Owned	USA
Additional Intellectual Property				
2014/0377340	N/A; not yet granted	HLA-DR Binding Peptides And Their Uses	Exclusive License Option	USA
8,858,952	2021	Methods And Materials For Generating T Cells	Exclusive License Option	USA
7,994,146	2017	Methods Of Enhancing An Immune Response	Exclusive License Option	USA

Competition

Our drug discovery, development and ultimate commercialization activities face, and will continue to face, intense competition from organizations such as pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies. We face significant competition from organizations, particularly fully integrated pharmaceutical companies, that are pursuing pharmaceuticals that are competitive with our drug candidates. Management believes that a number of companies, which are developing various types of similar in vivo T-cell immunotherapies and therapeutic cancer vaccines to treat cancer, could be our major competitors including: Advaxis, Genzyme Molecular Oncology, Immune Design, Oncothyreon, Celldex, BN Immunotherapeutics, Immunocellular, Galena, Antigen Express,Transgene S. A. , and Bavarian Nordic. Other immunotherapy approaches including adoptive T-cell therapies, monoclonal antibodies and checkpoint inhibitors also provide competition in the oncology space. In these areas competitors include, Lion Biotechnology, Juno Therapeutics, Kite Pharma, Roche Pharmaceuticals, Merck & Co, Bristol Myers Squibb, AstraZeneca plc, Medimmune, LLC. We believe that our in vivo T-cell therapy approaches will be synergistic with these approaches and might even improve them.

Many companies and institutions, either alone or together with their collaborative partners, have substantially greater financial resources, larger drug discovery, development and commercial staffs and significantly greater experience than we do in:

- drug discovery;
- developing products;

- undertaking preclinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of products; and
- manufacturing, marketing, distributing and selling products.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA and other regulatory approval or commercializing products that compete with our drug candidates.

In addition, any drug candidate that we successfully develop may compete with existing therapies that have long histories of safe and effective use. Competition may also arise from:

- other drug development technologies and methods of preventing or reducing the incidence of disease;
- new small molecules; or
- other classes of therapeutic agents.

We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions and for licenses to drug candidates or proprietary technology. These competitors, either alone or with their collaborative partners, may succeed in developing products that are more effective than ours.

Our ability to compete successfully will depend, in part, on our ability to:

- develop proprietary products;
- develop and maintain products that reach the market first, are technologically superior to and/or are of lower cost than other products in the market;
- attract and retain scientific, product development and sales and marketing personnel;
- obtain patent or other proprietary protection for our products and technologies;
- obtain required regulatory approvals; and
- manufacture, market, distribute and sell any products that we develop.

In a number of countries, including in particular, developing countries, government officials and other groups have suggested that pharmaceutical companies should make drugs available at a low cost. In some cases, governmental authorities have indicated that where pharmaceutical companies do not do so, their patents might not be enforceable to prevent generic competition. Some major pharmaceutical companies have greatly reduced prices for their drugs in certain developing countries. If certain countries do not permit enforcement of any of our patents, sales of our products in those countries, and in other countries by importation from low-price countries, could be reduced by generic competition or by parallel importation of our product. Alternatively, governments in those countries could require that we grant compulsory licenses to allow competitors to manufacture and sell their own versions of our products in those countries, thereby reducing our product sales, or we could respond to governmental concerns by reducing prices for our products. In all of these situations, our results of operations could be adversely affected.

Government Regulation

Our ongoing research and development activities and any manufacturing and marketing of our drug candidates are subject to extensive regulation by numerous governmental authorities in the United States and other countries. Before marketing in the United States, any drug developed by us must undergo rigorous preclinical testing, clinical trials, and an extensive regulatory clearance process implemented by the FDA under the United States Food, Drug and Cosmetic Act and its implementing regulations and, in the case of biologics, the Public Health Service Act. The FDA regulates, among other things, the research, development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution and import and export, of these products.

FDA Review and Approval Process

The regulatory review and approval process is lengthy, expensive and uncertain. The steps generally required before a drug may be marketed in the United States include:

- preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice and Good Manufacturing Practice regulations;
- submission to the FDA of an Investigational New Drug application (IND) for human clinical testing, which must become effective before human clinical trials may commence;
- performance of adequate and well-controlled clinical trials in three phases, as described below, to establish the safety and efficacy of the drug for each indication;
- submission of an NDA or Biologics License Application (BLA) to the FDA for review;
- random inspections of clinical sites to ensure validity of clinical safety and efficacy data;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices;
- FDA approval of the NDA or BLA; and
- payment of user and establishment fees, if applicable.

Similar requirements exist within foreign agencies as well. The time required to satisfy FDA requirements or similar requirements of foreign regulatory agencies may vary substantially based on the type, complexity and novelty of the product or the targeted disease.

Preclinical testing includes laboratory evaluation of product pharmacology, drug metabolism, and toxicity which includes animal studies, to assess potential safety and efficacy as well as product chemistry, stability, formulation, development, and testing. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time, the FDA raises safety concerns or questions about the conduct of the clinical trial(s) included in the IND. In the latter case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators and in accordance with good clinical practices regulations covering the protection of human subjects. These regulations require all research subjects to provide informed consent. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND and each trial must be reviewed and approved by an institutional review board (IRB) before it can begin.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase I usually involves the initial introduction of the investigational drug into healthy volunteers to evaluate its safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase II usually involves clinical trials in a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse effects and safety risks, and evaluate and gain preliminary evidence of the efficacy of the drug for specific indications. Phase III clinical trials usually further evaluate clinical efficacy and safety by testing the drug in its final form in an expanded patient population, providing statistical evidence of efficacy and safety, and providing an adequate basis for labeling. We cannot guarantee that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the IRB, or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

As a separate amendment to an IND, a clinical trial sponsor may submit to the FDA a request for a Special Protocol Assessment ("SPA"). Under the SPA procedure, a sponsor may seek the FDA's agreement on the design and size of a clinical trial intended to form the primary basis of an effectiveness claim. If the FDA agrees in writing, its agreement may not be changed after the trial begins, except when agreed by FDA or in limited circumstances, such as when a

substantial scientific issue essential to determining the safety and effectiveness of a drug candidate is identified after a Phase III clinical trial is commenced and agreement is obtained with the FDA. If the outcome of the trial is successful, the sponsor will ordinarily be able to rely on it as the primary basis for approval with respect to effectiveness. However, additional trials could also be requested by the FDA to support approval, and the FDA may make an approval decision based on a number of factors, including the degree of clinical benefit as well as safety. The FDA is not obligated to approve an NDA or BLA as a result of an SPA agreement, even if the clinical outcome is positive.

Even after initial FDA approval has been obtained, post-approval trials, or Phase IV studies, may be required to provide additional data, and will be required to obtain approval for the sale of a product as a treatment for a clinical indication other than that for which the product was initially tested and approved. Also, the FDA will require post-approval safety reporting to monitor the side effects of the drug. Results of post-approval programs may limit or expand the indication or indications for which the drug product may be marketed. Further, if there are any requests for modifications to the initial FDA approval for the drug, including changes in indication, manufacturing process, manufacturing facilities, or labeling, a supplemental NDA or BLA may be required to be submitted to the FDA.

The length of time and related costs necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or cause the costs of these clinical trials to increase, include:

- slow patient enrollment due to the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the study, competition with clinical trials for other drug candidates or other factors;
- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials;
- delays in approvals from a study site’s IRB;
- longer than anticipated treatment time required to demonstrate effectiveness or determine the appropriate product dose;
- lack of sufficient supplies of the drug candidate for use in clinical trials;
- adverse medical events or side effects in treated patients; and
- lack of effectiveness of the drug candidate being tested.

Any drug is likely to produce some toxicities or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for sufficiently long periods of time. Unacceptable toxicities or side effects may occur at any dose level, and at any time in the course of animal studies designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or in clinical trials of our drug candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates, and could ultimately prevent their marketing approval by the FDA or foreign regulatory authorities for any or all targeted indications.

The FDA’s fast track and breakthrough therapy designation programs are intended to facilitate the development and expedite the review of drug candidates intended for the treatment of serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for these conditions. Under these programs, FDA can, for example, review portions of an NDA or BLA for a drug candidate before the entire application is complete, thus potentially beginning the review process at an earlier time.

We cannot guarantee that the FDA will grant any of our requests for fast track or breakthrough therapy designations, that any such designations would affect the time of review or that the FDA will approve the NDA or BLA submitted for any of our drug candidates, whether or not these designations are granted. Additionally, FDA approval of a fast track/breakthrough product can include restrictions on the product’s use or distribution (such as permitting use only for specified medical conditions or limiting distribution to physicians or facilities with special training or experience). Approval of such designated products can be conditioned on additional clinical trials after approval.

Sponsors submit the results of preclinical studies and clinical trials to the FDA as part of an NDA or BLA. NDAs and BLAs must also contain extensive product manufacturing information and proposed labeling. Upon receipt, the FDA

initially reviews the NDA or BLA to determine whether it is sufficiently complete to initiate a substantive review. If the FDA identifies deficiencies that would preclude substantive review, the FDA will refuse to accept the NDA or BLA and will inform the sponsor of the deficiencies that must be corrected prior to resubmission. If the FDA accepts the submission for review (then deemed a "filing"), the FDA typically completes the NDA or BLA review within a pre-determined time frame. Under the Prescription Drug User Fee Act, the FDA agrees to review NDAs and BLAs under either a standard review or priority review. FDA procedures provide for priority review of NDAs and BLAs submitted for drugs that, compared to currently marketed products, if any, offer a significant improvement in the treatment, diagnosis or prevention of a disease. The FDA seeks to review NDAs and BLAs that are granted priority status more quickly than NDAs and BLAs given standard review status. The FDA's stated policy is to act on 90% of priority NDAs and BLAs within eight months of receipt (or six months after filing, which occurs 60 days after NDA or BLA submission). Although the FDA historically has not met these goals, the agency has made significant improvements in the timeliness of the review process. NDA and BLA review often extends beyond anticipated completion dates due to FDA requests for additional data or clarification, the FDA's decision to have an advisory committee review, and difficulties in scheduling an advisory committee meeting. The recommendations of an advisory committee are not binding on the FDA.

To obtain FDA approval to market a product, we must demonstrate that the product is safe and effective for the patient population that will be treated. If regulatory approval of a product is granted, the approval will be limited to those disease states and conditions for which the product is safe and effective, as demonstrated through clinical trials. Marketing or promoting a drug for an unapproved indication is prohibited. Furthermore, approval may entail requirements for post-marketing studies or risk evaluation and mitigation strategies, including the need for patient and/or physician education, patient registries, medication or similar guides, or other restrictions on the distribution of the product. If an NDA or BLA does not satisfy applicable regulatory criteria, the FDA may deny approval of an NDA or BLA or may issue a complete response, and require, among other things, additional clinical data or analyses.

In Canada, the Therapeutic Products Directorate and the Biologics and Genetic Therapies Directorate of HC ensure that clinical trials are properly designed and undertaken and that subjects are not exposed to undue risk. Regulations define specific Investigational New Drug Submission (or IND) application requirements, which must be complied with before a new drug can be distributed for trial purposes. The Directorates currently review the safety, efficacy and quality data submitted by the sponsor and approve the distribution of the drug to the investigator. The sponsor of the trial is required to maintain accurate records, report adverse drug reactions, and ensure that the investigator adheres to the approved protocol. Trials in humans should be conducted according to generally accepted principles of good clinical practice. Management believes that these standards provide assurance that the data and reported results are credible and accurate, and that the rights, integrity, and privacy of clinical trial subjects are protected.

Sponsors wishing to conduct clinical trials in Phases I to III of development must apply under a 30-day default system. Applications must contain the information described in the regulations, including: a clinical trial attestation; a protocol; statements to be contained in each informed consent form, that set out the risks posed to the health of clinical trial subjects as a result of their participation in the clinical trial; an investigator's brochure; applicable information on excipients (delivery vehicles); and chemistry and manufacturing information.

The sponsor can proceed with the clinical trial if the Directorates have not objected to the sale or importation of the drug within 30 days after the date of receipt of the clinical trial application and Research Ethics Board approval for the conduct of the trial at the site has been obtained. Additional information is available on Health Canada's website - www. hc-sc. gc. ca.

Outside the United States and Canada, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union (EU) registration procedures are available to companies wishing to market a product in more than one EU member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization may be granted. This foreign regulatory approval process involves all of the risks associated with FDA approval discussed above and may also include additional risks.

The Orphan Drug Act provides incentives to manufacturers to develop and market drugs for rare diseases and conditions affecting fewer than 200,000 persons in the United States at the time of application for orphan drug designation. The first developer to receive FDA marketing approval for an orphan drug is entitled to a seven year exclusive marketing period in the United States for the orphan drug indication. However, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven year exclusive marketing period.

Under the FDA Modernization Act of 1997, designation as a Fast Track product for a new drug or biological product means that the FDA will take such actions as are appropriate to expedite the development and review of the application for approval of such product.

Legislation similar to the Orphan Drug Act has been enacted in other countries outside of the United States, including the EU. The orphan legislation in the EU is available for therapies addressing conditions that affect five or fewer out of 10,000 persons, are life-threatening or chronically debilitating conditions and for which no satisfactory treatment is authorized. The market exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product does not justify maintenance of market exclusivity.

Regulation of Manufacturing Process

Even when NDA or BLA approval is obtained, a marketed product, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the FDA. The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product, manufacturer or facility, including costly recalls or withdrawal of the product from the market. Manufacturing facilities are always subject to inspection by the applicable regulatory authorities.

We and our third-party manufacturers are subject to current Good Manufacturing Practices, which are extensive regulations governing manufacturing processes, including but not limited to stability testing, record keeping and quality standards as defined by the FDA and the European Medicines Agency. Similar regulations are in effect in other countries. Manufacturing facilities are subject to inspection by the applicable regulatory authorities. These facilities, whether our own or our contract manufacturers, must be inspected before we can use them in commercial manufacturing of our related products. We or our contract manufacturers may not be able to comply with applicable Good Manufacturing Practices and FDA or other regulatory requirements. If we or our contract manufacturers fail to comply, we or our contract manufacturers may be subject to legal or regulatory action, such as suspension of manufacturing, seizure of product, or voluntary recall of product. Furthermore, continued compliance with applicable Good Manufacturing Practices will require continual expenditure of time, money and effort on the part of us or our contract manufacturers in the areas of production and quality control and record keeping and reporting, in order to ensure full compliance.

Post-Approval Regulation

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the drug and other reporting, advertising and promotion restrictions. The FDA's rules for advertising and promotion require, among other things, that our promotion be fairly balanced and adequately substantiated by clinical studies, and that we not promote our products for unapproved uses. We must also submit appropriate new and supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. On its own initiative, the FDA may require changes to the labeling of an approved drug if it becomes aware of new safety information that the agency believes should be included in the approved drug's labeling. The FDA also enforces the requirements of the Prescription Drug Marketing Act, or PDMA, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

In addition to inspections related to manufacturing, we may be subject to periodic unannounced inspections by the FDA and other regulatory bodies related to the other regulatory requirements that apply to marketed drugs manufactured or distributed by us. The FDA also may conduct periodic inspections regarding our review and reporting of adverse events, or related to compliance with the requirements of the PDMA concerning the handling of drug samples. When the FDA conducts an inspection, the inspectors will identify any deficiencies they believe exist in the form of a notice of inspectional observations. The observations may be more or less significant. If we receive a notice of inspectional observations, we likely will be required to respond in writing, and may be required to undertake corrective and preventive actions in order to address the FDA's concerns.

There are a variety of state laws and regulations that apply in the states or localities where our drug candidates may be marketed. For example, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in that state, including, in certain states, manufacturers and distributors who

ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Any applicable state or local regulations may hinder our ability to market, or increase the cost of marketing, our products in those states or localities.

The FDA's policies may change and additional government regulations may be enacted which could impose additional burdens or limitations on our ability to market products after approval. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations which could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation which might arise from future legislative or administrative action, either in the United States or abroad.

Marketing Exclusivity

The FDA may grant five years of exclusivity in the United States for the approval of NDAs for new chemical entities, and three years of exclusivity for supplemental NDAs, for among other things, new indications, dosages or dosage forms of an existing drug if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the supplemental application. Additionally, six months of marketing exclusivity in the United States is available if, in response to a written request from the FDA, a sponsor submits and the agency accepts requested information relating to the use of the approved drug in the pediatric population. The six month pediatric exclusivity is added to any existing patent or non-patent exclusivity period for which the drug is eligible. Orphan drug products are also eligible for pediatric exclusivity if the FDA requests and the company completes pediatric clinical trials. Under the Biologics Price Competition and Innovation Act, the FDA may grant 12 years of data exclusivity for innovative biological products.

Health Law Compliance

In addition to FDA laws and regulations, we must also comply with various federal and state laws and regulations pertaining to healthcare "fraud and abuse" laws which govern, among other things, our relationships with healthcare providers, and organizations such as specialty pharmacies, wholesalers and group purchasing organizations relating to the marketing and pricing of prescription drug products. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, and physician payment sunshine laws.

The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated.

Federal false claims and false statement laws, including the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. Entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, or for providing medically unnecessary services or items.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, require certain types of individuals and entities to protect the privacy, security, and electronic exchange of certain patient data.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members.

Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government. Further, we may be subject to state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, as well as state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. If our operations are found to be in violation of any of these federal, state or foreign laws or regulations, we may be subject to penalties, including without limitation, administrative or civil penalties, imprisonment, damages, fines, disgorgement, exclusion from participation in government healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, or the curtailment or restructuring of our operations.

There are also an increasing number of state laws that require manufacturers to make reports to those states on certain pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the state authorities.

Healthcare Reform and Reimbursement and Pricing Controls

There has been an increased focus on drug pricing in recent years in the United States. Although there are no direct government price controls over private sector purchases in the United States, there are rebates and other financial requirements for federal and state health care programs. The Medicare Modernization Act, enacted in December 2003, established the Medicare Part D outpatient prescription drug benefit, which is provided primarily through private entities that attempt to negotiate price concessions from pharmaceutical manufacturers. The health care reform legislation enacted in 2010, known as the Affordable Care Act, requires drug manufacturers to pay 50% of the Medicare Part D coverage gap, also known as the "donut hole," on prescriptions for branded products filled when the beneficiary reaches this coverage. The Deficit Reduction Act of 2005 resulted in changes to the way drug prices are reported to the government and the formula using such information to calculate the required Medicaid rebates. The Affordable Care Act increased the minimum basic Medicaid rebate for branded prescription drugs from 15.1% to 23.1% and requires pharmaceutical manufacturers to pay states rebates on prescription drugs dispensed to Medicaid managed care enrollees. In addition, the Affordable Care Act increased the additional Medicaid rebate on "line extensions" (such as extended release formulations) of solid oral dosage forms of branded products, revised the definition of average manufacturer price by changing the classes of purchasers included in the calculation, and expanded the entities eligible for discounted pricing under the federal 340B drug pricing program. Current orphan drugs are excluded from the expanded 340B hospitals eligible for discounts.

The Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. The fee (which is not deductible for federal income tax purposes) is based on the manufacturer's market share of sales of branded drugs and biologics (excluding orphan drugs) to, or pursuant to coverage under, specified U. S. government programs. The Affordable Care Act also contains a number of provisions, including provisions governing the way that health care is financed by both governmental and private insurers, enrollment in federal health care programs, reimbursement changes, the increased use of comparative effectiveness research in health care decision-making, and enhancements to fraud and abuse requirements and enforcement, that are affecting existing government health care programs and will result in the development of new programs. The Affordable Care Act also contains requirements for manufacturers to publicly report certain payments or other transfers of value made to physicians and teaching hospitals. We are unable to predict the future course of federal or state health care legislation and regulations, including regulations that will be issued to implement provisions of the Affordable Care Act. The Affordable Care Act and further changes in the law or regulatory framework that reduce our revenues or increase our costs could also have a material adverse effect on our business, financial condition and results of operations and cash flows.

Public and private health care payers control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payers also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. Payers may require physicians to seek approval from them before a product will be reimbursed or covered, commonly referred to as prior authorization. In particular, many public and private health care payers limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA. For example, in the case of Medicare Part D coverage for oncology drugs, the Medicare Modernization Act, with certain exceptions, provides for Medicare coverage of unapproved uses of an FDA-approved drug if the unapproved use is reasonable and necessary and is supported by one or more citations in CMS-approved compendia, such as the National Comprehensive Cancer Network Drugs and Biologics Compendium. Different pricing and reimbursement schemes exist in other countries. For example, in the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits and may limit or restrict reimbursement. The downward pressure on health care costs in general, and prescription drugs in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the actions of the National Institute for Clinical Excellence in the United Kingdom, which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert a commercial pressure on pricing within a country.

Manufacturing

Our manufacturing strategy is to contract with third parties to manufacture the raw materials, our active pharmaceutical ingredients, or API, and finished solid dose products for clinical and ultimately commercial uses. We currently do not operate manufacturing facilities for clinical or commercial production our drug candidates. In addition, we expect for the foreseeable future to continue to rely on third parties for the manufacture of commercial supplies of the raw materials, API and finished drug product for any drugs that we successfully develop and are approved for commercial sale. In this manner, we expect to continue to build and maintain our supply chain and quality assurance resources.

Manufacturing of our Products

Our supply chain for manufacturing raw materials, API and drug product ready for distribution and commercialization is a multi-step international process. Establishing and managing the supply chain requires a significant financial commitment and the creation and maintenance of numerous third-party contractual relationships.

We contract with third parties to manufacture our drug candidates for clinical purposes. Third-party manufacturers supply us with raw materials, and other third-party manufacturers convert these raw materials into API or convert the API into final dosage form. For most of our drug candidates, once our raw materials are produced, we rely on one third party to manufacture the API, another to make finished drug product and a third to lyophilize, package and label the finished product. While we currently have focused on single vendors for manufacturing of peptide, formulation development, and lyophilization and vialing, there are a number of vendors we are in contact with and can also use if required.

We may not be able to obtain sufficient quantities of any of our raw materials or drug candidates if our designated manufacturers do not have the capacity or capability to manufacture our products according to our schedule and specifications. If any of these single source suppliers were to become unable or unwilling to supply us with API or finished product that complies with applicable regulatory requirements, we could incur significant delays in our clinical trials which could have a material adverse effect on our business.

We have established a quality assurance program intended to ensure that our third-party manufacturers and service providers produce materials and provide services, when applicable, in accordance with the FDA’s current Good Manufacturing Practices and other applicable regulations.

For our future products, we intend to continue to establish third-party suppliers to manufacture sufficient quantities of our drug candidates to undertake clinical trials and to manufacture sufficient quantities of any product that is approved

for commercial sale. If we are unable to contract for large scale manufacturing with third parties on acceptable terms for our future products or develop manufacturing capabilities internally, our ability to conduct large scale clinical trials and ultimately meet customer demand for commercial products will be adversely affected.

Third-party Manufacturers

Our third-party manufacturers are independent entities, under contract with us, who are subject to their own unique operational and financial risks which are out of our control. If we or any of our third-party manufacturers fail to perform as required, this could impair our ability to deliver our products on a timely basis or cause delays in our clinical trials and applications for regulatory approval. To the extent these risks materialize and affect their performance obligations to us, our financial results may be adversely affected.

While we believe there are multiple third parties capable of providing most of the materials and services we need in order to manufacture our product candidates, and that supply of materials that cannot be second-sourced can be managed with inventory planning, there is always a risk that we may underestimate demand, and that our manufacturing capacity through third-party manufacturers may not be sufficient.

Access to Supplies and Materials

Our third-party manufacturers need access to certain supplies and products to manufacture our drug candidates. If delivery of material from their suppliers were interrupted for any reason or if they are unable to purchase sufficient quantities of raw materials used to manufacture our drug candidates, they may be unable to supply our drug candidates in development for clinical trials.

Research and Development

Since our inception, we have made substantial investments in research and technology development. During the years ended December 31, 2015 and 2014, we incurred research and development expenses of $1,711,000, and $189,000, respectively.

Product Liability and Insurance

Once we are able to commence the sale of our products into the market, we will face the risk of product liability claims. Because we are not yet selling our products, we have not experienced any product liability claims to date and we do not yet maintain product liability insurance. Management intends to maintain product liability insurance consistent with industry standards upon commencement of the marketing and distribution. There can be no assurance that product liability claims will not exceed such insurance coverage limits, which could have a materially adverse effect on our business, financial condition or results of operations or that such insurance will continue to be available on commercially reasonable terms, if at all.

Human Resources

Employees. We currently have four full-time employees. The management team is comprised of Dr. Glynn Wilson (Chief Executive Officer, Principal Executive Officer and Acting Principal Accounting Officer), a Director of Administration and a VP & Chief Medical Officer (Patrick Yeramian, MD), a Senior Clinical Associate, and a Project Management Director.

Consultants. We have consulting agreements with a number of leading academic scientists, clinicians and regulatory experts. These individuals serve as key consultants or expert witnesses with respect to the imetelstat program or in legal proceedings. They also serve as important contacts for us throughout the broader scientific and clinical communities. They are distinguished individuals with expertise in numerous fields, including cellular biology, molecular biology, oncology, clinical, manufacturing and regulatory. Dr. Robert Florkiewicz, formerly an employee serving as Senior Director of Molecular Biology and Virology, is now a consultant to the Company and also serves as a strategic advisor. Dr. John Bonfiglio serves as a consultant to us and provides strategic advice as part of his services.

We retain each consultant according to the terms of a consulting agreement. Under such agreements, we pay them a consulting fee and reimburse them for out-of-pocket expenses incurred in performing their services for us. In addition, some consultants hold options to purchase our common stock, subject to the vesting requirements contained in the consulting agreements. Our consultants may be employed by other entities and therefore may have commitments to their employer, or may have other consulting or advisory agreements that may limit their availability to us.

Available Information

Our website is located at *www. tapimmune. com*. We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission. Our website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below before making an investment decision in our securities. These risk factors are effective as of the date of this Form 10-K and shall be deemed to be modified or superseded to the extent that a statement contained in our future filings modifies or replaces such statement. All of these risks may impair our business operations. The forward-looking statements in this Form 10-K involve risks and uncertainties and actual results may differ materially from the results we discuss in the forward-looking statements. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected. In that case, the trading price of our stock could decline, and you may lose all or part of your investment.

Risks Related to our Financial Position and Capital Needs

We will need to raise additional capital in the future to continue to operate our business and this capital might not be available on acceptable terms, if at all.

Since we have no sources of revenue to provide incoming cash flows to sustain our future operations, our ability to pursue our planned business activities is dependent upon our successful efforts to raise additional capital. As of December 31, 2015, we had cash and cash equivalents of approximately $6,577,000 and we anticipate that our cash resources will be sufficient to fund our research efforts and operations as presently structured through the end of 2016. Accordingly, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings or debt financings or through a business combination or strategic partnership. Additional capital, if needed, may not be available on satisfactory terms, or at all. Furthermore, if we raise additional funds by issuing equity securities, dilution to our existing stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we are unable to obtain adequate financing or financing on terms acceptable to we may not be able to sustain our future operations and may be required to suspend our research efforts and reduce or cease our operations.

Our auditor has expressed substantial doubt about our ability to continue as a going concern and absent additional financing we may be unable to remain a going concern.

In light of our recurring losses, accumulated deficit and negative cash flow as described in our notes to our audited financial statements, the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2015 contains an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may be necessary in the event we are unable to continue as a going concern. If we are unable to establish to the satisfaction of our independent registered public accounting firm that the net proceeds from our financing efforts will be sufficient to allow for the removal of this going concern qualification, we may need to significantly modify our operational plans for us to continue as a going concern. We believe we can continue our current level of operations with the cash we have on hand without additional financing until the end of 2016. Absent sufficient additional financing, we may be unable to remain a going concern.

We are a development stage company with a history of operating losses.

We are a clinical-stage immunotherapy company with a history of losses, and we may always operate at a loss. We expect that we will continue to operate at a loss throughout our development stage, and as a result, we may exhaust our financial resources and be unable to complete the development of our products. We anticipate that our ongoing operational costs will increase significantly as we continue conducting our clinical development program. Our deficit will continue to grow during our drug development period. We have no sources of revenue to provide incoming cash flows to sustain our future operations. As outlined above, our ability to pursue our planned business activities depends upon our successful efforts to raise additional equity financing

We have sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future due to the substantial investment in research and development. As of December 31, 2015, we had an accumulated deficit of $133,508,000 since inception. We expect to spend substantial additional sums on the continued administration and research and development of licensed and proprietary products and technologies with no certainty that our approach and associated technologies will become commercially viable or profitable as a result of

these expenditures. If we fail to raise a significant amount of capital, we may need to significantly curtail operations or cease operations in the near future. If any of our product candidates fails in clinical trials or does not gain regulatory approval, we may never generate revenue. Even if we generate revenue in the future, we may not be able to become profitable or sustain profitability in subsequent periods.

We have not yet sold any products or received regulatory approval to sell our products.

We have no approved products or products pending approval. As a result, we have not derived any revenue from the sales of products and have not yet demonstrated ability to obtain regulatory approval, formulate and manufacture commercial scale products, or conduct sales and marketing activities necessary for successful product commercialization. Without revenue, we can only finance our company through debt and equity financings.

Upon certain fundamental transactions involving the Company, such as a merger or sale of substantially all of our assets, we may be required to make cash payments to our warrant holders which would reduce the amount of the distributions otherwise to be made to the holders of our common stock in connection with such transactions.

As of March 15, 2016, we had outstanding warrants to purchase an aggregate of 52,106,497 shares of our common stock with exercise prices ranging between $0.10 and $25.00. The terms of the warrants provide that upon a Fundamental Transaction (as defined in the warrant) the holder shall have the right to have the warrant purchased by the Company for cash at its Black Scholes Value (as defined in the warrant). The term Fundamental Transaction includes a merger, sale of substantially all of our assets, or if any person shall acquire 50% or more of the voting power of our shares. The Black Scholes Value (as defined in the warrants) payable for all of the outstanding warrants as of December 31, 2015 was approximately $26 million.

Risks Related to our Business and Intellectual Property

We may be required to make additional cash payments to warrant holders in the event any registration statement we have filed with the SEC to register the shares issuable upon exercise of the warrants ceases to be effective and we are unable to deliver registered shares.

Since we are required to deliver unlegended registered shares of common stock to certain of the warrant holders acquiring warrants in our 2015 Financings upon exercise of such outstanding warrants, we have filed a registration statement with the SEC to register such shares. The registration statement permits registered shares of common stock to be issued upon the exercise of such warrants. In some cases, we would be required to make additional cash payments to such warrant holders if we fail to maintain the effectiveness of the relevant registration statement for the issuance of such registered shares upon an exercise by the warrant holder. For each trading day that the shares are not timely delivered we would be required to pay an amount to the holder equal to 1% of the product of (A) the aggregate number of shares not issued to the holder on a timely basis and to which the holder is entitled and (B) the closing sale price of our common stock on the trading day immediately preceding the last possible date on which we could have issued such shares to the holder. Additionally we could be required to pay the holder a “buy-in” if the holder is required to purchase shares on the open market to cover any warrant shares sold. As such, the amount of additional cash payments we would be required to make could be substantial, as a percentage of our cash, if we are unable to deliver registered shares upon the warrant exercise. Currently, the registration statements we have filed are not able to be used until such time as appropriate post-effective amendments to the registration statements can be filed by us and ultimately be declared effective by the Securities and Exchange Commission. While we expect to file such amendments to our registration statements promptly after our Form 10-K is filed, there can be no assurance that we will be able to file such amendments or have the post-effective amendments to our registration statements declared effective. During such time that we are not able to provide an effective registration statement and to the extent we receive any notices of exercises related to the warrants with such rights, we would be unable to deliver registered shares. In such event we could be required to make cash payments to an exercising warrant holder. We may not be able to make the required cash payments and the failure to do so could materially harm our financial condition and operations.

We may not be able to develop products successfully or develop them on a timely basis.

Our immunotherapy product candidates are at various stages of research and development. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. We will need to complete significant additional clinical trials demonstrating that our product candidates are safe and effective to the satisfaction of the FDA and other non-U. S. regulatory authorities. The drug approval process is time-consuming, which involves substantial expenditures of resources, and depends upon a number of factors, including the severity of the illness in question, the availability of alternative treatments, and the risks and benefits demonstrated in the clinical

trials. Our success depends on our ability to achieve scientific and technological advances and to translate such advances into licensable, FDA-approvable, commercially competitive products on a timely basis. Failure can occur at any stage of the process. If such programs are not successful, we may be unable to develop revenue-producing products. As we enter a more extensive clinical program for our product candidates, the data generated in these studies may not be as compelling as the earlier results.

Immunotherapies and vaccines that we may develop are not likely to be commercially available for three or more years. Any delay in obtaining FDA and/or other necessary regulatory approvals in the United States and in countries outside the United States for any investigational new drug and failure to receive such approvals would have an adverse effect on the investigational new drug's potential commercial success and on our business, prospects, financial condition and results of operations. The time required to obtain approval by the FDA and non-U. S. regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. For example, the FDA or non-U. S. regulatory authorities may disagree with the design or implementation of our clinical trials or study endpoints; or we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks. In addition, the FDA or non-U. S. regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials or the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application ("NDA") or other submission or to obtain regulatory approval in the United States or elsewhere. The FDA or non-U.S. regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA or non-U.S. regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. The proposed development schedules for our immunotherapy product candidates may be affected by a variety of other factors, including technological difficulties, clinical trial failures, regulatory hurdles, competitive products, intellectual property challenges and/or changes in governmental regulation, many of which will not be within our control.

Any delay in the development, approval, introduction or marketing of our products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects, the unproven technology involved and the other factors described elsewhere in this section, we might not be able to successfully complete the development or marketing of any new products, and as a result, our business, prospects, financial condition and results of operations could be materially and adversely affected. We may be required to reduce our staff, discontinue certain research or development programs of our future products and cease to operate.

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and the medical community.

Even if we obtain regulatory approval for our product candidates, they may not gain market acceptance among physicians, healthcare payors, patients or the medical community. Market acceptance of our product candidates, if we receive approval, depends on a number of factors, including the:

- efficacy and safety of our product candidates as demonstrated in clinical trials and post-marketing experience;
- clinical indications for which our product candidates may be approved;
- acceptance by physicians and patients of our product candidates as safe and effective;
- potential and perceived advantages of our product candidates over alternative treatments;
- safety of our product candidates seen in a broader patient group, including its use outside the approved indications should physicians choose to prescribe for such uses;
- prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- timing of market introduction of our product candidates as well as competitive products;
- cost in relation to alternative treatments;
- availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration; and
- effectiveness of any sales and marketing efforts.

Moreover, if our product candidates are approved but fail to achieve market acceptance among physicians, patients, healthcare payors and the medical community, we may not be able to generate significant revenues, which would compromise our ability to become profitable.

We may face legal claims; Litigation is expensive and we may not be able to afford the costs.

We may face legal claims involving stockholders, consumers, competitors, entities from whom we license technology, entities with whom we collaborate, persons claiming that we are infringing on their intellectual property and others. As described in the discussion entitled “Legal Proceedings” in this statement, we are engaged in one legal proceeding, in which we could suffer significant financial losses. Legal proceedings are inherently uncertain, and adverse rulings could occur, including monetary damages, or an injunction stopping us from engaging in business practices, or requiring other remedies, such as compulsory licensing of patents.

The costs of litigation or any proceeding relating to our intellectual property or contractual rights could be substantial even if resolved in our favor. Some of our competitors or financial funding sources have far greater resources than we do and may be better able to afford the costs of complex legal procedures. Also, in a law suit for infringement or contractual breaches, even if frivolous, will require considerable time commitments on the part of management, its attorneys and consultants. Defending these types of proceedings or legal actions involve considerable expense and could negatively affect our financial results.

Our research and development programs are subject to uncertainty.

Factors affecting our research and development programs include, but are not limited to:

- competition from companies that are substantially and financially stronger than we are;
- need for acceptance of our Immunotherapies;
- our ability to anticipate and adapt to a competitive market and rapid technological developments;
- amount and timing of operating costs and capital expenditures relating to expansion of our business, operations and infrastructure;
- need to rely on multiple levels of outside funding due to the length of drug development cycles and governmental approved protocols associated with the pharmaceutical industry; and
- dependence upon key personnel including key independent consultants and advisors.

Our research and development expenses may not be consistent from time to time. We may be required to accelerate or delay incurring certain expenses depending on the results of our studies and the availability of adequate funding.

Certain of our technologies are in-licensed from third parties, and the protection of those technologies is not entirely within our control.

We license technologies from a third party, the Mayo Clinic, for: (i) the Her2/neu peptide epitopes, (ii) a novel set of Class II HER2/neu antigens discovered in breast cancer patients and (iii) a novel smallpox peptide antigens. In addition, we have an option, which we intend to exercise, to license the Folate Alpha Receptor technology from the Mayo Clinic. As a result of these in-licenses, we could lose the right to develop each of the technologies if:

- the owners of the patent rights underlying the technologies that we license do not properly maintain or enforce the patents and intellectual property underlying those properties,
- the Mayo Clinic seeks to terminate our license in contravention of the license agreements,
- we fail to make all payments due and owing under any of the licenses or,
- we fail to obtain on commercially reasonable terms, if at all, in-licenses from the Mayo Clinic or other for other rights that are necessary to develop the technology that we have already in-licensed.

If any of the above occurs, we could lose the right to use the in-licensed intellectual property, which would adversely affect our ability to commercialize our technologies, products or services. The loss of any current or future licenses from Mayo Clinic or the exclusivity rights provided therein could materially harm our financial condition and operating results.

We have an option to acquire an exclusive in-license technology from a third party, and if that party does not protect its license, we could lose the opportunity to develop that technology.

In 2014, Ayer Special Situations Funds I, LP ("Ayer") obtained an exclusive in-license from the Mayo Clinic to the Folate Alpha Receptor technology, and we obtained an option to acquire that exclusive in-license from Ayer. If Ayer does not maintain the in-license technology or, in contradiction of the terms of our agreement with Ayer, transfers it another party or relinquishes the in-license, our competitive position and business prospects could be harmed. Ayer also may seek to terminate our option to acquire the in-license, which could cause us to lose the right to use the right to develop intellectual property and adversely affect our ability to commercialize our technologies, products or services.

We rely upon patents to protect our technology. We may be unable to protect our intellectual property rights, and we may be liable for infringing the intellectual property rights of others.

Our ability to compete effectively depends on our ability to maintain the proprietary nature of our technologies, including Polystart, and the proprietary technology of others with whom we have entered into collaboration and licensing agreements.

We own or hold licenses to a number of issued patents and U. S. pending patent applications, as well as foreign patents and foreign counterparts. Our success depends in part on our ability to obtain patent protection both in the United States and abroad for our product candidates, as well as the methods for treating patients in the product indications using these product candidates. Such patent protection is costly to obtain and maintain, and sufficient funds might not be available. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if our product candidates, as well as methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Accordingly, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes.

In addition, we cannot guarantee that any patents will be issued from any pending or future patent applications owned by or licensed to us. Even if patents have been issued or will be issued, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries offer different degrees of protection against use of the patented invention by others. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated, or circumvented. Our patents can be challenged by our competitors who can argue that our patents are invalid, unenforceable, lack sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without infringing our patents.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our technologies, methods of treatment, product candidates, and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets and we have the funds to enforce our rights, if necessary.

The expiration of our owned or licensed patents before completing the research and development of our product candidates and receiving all required approvals in order to sell and distribute the products on a commercial scale can adversely affect our business and results of operations.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

If we are unable to obtain licenses needed for the development of our product candidates, or if we breach any of the agreements under which we license rights to patents or other intellectual property from third parties, we could lose license rights that are important to our business.

If we are unable to maintain and/or obtain licenses needed for the development of our product candidates in the future, we may have to develop alternatives to avoid infringing on the patents of others, potentially causing increased costs and delays in drug development and introduction or precluding the development, manufacture, or sale of planned products. Some of our licenses provide for limited periods of exclusivity that require minimum license fees and payments and/or may be extended only with the consent of the licensor. We might not meet these minimum license fees in the future or these third parties might not grant extensions on any or all such licenses. This same restriction may be contained in licenses obtained in the future.

Additionally, the patents underlying the licenses might not be valid and enforceable. To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical. In addition, the loss of any current or future licenses or the exclusivity rights provided therein could materially harm our business financial condition and our operations.

We may not obtain or maintain the benefits associated with orphan drug designation, including market exclusivity.

We plan to present Phase II advancement plans in early 2016 for the Folate Alpha Receptor technology in the form of an application for orphan drug status. If we are not granted orphan drug designation, the Phase II trial will be significantly longer and costlier than we currently anticipate. Even if granted, we may not receive the benefits associated with orphan drug designation. This may result from a failure to maintain orphan drug status, or result from a competing product reaching the market that has an orphan designation for the same disease indication. Under U. S. regulations for orphan drugs, if such a competing product reaches the market before ours does, the competing product could potentially obtain a scope of market exclusivity that limits or precludes our product from being sold in the United States for seven years. Even if we obtain exclusivity, the FDA could subsequently approve a drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. A competitor also may receive approval of different products for the same indication for which our orphan product has exclusivity, or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

In addition, if and when we request orphan drug designation in Europe, the European exclusivity period is ten years but can be reduced to six years if the drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMEA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We have no manufacturing experience and have no manufacturing facility. We are dependent on third-party manufacturers for the manufacture of our product candidates as well as on third parties for our supply chain, and if we experience problems with any such third parties, the manufacturing of our product candidates could be delayed.

We do not own or operate facilities for the manufacture of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently rely on third party contract manufacturing organizations, or CMOs. To meet our projected needs for pre-clinical and clinical supplies to support

our activities through regulatory approval and commercial manufacturing, the CMOs with whom we currently work may need to increase the scale of production. We may need to identify additional CMOs for continued production of supply for our product candidates. Although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute our product candidates.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to synthesize and manufacture our product candidates or any drugs we may eventually commercialize in accordance with our specifications, and the possibility of termination or nonrenewal of agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities would require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of our product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for such product candidate previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of our product candidates, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties.

Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of our product candidates or their respective key materials for an ongoing pre-clinical study or clinical trial could considerably delay completion of such pre-clinical study or clinical trial, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these key materials after regulatory approval has been obtained for one of our product candidates, the commercial launch of such product candidate would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of that product candidate.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We do not currently have an organization for the sale, marketing and distribution of products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products approved by the FDA or comparable foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

If we are unable to establish or manage strategic collaborations in the future, our revenue and drug development may be limited.

Our strategy includes eventual substantial reliance upon strategic collaborations for marketing and commercialization of our cancer vaccines, and we may rely even more on strategic collaborations for research, development, marketing and commercialization of our other Immunotherapies. If we are unsuccessful in securing such strategic collaborations we may be unable to commercialize our products as we have not yet licensed, marketed or sold any of our Immunotherapies or entered into successful collaborations for these services in order to ultimately commercialize our Immunotherapies. Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, clinical, regulatory or intellectual property position. If we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our Immunotherapies or the generation of sales revenue. To the extent that we enter into co-promotion or other collaborative arrangements, our product revenues are likely to be lower than if we directly marketed and sold any products that we may develop.

Management of our relationships with our collaborators will require:

- significant time and effort from our management team;
- coordination of our research and development programs with the research and development priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

If we continue to enter into research and development collaborations at the early phases of drug development, our success will in part depend on the performance of our corporate collaborators. We will not directly control the amount or timing of resources devoted by our corporate collaborators to activities related to our Immunotherapies. Our corporate collaborators may not commit sufficient resources to our research and development programs or the commercialization, marketing or distribution of our Immunotherapies. If any corporate collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to this collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements.

We need to attract and retain highly skilled personnel; we may be unable to effectively manage growth with our limited resources.

As of March 1, 2016, we had four full-time employees and a number of management and scientific consultants. Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other technology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than we have. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, or integrating them into our operations, our business, prospects, financial condition and results of operations will be materially adversely affected. In such circumstances we may be unable to conduct certain research and development programs, unable to adequately manage our clinical trials and other products, and unable to adequately address our management needs.

We depend upon our senior management and key consultants and their loss or unavailability could put us at a competitive disadvantage.

We depend upon the efforts and abilities of our senior executive, Dr. Glynn Wilson, as well as the services of several key consultants, including Dr. John Bonfiglio and Dr. Robert Florkiewicz. The loss or unavailability of the services of either of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition and results of operations.

Our business and operations would suffer in the event of computer system failures.

Despite the implementation of security measures, our internal computer systems, and those of our manufacturers and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. In addition, our systems safeguard important confidential personal data regarding our subjects. If a disruption event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Risks Related to our Industry

The biotechnology and immunotherapy industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed Immunotherapies could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

We are aware of certain investigational new drugs under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that have the potential to directly compete with our Immunotherapies even though their approach may be different. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical companies. Many of these companies have substantially greater financial, marketing, and human resources than we do. We also experience competition in the development of our Immunotherapies from universities, other research institutions and others in acquiring technology from such universities and institutions.

In addition, certain of our Immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

We are subject to numerous risks inherent in conducting clinical trials.

We outsource the management of our clinical trials to third parties. Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services, place substantial responsibilities on these parties that, if unmet, could result in delays in, or termination of, our clinical trials. If any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, agents. We cannot be certain that we will successfully recruit enough patients to complete our clinical trials nor that we will reach our primary endpoints. Delays in recruitment, lack of clinical benefit or unacceptable side effects would delay or prevent the initiation of the Phase II, clinical trials, planned for early 2016.

We or our regulators may suspend or terminate our clinical trials for a variety of reasons. We may voluntarily suspend or terminate our clinical trials at any time if we believe they present an unacceptable risk to the patients enrolled in our clinical trials or do not demonstrate clinical benefit. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in our clinical trials.

Our clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, and we may be fined, we or our investigators may be precluded from conducting any ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted.

The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval for our product candidates, which would materially harm our business, results of operations and prospects.

The successful development of Immunotherapies is highly uncertain.

Successful development of biopharmaceuticals is highly uncertain and depends on numerous factors, many of which are beyond our control. Immunotherapies that appear promising in the early phases of development may fail to reach the market for several reasons including:

- preclinical study results that may show the immunotherapy to be less effective than desired (e. g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;
- clinical study results that may show the immunotherapy to be less effective than expected (e. g., the study failed to meet its primary endpoint) or to have unacceptable side effects;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis, or Biologics License Application preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the immunotherapy uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent the immunotherapy from being commercialized.

Success in preclinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one immunotherapy to the next, and may be difficult to predict.

Even if we are successful in getting market approval, commercial success of any of our product candidates will also depend in large part on the availability of coverage and adequate reimbursement from third-party payers, including government payers such as the Medicare and Medicaid programs and managed care organizations, which may be affected by existing and future health care reform measures designed to reduce the cost of health care. Third-party payers could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other health care payers were not to provide adequate coverage and reimbursement levels for one any of our products once approved, market acceptance and commercial success would be reduced.

In addition, if one of our products is approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third party providers) comply with Good Manufacturing Practices (“GMPs”) and Good Clinical Practices (‘GCPs’), for any clinical trials that we conduct post-approval. In addition, there is always the risk that we or a regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-market approval could have a material adverse effect on our business, financial condition and results of operations.

We must comply with significant government regulations.

The research and development, manufacture and marketing of human therapeutic and diagnostic products are subject to regulation, primarily by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state, local and foreign entities regulate, among other things, research and development

activities (including testing in animals and in humans) and the testing, manufacturing, handling, labeling, storage, record keeping, approval, advertising and promotion of the products that we are developing. If we obtain approval for any of our product candidates, our operations will be directly or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statue and the federal False Claims Act, and privacy laws. Noncompliance with applicable laws and requirements can result in various adverse consequences, including delay in approving or refusal to approve product licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, civil and criminal penalties, recall or seizure of products, exclusion from having our products reimbursed by federal health care programs, the curtailment or restructuring of our operations, injunctions against shipping products and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts.

The process of obtaining requisite FDA approval has historically been costly and time-consuming. Current FDA requirements for a new human biological product to be marketed in the United States include: (1) the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (2) filing with the FDA of an IND to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational new drug for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a Biologic License Application, or BLA, for a biological investigational new drug, to allow commercial distribution of a biologic product. The FDA also requires that any drug or formulation to be tested in humans be manufactured in accordance with its Good Manufacturing Practices, or GMP, regulations. This has been extended to include any drug that will be tested for safety in animals in support of human testing. The GMPs set certain minimum requirements for procedures, record-keeping and the physical characteristics of the laboratories used in the production of these drugs. A delay in one or more of the procedural steps outlined above could be harmful to us in terms of getting our Immunotherapies through clinical testing and to market.

Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing product candidates to market and harm our ability to operate.

Our success depends in part on our ability to operate without infringing the proprietary rights of third parties. The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the products or use of our technologies infringe these patent claims or that we are employing their proprietary technology without authorization.

In addition, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

- the patentability of our inventions relating to our product candidates; and/or
- the enforceability, validity or scope of protection offered by our patents relating to our product candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

- incur substantial monetary damages;
- encounter significant delays in bringing our product candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of our product candidates or methods of treatment requiring licenses.

We may incur substantial liabilities from any product liability claims if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability exposure related to the testing of our Immunotherapies in human clinical trials, and will face an even greater risk if the approved products are sold commercially. An individual may bring a liability claim against us if one of the Immunotherapies causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our Immunotherapies;
- damage to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- the inability to commercialize Immunotherapies; and
- increased difficulty in raising required additional funds in the private and public capital markets.

We do not have product liability insurance because we are not selling our products yet. We intend to maintain product liability insurance consistent with industry standards upon commencement of the marketing and distribution. There can be no assurance that product liability claims will not exceed such insurance coverage limits, which could have a materially adverse effect on our business, financial condition or results of operations, we may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Risks Related to our Securities

The price of our common stock may be volatile.

The trading price of our common stock may fluctuate substantially. The price of our common stock that will prevail in the market may be higher or lower than the price at which our shares of common stock, depending on many factors, some of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose part or all of your investment in our common stock. Those factors that could cause fluctuations include, but not limited to, the following:

- price and volume of fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in our net loss or fluctuations in our operating results or in the expectations of securities analysts;
- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- general economic conditions and trends;
- positive and negative events relating to healthcare and the overall pharmaceutical and biotech sector;
- major catastrophic events;
- sales of large blocks of our stock;
- significant dilution caused by the anti-dilutive clauses in our financial agreements;
- departures of key personnel;
- changes in the regulatory status of our Immunotherapies, including results of our clinical trials;
- events affecting Mayo Clinic, Mayo Foundation for Medical Education and Research or any future collaborators;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;
- regulatory developments in the United States and other countries;

- failure of our common stock to be listed or quoted on the OTCQB, the NASDAQ Capital Market, NYSE Amex Equities or other national market system;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Due to the potential volatility of our stock price, we may therefore be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

A DTC "Chill" on the electronic clearing of trades in our securities in the future may affect the liquidity of our stock and our ability to raise capital.

There is a risk that the Depository Trust Company (DTC) may place a "chill" on the electronic clearing of trades in our securities. This may lead some brokerage firms to be unwilling to accept certificates and/or electronic deposits of our stock and other securities and also some may not accept trades in our securities altogether. There is no assurance that a chill will not occur in the future. A future DTC chill would affect the liquidity of our securities and make it difficult to purchase or sell our securities in the open market. It may also have an adverse effect on our ability to raise capital because investors may be unable to easily resell our securities into the market. Our inability to raise capital on terms acceptable to us, if at all, could have a material and adverse effect on our business and operations.

You may have difficulty selling our shares because they may be deemed "penny stocks."

If our common stock price does not increase above $5.00 per share or we are unsuccessful in listing on a "recognized" national exchange, our common stock may continue to be deemed a "penny stock" as that term is defined in Rule 3a51-1, promulgated under the Exchange Act. Penny stocks are, generally, stocks:

- with a price of less than $5.00 per share;
- that are neither traded on a "recognized" national exchange nor listed on an automated quotation system sponsored by a registered national securities association meeting certain minimum initial listing standards; and
- of issuers with net tangible assets less than $2.0 million (if the issuer has been in continuous operation for at least three years) or $5.0 million (if in continuous operation for less than three years), or with average revenue of less than $6.0 million for the last three years.

Section 15(g) of the Exchange Act and Rule 15g-2 promulgated thereunder require broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document before effecting any transaction in a "penny stock" for the investor's account. We urge potential investors to obtain and read this disclosure carefully before purchasing any shares that are deemed to be "penny stock."

Rule 15g-9 promulgated under the Exchange Act requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any "penny stock" to that investor. This procedure requires the broker-dealer to:

- obtain from the investor information about his or her financial situation, investment experience and investment objectives;
- reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has enough knowledge and experience to be able to evaluate the risks of "penny stock" transactions;
- provide the investor with a written statement setting forth the basis on which the broker-dealer made his or her determination; and
- receive a signed and dated copy of the statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives.

Compliance with these requirements may make it harder for investors in our common stock to resell their shares to third parties. Accordingly, our common stock should only be purchased by investors, who understand that such investment is a long-term and illiquid investment, and are capable of and prepared to bear the risk of holding our common stock for an indefinite period of time.

The per share price of our common stock might not obtain or maintain the necessary levels to prevent our stock being subject to these rules in the future.

A limited public trading market may cause volatility in the price of our common stock.

The quotation of our common stock on the OTCQB does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility. Sales of substantial amounts of common stock, or the perception that such sales might occur, could adversely affect prevailing market prices of our common stock and our stock price may decline substantially in a short time and our shareholders could suffer losses or be unable to liquidate their holdings. Our stock is thinly traded due to the limited number of shares available for trading on the market thus causing large swings in price. In addition, there is no established trading market for our warrants.

The market prices for our common stock may be adversely impacted by future events.

Market prices for our common stock will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- changes in interest rates;
- significant dilution caused by the anti-dilutive clauses in our financial agreements;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- variations in quarterly operating results;
- change in financial estimates by securities analysts;
- the depth and liquidity of the market for our common stock and warrants;
- investor perceptions of our company and the pharmaceutical and biotech industries generally; and
- general economic and other national conditions.

If we fail to remain current with our listing requirements, we could be removed from the OTCQB which would limit the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market.

Companies trading on the OTCQB must be reporting issuers under Section 12 of the Securities Exchange Act, as amended. If we fail to file such reports in a timely manner, the shares of our common stock would eventually cease to be quoted on the OTCQB, and the market liquidity for our securities could be severely adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of shareholders to sell their securities in the secondary market.

Our internal control over financial reporting and our disclosure controls and procedures have been ineffective in the past, and may be ineffective again in the future, and failure to improve them at such time could lead to errors in our financial statements that could require a restatement or untimely filings, which could cause investors to lose confidence in our reported financial information, and a decline in our stock price.

Certain of our outstanding warrants contain, or may be deemed to contain from time to time, embedded derivative rights in accordance with U. S. Generally Accepted Accounting Principles, or GAAP. These derivative rights, or similar rights in securities we may issue in the future, need to be, or may need to be, separately valued as of the end of each accounting period in accordance with GAAP.

The Company has evaluated the application ASC 480-10 Distinguishing liabilities from equity, ASC 815-40 Contracts in an Entity's Own Equity and ASC 718-10 Compensation – Stock Compensation to the issued and outstanding warrants to purchase common stock that were issued with the convertible notes, private placements, consulting agreements, and various debt settlements during 2009 through 2012. Based on the guidance, management concluded these instruments are required to be accounted for as derivatives either due to a ratchet down protection feature available on the exercise price or a holder's right to put the warrants back to the Company for cash under certain conditions or a conversion option feature with conversion into variable number of shares. Under ASC 815-40-25, the Company records the fair value of these warrants and conversion options (derivatives) on its balance sheet, at fair value, with changes in the values reflected in the statements of operations as "Changes in fair value of derivative liabilities". The fair value of the share purchase warrants are recorded on the balance sheet under 'Derivative liability – warrants' and the fair value of the conversion options are recorded on the balance sheet under 'Derivative liability – conversion option'.

Sales of additional equity securities may adversely affect the market price of our common stock and your rights may be reduced.

We expect to continue to incur drug development and sale, general and administrative costs, and to satisfy our funding requirements, we will need to sell additional equity securities, which may be subject to registration rights and warrants with anti-dilutive protective provisions. The sale or the proposed sale of substantial amounts of our common stock or other equity securities in the public markets may adversely affect the market price of our common stock and our stock price may decline substantially. Our shareholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, new equity securities issued may have greater rights, preferences or privileges than our existing common stock.

Because we have a significant number of additional authorized shares of common stock available for issuance and outstanding warrants to purchase our common stock our stockholders may experience dilution in the future and it may adversely affect the market price of our securities.

We are currently authorized to issue 500,000,000 shares of our common stock. As of March 1, 2016, we had 70,551,000 shares of our common stock issued and outstanding, excluding shares issuable upon exercise of our outstanding warrants, options and shares of common stock earned but not yet issued under Omnibus Stock Option Plan. Those outstanding shares represent 14% of our authorized shares, meaning that the ownership position of the current shareholders could be diluted significantly were we to issue a large number of additional shares. For example, as of March 15, 2016, we had outstanding warrants to purchase an aggregate of 52,106,000 shares of our common stock with exercise prices ranging between $0.10 and $25.00 will result in dilution if and when exercised. Fear of such ownership dilution could reduce the desirability of our shares and reduce the price at which you are able to resell your shares.

The accounting treatment for certain of our warrants is complex and subject to judgments concerning the valuation of embedded derivative rights within the applicable securities. Fluctuations in the valuation of these rights could cause us to take charges to our statement of operations and make our financial results unpredictable.

Certain of our outstanding warrants contain, or may be deemed to contain from time to time, embedded derivative rights in accordance with U. S. Generally Accepted Accounting Principles, or GAAP. These derivative rights, or similar rights in securities we may issue in the future, need to be, or may need to be, separately valued as of the end of each accounting period in accordance with GAAP. We record these embedded derivatives as liabilities at issuance, valued using the Black Scholes Option Pricing Model and are subject to revaluation at each reporting date. Any change in fair value between reporting periods is reported on our statement of operations. At December 31, 2015, the fair value of the derivative liability – warrants was $26,493,000. Changes in the valuations of these rights, the valuation methodology or the assumptions on which the valuations are based could cause us to take charges to our earnings, which would adversely impact our results of operations. Moreover, the methodologies, assumptions and related interpretations of accounting or regulatory authorities associated with these embedded derivatives are complex and in some cases uncertain, which could cause our accounting for these derivatives, and as a result, our financial results, to fluctuate. There is a risk that questions could arise from investors or regulatory authorities concerning the appropriate accounting treatment of these instruments, which could require us to restate previous financial statements, which in turn could adversely affect our reputation, as well as our results of operations.

We do not intend to pay cash dividends.

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying

cash dividends for the foreseeable future. Any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and depends on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

Nevada law has anti-takeover provisions that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Nevada law contains provisions which could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our shareholders. We are authorized to issue up to 5,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our Board of Directors without further action by shareholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of Nevada law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a shareholder might consider favorable. Such provisions may also prevent or frustrate attempts by our shareholders to replace or remove our management. In particular, Nevada law, among other things, provides the Board of Directors with the ability to alter the Bylaws without shareholder approval, and provide that vacancies on the Board of Directors may be filled by a majority of directors in office, although less than a quorum.

We are also subject to Section 78.378 and 78.379 of Nevada Revised Statutes Section, which, subject to certain exceptions, imposes regulations over the acquisition of a controlling interest in certain Nevada corporations unless the articles of incorporation or bylaws of the corporation provide that the provisions of these sections do not apply to the corporation or to an acquisition of a controlling interest specifically by types of existing or future stockholders, whether or not identified. In addition, the articles of incorporation, the bylaws or a resolution adopted by the directors of the issuing corporation may impose stricter requirements on the acquisition of a controlling interest in the corporation than the provisions of NRS 78.378 to 78.379.

These provisions are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of our company to first negotiate with its board. These provisions may delay or prevent someone from acquiring or merging with us, which may cause the market price of our common stock to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We do not own any real estate or other properties. We lease approximately 306 square feet of space at 50 N. Laura Street, Suite 2500, Jacksonville, Florida 32202, for our principal business office on a one-year agreement due to expire on July 24, 2016. The rent is $2,500 per month. We also rent a single office at 2815 Eastlake Avenue East in Seattle, WA on a month by month agreement which expires on May 30, 2016. We expect to continue to renew this month to month arrangement for the forseeable future. The monthly rent is $1,072.

ITEM 3. LEGAL PROCEEDINGS

Management is not aware of any material legal proceedings and there are no pending material procedures that would affect the property of the Company. Management is not aware of any legal proceedings and tcontemplated by any government authority or any other party involving the Company. As of the date of this Annual Report, no director, officer or affiliate is (i) a party adverse to us in any legal proceeding, or (ii) has an adverse interest to us in any legal proceeding. Management is not aware of any other legal proceedings pending or threatened against the Company.

ITEM 4. MINE SAFETY DISCLOSURE

Not Applicable

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on the Over the Counter Bulletin Board ("OTCQB") under the symbol "TPIV" and on the Berlin and Munich Stock Exchanges under the symbol "GX1A." The Berlin and Munich Stock Exchange listings were done without the Company's knowledge and consent and appear to still be active.

The market for our common stock is limited, volatile and sporadic. The following table sets forth, for the periods indicated, the high and low sales prices for the Company's common stock for the quarters within 2014 and 2015, as reported on Nasdaq. com.

	High Bid	Low Bid
Fiscal Year 2015		
Fourth Quarter	$ 0.97	$ 0.53
Third Quarter	$ 1.17	$ 0.31
Second Quarter	$ 1.71	$ 0.17
First Quarter	$ 0.36	$ 0.12
Fiscal Year 2014		
Fourth Quarter	$ 0.32	$ 0.28
Third Quarter	$ 0.66	$ 0.62
Second Quarter	$ 1.93	$ 1.80
First Quarter	$ 4.09	$ 3.50

As of March 15, 2016, we had 617 shareholders of record.

Dividend Policy

No dividends have been declared or paid on our common stock. We have incurred recurring losses and do not currently intend to pay any cash dividends in the foreseeable future.

Warrants

As of March 15, 2016, there were an aggregate of 52,106,000 common stock purchase warrants issued and outstanding, with exercise prices ranging between $0.10 and $25.00.

Recent Sales of Unregistered Securities

(a) We issued the following restricted securities during the period covered by this report to the named individual pursuant to exemptions under the Securities Act of 1933 including Section 4(2):

On November 6, 2015 we issued 70,000 shares to Corporate Profile, LLC pursuant to an investor relations agreement.

ITEM 6. SELECTED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition, changes in financial condition, plan of operations and results of operations should be read in conjunction with (i) our audited consolidated financial statements as at December 31, 2015 and December 31, 2014 and (ii) the section entitled "Business", included in this annual report. The discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors.

Company Overview

Our Cancer Vaccines

We are an immuno-oncology company specializing in the development of innovative peptide and gene-based immunotherapeutics and vaccines for the treatment of cancer. We combine a set of proprietary technologies to improve the ability of the cellular immune system to destroy diseased cells. These are peptide antigen technologies and DNA expression technologies and Polystart.

To enhance shareholder value and taking into account development timelines, we plan to focus on advancing our clinical programs including our Folate Receptor Alpha program for breast and ovarian and our HER2/neu peptide antigen program into Phase II clinical trials. In parallel, we plan to complete the preclinical development of our Polystart technology as an integral component of our prime-and-boost vaccine methodology.

The Immunotherapy Industry for Cancer

Immuno-oncology has become the most rapidly growing sector in the pharmaceutical and biotech industry. The approval and success of checkpoint inhibitors Yervoy and Opdivo (Bristol Myers Squibb) and Keytruda (Merck) together with the development of CAR T-cell therapies (Juno, Kite) has provided much momentum in this sector. In addition, new evidence points to the increasing use of combination immunotherapies for the treatment of cancer. This has provided greater opportunities for the successful development of T-cell vaccines in combination with other approaches.

Products and Technology in Development

Clinical

***Phase I Human Clinical Trials* – Folate Alpha Breast and Ovarian Cancer – Mayo Foundation**

Folate Receptor Alpha is expressed in over 80% of triple negative breast cancers and in addition, over 90% of ovarian cancers, for which the only treatment options are surgery and chemotherapy, leaving a very important and urgent clinical need for a new therapeutic. Time to recurrence is relatively short for these types of cancer and survival prognosis is extremely poor after recurrence. In the United States alone, there are approximately 30,000 ovarian cancer patients and 40,000 triple negative breast cancer patients newly diagnosed every year.

A 24 patient Phase I clinical trial has been completed. The vaccine is well tolerated and safe and 20 out of 21 evaluable patients showed positive immune responses providing a strong rationale rational for progressing to phase II trials. GMP manufacturing for Phase II trials is progressing well towards a commercial formulation and final analyses of clinical plans are near completion. On July 27, 2015, we exercised our option agreement with Mayo Foundation with the signing of a worldwide exclusive license agreement to commercialize a proprietary folate receptor alpha vaccine technology for all cancer indications. Our obligations under this agreement are license fees ($350,000 upon signing; $100,000 on March 27, 2016 and $250,000 on June 27, 2016), clinical development and commercial milestones, and a 6% royalty on net sales. Our obligations include a $50,000 license maintenance fee starting on the second anniversary of the signing of the license. As part of this Agreement, the IND for the folate receptor alpha Phase I trial was transferred from Mayo to us for amendment for our Phase II Clinical Trials on our lead product.

On September 15, 2015, we announced that our collaborators at the Mayo Foundation had been awarded a grant of $13.3 million from the U. S. Department of Defense. This grant, commencing September 15, 2015, will cover the costs for a 280 patient Phase II Clinical Trial of Folate Receptor Alpha Vaccine in patients with Triple Negative Breast Cancer. We will work closely with Mayo Foundation on this clinical trial by providing clinical and manufacturing expertise as well as providing GMP vaccine formulations. These vaccine formulations are being developed for multiple Phase II clinical programs in triple negative breast and ovarian cancer in combination with other immunotherapeutics.

On December 9, 2015, we announced that we received Orphan Drug Designation from the U. S. Food & Drug Administration's Office of Orphan Products Development (OOPD) for our cancer vaccine TPIV 200 in the treatment of ovarian cancer. The TPIV 200 ovarian cancer clinical program will now receive benefits including tax credits on clinical research and 7-year market exclusivity upon receiving marketing approval. TPIV 200 is a multi-epitope peptide vaccine that targets Folate Receptor Alpha which is overexpressed in multiple cancers.

***Phase I Human Clinical Trials* – HER2/neu+ Breast Cancer – Mayo Foundation**

Patient dosing has been completed. Final safety analysis on all the patients treated is complete and shown to be safe. In addition, 19 out of 20 evaluable patients showed robust T-cell immune responses to the antigens in the vaccine composition providing a solid case for advancement to Phase II in 2016. An additional secondary endpoint incorporated into this Phase I Trial will be a two year follow on recording time to disease recurrence in the participating breast cancer patients.

For Phase I(b)/II studies, we plan to add a Class I peptide, licensed from the Mayo Foundation (April 16, 2012), to the four Class II peptides. Management believes that the combination of Class I and Class II HER2/neu antigens, gives us the leading HER2/neu vaccine platform. As the folate receptor alpha vaccine is our lead product our plans are now initiating formulation studies to progress the HER2/neu vaccine towards a Phase II Clinical Trial in 2016.

Preclinical

Polystart

We have converted the previously filed U. S. Provisional Patent Application on Polystart into a full Patent Application, and will extend technology constructs as boost strategies for the current clinical programs in breast and ovarian cancer.

Financings

Our current available funding has come from financings that we conducted in August 2014, January and March of 2015 and from warrants issued in connection with our January and March, 2015 financings.

August 2014 Financing

In August, 2014, we entered into a Securities Purchase Agreement with a single institutional investor for the sale of 1,886,792 units at a purchase price of $1.06 per unit, for a total purchase price of $1,832,500, net of finders' fee. Each unit consists of one common share and one share purchase warrant exercisable at $1.17 for a period of 5 years.

In August, 2014, we received subscription proceeds of $265,000 for 265,000 units. Each unit consists of one share of common stock and one share purchase warrant exercisable at $2.50 for a period of 3 years. We also issued 5,250 shares of common stock as finders' fee relating to the subscription proceeds.

January 2015 Financing

In January, 2015, we entered into a Securities Purchase Agreement with certain investors for the sale of 7,320,000 units at a purchase price of $0.20 per unit, for a total purchase price of approximately $1,250,000, net of finders' fee and offering expenses of approximately $214,000. Each unit consisting of (i) one share of the Company's Common Stock, (ii) one Series A warrant to purchase one share of common stock, (iii) one Series B warrant to purchase one share of common stock (iv) one Series C warrant to purchase one share of common stock, (v) one Series D warrant to purchase one share of common stock, and (vi) one Series E warrant to purchase one share of common stock (the Series A, B, C, D and E warrants are hereby collectively referred to as the "January 2015 Warrants"). Series A warrants are exercisable at $1.50 per share, with a five year term. Series B warrants are exercisable at $0.40 per share, with a six month term. Series C warrants are exercisable at $1. 00 per share, with a five year term. Series D warrants are exercisable at $0.75 per share only if and to the extent that the Series B warrants are exercised, with a five year term from the date that the Series B warrants are exercised. Series E warrants are exercisable at $1.25 per share, only if and to the extent that the Series C warrants are exercised, with a five year term from the date that the Series C warrants are exercised.

Pursuant to a placement agent agreement, we agreed to issue warrants to purchase 366,000 common shares with substantially the same terms as the January 2015 Warrants.

March 2015 Financing

In March, 2015, we entered into a Securities Purchase Agreement with certain accredited investors for the sale of 5,000,000 units at a purchase price of $0.20 per unit, for a total purchase price of approximately $950,000, net of finders' fee and offering expenses of approximately $50,000. Each unit consisting of (i) one share of the Company's Common Stock, (ii) one Series A-1 warrant to purchase one share of common stock, (iii) one Series B-1 warrant to purchase one share of common stock (iv) one Series C-1 warrant to purchase one share of common stock, (v) one Series D-1 warrant to purchase one share of common stock, and (vi) one Series E-1 warrant to purchase one share of common stock (the Series A-1, B-1, C-1, D-1 and E-1 warrants are hereby collectively referred to as the "March 2015 Warrants"). The March 2015 Warrants have substantially the same terms as the January 2015 Warrants.

Pursuant to a placement agent agreement, we agreed to issue warrants to purchase 125,000 common shares with substantially the same terms as the March 2015 Warrants.

Restructuring of January and March 2015 Financings

In May 2015, we entered into a restructuring agreement with the investors of the January 2015 and March 2015 financings, where:

- The exercise price of the Series A and Series A-1 warrants was changed from $1.50 per warrant to $0.10 per warrant,
- The exercise price of Series B and Series B-1 warrants was changed from $0.40 per warrant to $0.20 per warrant,
- Each warrant of Series B and Series B-1 existing prior to the restructuring agreement was replaced with two warrants of such series,
- The exercise price of the Series C and Series C-1 warrants was changed from $1.00 per warrant to $0.50 per warrant, and
- Each warrant of Series C and Series C-1 existing prior to the restructuring agreement was replaced with two warrants of such series.

As a result of the restructuring agreement, we issued an additional 12,320,000 Series B warrants and 12,320,000 Series C Warrants. See—liquidity and capital resources.

Warrant Descriptions

- **Series A and Series A-1 Warrants.** The Series A and Series A-1 Warrants have a five year term and exercise prices of $0.10. They have a cashless exercise only if not freely tradable upon exercise. The Series A and Series A-1 Warrants have anti-dilution protection which provides that the exercise price of the Series A and Series A-1 warrants would adjust to the price of any securities sold by us below the warrant exercise price.
- **Series B and Series B-1 Warrants**. The Series B and B-1 Warrants had a six month term and an exercise price of $0.20. These Series B and Series B-1 Warrants were exercised prior to expiration.
- **Series C and Series C-1 Warrants**. The Series C and Series C-1 Warrants have a 5 year term and an exercise price of $0.50. There is a mandatory exercise if the stock trades at or above $1.00 for 10 trading days. These warrants have anti-dilution protection for subsequent securities issuances by us at prices below the exercise price which would require an adjustment to the warrant exercise price (excluding warrant exercises).
- **Series D and Series D-1 Warrants.** The Series D and Series D-1 Warrants have a term of 5 years from the date of the exercise of the Series B and Series B-1 Warrants and an exercise price of $0.75. These warrants have anti-dilution protection for subsequent securities issuances by us at prices below the exercise price which would require an adjustment to the warrant exercise price (excluding warrant exercises).

- **Series E and Series E-1 Warrants.** The Series E and Series E-1 warrants have a term of 5 years from the date of the exercise of the Series C and Series C-1 Warrants and an exercise price of $1.25. These warrants have anti-dilution protection for subsequent securities issuances by us at prices below the exercise price which would require an adjustment to the warrant exercise price (excluding warrant exercises).
- **Warrant Holder Contingent Put Right.** Each of the warrants provide that at the request of a Warrant holder delivered at any time commencing on the earliest to occur of (x) the public disclosure of any Fundamental Transaction, (y) the consummation of any Fundamental Transaction and (z) such Warrant holder first becoming aware of any Fundamental Transaction through the date that is ninety (90) days after the public disclosure of the consummation of such Fundamental Transaction by the Company, the Company or the successor entity (as the case may be) shall purchase the Warrant from such Warrant holder on the date of such request by paying to the holder cash in an amount equal to the Black Scholes Value. A **Fundamental Transaction** means:

  (i) the Company or any of its Subsidiaries shall, directly or indirectly, in one or more related transactions,

  (1) consolidate or merge with or into (whether or not the Company or any of its Subsidiaries is the surviving corporation) any other Person, or

  (2) sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of its respective properties or assets to any other Person, or

  (3) allow any other Person to make a purchase, tender or exchange offer that is accepted by the holders of more than 50% of the outstanding shares of voting stock of the Company (not including any shares of Voting Stock of the Company held by the Person or Persons making or party to, or associated or affiliated with the Persons making or party to, such purchase, tender or exchange offer), or

  (4) consummate a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with any other Person whereby such other Person acquires more than 50% of the outstanding shares of voting stock of the Company (not including any shares of voting stock of the Company held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination), or

  (5) (I) reorganize, recapitalize or reclassify the common stock, (II) effect or consummate a stock combination, reverse stock split or other similar transaction involving the common stock or (III) make any public announcement or disclosure with respect to any stock combination, reverse stock split or other similar transaction involving the common stock (including, without limitation, any public announcement or disclosure of (x) any potential, possible or actual stock combination, reverse stock split or other similar transaction involving the common stock or (y) board or shareholder approval thereof, or the intention of the Company to seek board or shareholder approval of any stock combination, reverse stock split or other similar transaction involving the common stock), or

  (ii) any “person” or “group” (as these terms are used for purposes of Sections 13(d) and 14(d) of the 1934 Act and the rules and regulations promulgated thereunder) is or shall become the “beneficial owner” (as defined in Rule 13d-3 under the 1934 Act), directly or indirectly, of 50% of the aggregate ordinary voting power represented by issued and outstanding voting stock of the Company.

  Assuming a Fundamental Transaction occurs we estimate, using the Black Scholes value method required by the terms of the warrants and assuming all warrant holders exercise their rights to require us to purchase their warrants, the aggregate amount we would be obligated to pay would be approximately $26 million.

- ***Variable Rate Transaction Prohibition***. During the two year period commencing on the closing date under both the January 2015 and March 2015 Financings (dated January 12, 2015 and March 9, 2015, respectively), the Company and each subsidiary are prohibited from entering into an agreement related to any subsequent issuance of securities involving a Variable Rate Transaction. A **Variable Rate Transaction** means: a transaction in which the Company or any subsidiary:

  (i) issues or sells any securities convertible into shares of Common Stock either

  (A) at a conversion, exercise or exchange rate or other price that is based upon and/or varies with the trading prices of, or quotations for, the shares of Common Stock at any time after the initial issuance of such convertible securities, or

  (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such convertible securities or upon the occurrence of specified contingent events directly or indirectly related to the business of the Company or the market for the Common Stock, other than pursuant to a customary "weighted average" anti-dilution provision or

  (ii) enters into any agreement (including, without limitation, an equity line of credit) whereby the Company or any subsidiary may sell securities at a future determined price (other than standard and customary "preemptive" or "participation" rights).

- ***Failure to Timely Deliver Securities.*** If we fail, to issue to a warrant holder within three (3) trading days after receipt of the applicable exercise notice, a certificate for the number of shares of our common stock to which the warrant holder is entitled upon the holder's exercise of the warrant, then, in addition to all other remedies available to the warrant holder, we shall pay in cash to the holder on each trading day after such third (3rd) trading day that the issuance of such shares of our common stock is not timely effected an amount equal to 1% of the product of (A) the aggregate number of shares of our common stock not issued to the warrant holder on a timely basis and to which the warrant holder is entitled and (B) the closing sale price of our common stock on the trading day immediately preceding the last possible date on which we could have issued such shares of our common stock to the warrant holder without violating the exercise provision of the warrant. In addition, if within three (3) trading days after our receipt of the applicable exercise notice, we shall fail to issue and deliver a certificate to the warrant holder without restrictive legend to which the holder is entitled upon the holder's exercise, and (Y) on or after such third (3rd) trading day the warrant holder purchases (in an open market transaction or otherwise) shares of our common stock to deliver in satisfaction of a sale by the warrant holder of all or any portion of the number of shares of our common stock, or a sale of a number of shares of our common stock equal to all or any portion of the number of shares of our common stock, issuable upon such exercise that the warrant holder so anticipated receiving from us, then, in addition to all other remedies available to the warrant holder, we shall within three (3) business days after the holder's request and in the holder's discretion, either (i) pay cash to the warrant holder in an amount equal to the warrant holder's total purchase price (including brokerage commissions and reasonable out-of-pocket expenses, if any) for the shares of our common stock so purchased (the "Buy-In Price"), at which point our obligation to so issue and deliver such certificate or credit the warrant holder's balance account with DTC for the number of shares of our common stock to which the warrant holder is entitled upon the holder's exercise hereunder (as the case may be) (and to issue such shares of our common stock) shall terminate, or (ii) promptly honor our obligation to so issue and deliver to the warrant holder a certificate or certificates representing such shares of our common stock or credit the holder's balance account with DTC for the number of shares of common stock to which the holder is entitled upon the warrant holder's exercise and pay cash to the holder in an amount equal to the excess (if any) of the Buy-In Price over the product of (A) such number of shares of common stock multiplied by (B) "B" as set out in the formula above.

Recent Developments and Highlights

Company Headquarters. In August 2015, we relocated our headquarters from Seattle, Washington to Jacksonville, Florida to be in closer proximity to our research and clinical development collaborators at the Mayo Foundation in Jacksonville and two key advisors (Business & Clinical) who are resident in Florida.

Option Plan Amendment. On November 6, 2015, the Board of Directors approved an amendment to the Company's 2014 Omnibus Stock Ownership Plan which provided for an increase in the number of shares reserved for issuance under the Plan by 5 million shares to 7 million shares.

Board Expansion. We added three new directors Mr. David Laskow Pooley on March 19, 2015, Dr. John Bonfiglio on July 23, 2015 and Mr. Frederick G. Wasserman on January 27, 2016, to add experience in various strategic areas.

Employment Agreement. On November 12, 2015, we entered into a new employment agreement with our Chief Executive Officer that has been responsible for our continued operations over many years.

Mayo License. On July 21, 2015 we exercised our option regarding the Mayo license.

Polystart Patent. On February 11, 2016 the United States Patent and Trademark Office issued a Notice of Allowance.

Phase 1 Trials. Phase I trials on our HER2/neu vaccine (TPIV 100) and our Folate Receptor Alpha vaccine (TPIV 200 were successfully completed at the Mayo Clinic. The results on both vaccines provide the rationale for starting Phase II clinical activities.

Fast Track Designation. On February 3, 2016 we announced that that the U. S. Food & Drug Administration (FDA) has granted Fast Track Designation for our cancer vaccine TPIV 200 in the treatment of ovarian cancer.

Current State of the Company

We are a clinical-stage immunotherapy company specializing in the development of innovative peptide and gene-based immunotherapeutics and vaccines for the treatment of cancer. We now plan to conduct multiple Phase II clinical trials on our vaccines. The largest of these studies in triple-negative breast cancer will be totally funded by a $13.3 million grant from the US Department of Defense to our collaborators at the Mayo Foundation in Jacksonville, FL. We believe that our development pipeline is strong and provides us the opportunity to continue to expand on collaborations with leading institutions and corporations.

In the third quarter of 2015, we strengthened our cash position by raising additional $2.5 million in working capital, giving us confidence in our ability to continue developing our products on the path to commercialization. The structure of this financing gives us additional opportunities to raise additional capital through the exercise of short-term and long-term warrants. The strength of our science and development approaches is becoming more widely appreciated, particularly as our clinical program has now generated positive interim data on both clinical programs in Breast and Ovarian Cancer. We continue discussions with a major pharmaceutical organization and a leading US cancer institute on a Phase II clinical trial in ovarian cancer using our folate receptor alpha vaccine in combination with a checkpoint inhibitor.

We continue to be focused on our entry into Phase II Triple Negative Cancer Trials including application for Fast Track & Orphan Drug Status as well as planning for Phase II HER2/neu+ Breast Cancer Trials.

We will also continue to prosecute our PolyStart patent filings and develop new constructs to facilitate collaborative efforts in our current clinical indications and those where others have already indicated interest in combination therapies.

We believe that these fundamental programs and corporate activities have positioned us to capitalize on the acceptance of immunotherapy as a leading therapeutic strategy in cancer and infectious disease resulting in exploding valuations in the market.

TapImmune’s Pipeline

We have a pipeline of potential immunotherapies under development. Phase I clinical programs on HER2/neu and breast and ovarian cancer have been completed and strong immune responses in over 90% of patients treated has provided the rationale and catalyst to advance these programs to Phase II clinical trials in 2016. These are major inflection and valuation events, and we believe that, in light of these assets, we are significantly undervalued. Over the past year a number of highly visible transactions and billion dollar acquisitions have taken place that validate the work we are doing. We believe that, if our treatment successfully reaches commercialization, our treatment is applicable to 50% of the HER2/neu Breast Cancer market, which is a $21 billion annual market. We further believe that if our Ovarian Cancer treatment reaches commercialization, it will be applicable to 95% of the market which Decision Resources, one of the world’s leading research firms for pharmaceuticals and healthcare, believes will triple in the next 10 years to at least $1.5 billion annually.

In addition to the exciting clinical developments, our peptide vaccine technology may be coupled with our recently developed in-house Polystart nucleic acid-based technology designed to make vaccines significantly more effective by producing four times the required peptides for the immune systems to recognize and act on. Our nucleic acid-based systems can also incorporate “TAP” which stands for Transporter associated with Antigen Presentation. With respect to

validation of our technologies, it is important to note that the majority of our technologies have been published in leading peer-reviewed journals and we believe that the recent grant award from the US Department of Defense to the Mayo Foundation is a strong validation of our approach.

A key component to success is having a comprehensive patent strategy that continually updates and extends patent coverage for key products. It is highly unlikely that early patents will extend through ultimate product marketing, so extending patent life is an important strategy for ensuring product protection.

We have three active patent families that we are supporting:

1. Filed patents on PolyStart expression vector (owned by TapImmune and filed in 2014: this IP covers the use with TAP)

2. Filed patents on HER2/neu Class II and Class I antigens: exclusive license from Mayo Foundation; and

3. Filed patents on Folate Receptor Alpha antigens exclusive license from Mayo Foundation

While the pathway to successful product development takes time, we believe we have put in place significant resources in technical and corporate fundamentals for success. The strength of our product pipeline and access to leading scientists and institutions gives us a unique opportunity to make a major contribution to global health care.

With respect to the broader market, a major driver and positive influence on our activities has been the emergence and general acceptance of the potential of a new generation of immunotherapies that promise to change the standard of care for cancer. The immunotherapy sector has been greatly stimulated by the approval of Provenge® for prostate cancer and Yervoy™ for metastatic melanoma, progression of the areas of checkpoint inhibitors and adoptive T-cell therapy and multiple approaches reaching Phase II and Phase III status.

We believe that through our combination of technologies, we are well positioned to be a leading player in this emerging market. It is important to note that many of the late stage immunotherapies currently in development do not represent competition to our programs, but instead offer synergistic opportunities to partner our antigen based immunotherapeutics, Polystart and/or TAP expression systems. Thus, the use of naturally processed T-cell antigens discovered using samples derived from cancer patients plus our Polystart expression technology to improve antigen presentation to T-cells could not only produce an effective cancer vaccines in its own right but also to enhance the efficacy of other immunotherapy approaches such as CAR-T and PD1 inhibitors for example.

On the technology and product pipeline side, management believes that the Company is fundamentally strong and poised to be a leading company in a highly attractive, multi-billion dollar and expanding market, a position reinforced by our recruitment of top-class managers, advisors and investors who all share our vision.

Financial Overview

Critical Accounting Policies

Our consolidated financial statements and accompanying notes have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis. The preparation of financial statements in conformity with U. S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods.

We regularly evaluate the accounting policies and estimates that we use to prepare our consolidated financial statements. In general, management’s estimates are based on historical experience, on information from third party professionals, and on various other assumptions that are believed to be reasonable under the facts and circumstances. Actual results could differ from those estimates made by management.

Use of Estimates

Preparation of our financial statements in conformity with GAAP requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ materially from those estimates. Significant areas requiring management’s estimates and assumptions include deferred taxes and related tax balances and disclosures, determining the fair value of stock-based compensation and stock based

transactions, the fair value of the components of the convertible notes payable, foreign exchange gains and losses, and accrued liabilities. Matters impacting our ability to continue as a going concern and contingencies also involve the use of estimates and assumptions.

Fair Value Measurements

The fair value of certain of our financial instruments, including cash and cash equivalents, accrued compensation, and other accrued liabilities, approximate cost because of their short maturities. We measure the fair value of certain of our financial assets and liabilities on a recurring basis. A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value will be classified and disclosed in one of the following three categories:

- Level 1-Quoted prices (unadjusted) in active markets for identical assets and liabilities.
- Level 2-Inputs other than Level 1 that are observable, either directly or indirectly, such as unadjusted quoted prices for similar assets and liabilities, unadjusted quoted prices in the markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3-Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Stock-Based Compensation

Stock-based compensation is measured at the grant date based on the fair value of the award. The fair value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. The expense recognized for the portion of the award that is expected to vest has been reduced by an estimated forfeiture rate. The forfeiture rate is determined at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Expected Term — The expected term of options represents the period that our stock-based awards are expected to be outstanding based on the simplified method, which is the half-life from vesting to the end of its contractual term.

Expected Volatility — We compute stock price volatility over expected terms based on our historical common stock trading prices.

Risk-Free Interest Rate — We base the risk-free interest rate on the implied yield available on U. S. Treasury zero-coupon issues with an equivalent remaining term.

Expected Dividend — We have never declared or paid any cash dividends on our common shares and does not plan to pay cash dividends in the foreseeable future, and, therefore, use an expected dividend yield of zero in our valuation models. We recognize fair value of stock options granted to nonemployees as stock-based compensation expense over the period in which the related services are received.

Derivative Liability

We evaluate our convertible debt, options, warrants or other contracts to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted. This accounting treatment requires that the carrying amount of embedded derivatives be marked-to-market at each balance sheet date and carried at fair value. In the event that the fair value is recorded as a liability, the change in fair value during the period is recorded in the Statement of Operations as either income or expense. Upon conversion, exercise or modification to the terms of a derivative instrument, the instrument is marked to fair value at the conversion date and then the related fair value is reclassified to equity.

In circumstances where the embedded conversion option in a convertible instrument is required to be bifurcated and there are also other embedded derivative instruments in the convertible instrument that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instruments.

The classification of financial instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period. Equity instruments that are initially classified as equity that

become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities will be classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is expected within 12 months of the balance sheet date.

Management must determine whether an instrument (or an embedded feature) is indexed to our stock. An entity should use a two-step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. The application of this exercise affects the accounting for (i) certain freestanding warrants that contain exercise price adjustment features and (ii) convertible notes containing full-ratchet and anti-dilution protections (iii) certain free standing warrants that contain contingently puttable cash settlement.

Results of Operations

Year Ended December 31, 2015 Compared to the Year Ended December 31, 2014

In this discussion of our results of operations and financial condition, amounts, other than per-share amounts, have been rounded to the nearest thousand dollars.

We recorded a net loss of $34,066,000 or ($0.78) during the year ended December 31, 2015 compared to $30,883,000 or ($2.00) for the year ended December 31, 2014.

Operating Expenses

Operating expenses incurred during the fiscal year ended December 31, 2015 were $6,159,000 compared to $3,371,000 in the prior year. Significant changes and expenditures are outlined as follows:

- General and administrative expenses increased to $4,448,000 during the year ended December 31, 2015 from $3,182,000 during the prior period. The increase was primarily due to higher salaries for administration, professional fee, business development, investor relations, management fee, travel expenses and more significantly, higher non-cash consulting and management fees paid as stock-based compensation of $1,705,000 during the year ended December 31, 2015 from $1,391,000 during the prior period. The increase in stock-based compensation from the prior year was primarily due to us issuing stock options to management and board members in the current year.
- Research and development costs during the fiscal year ended December 31, 2015 were $1,711,000 compared to $189,000 during the prior fiscal year. This was due to higher technology licensing fee due to Mayo clinic and increased in house research activity in the current year.

The weighted average number of shares outstanding was 43,947,067 for the year ended December 31, 2015 compared to 15,465,213 for the prior year.

Liquidity and Capital Resources

As we have had no revenues since inception, we have financed our operations primarily through public and private offerings of our stock and debt including warrants and the exercise thereof.

The following table sets forth our cash and working capital as of December 31, 2015 and 2014:

	December 31, 2015	December 31, 2014
Cash reserves	$ 6,577,000	$ 142,000
Working capital (deficit)	$ (21,360,000)	$ (1,024,000)

Net Cash Used in Operating Activities

Operating activities in the year ended December 31, 2015 used cash of $4,343,000 compared to $2,187,000 in the year ended December 31, 2014. Operating activities have primarily used cash as a result of the operating and organizational activities such as consulting fees, management fees, professional fees and research and development.

Net Cash Provided by Financing Activities

Financing activities in the year ended December 31, 2015 provided cash of $10,778,000 compared to $2,281,000 in the year ended December 31, 2014.

Financings

Additional details of our financing activities for the periods reflected in this report are provided below:

2014 Financing. In fiscal year 2014, we raised $2,097,500 and issued warrants to acquire an aggregate of up to 2,151,792 shares of common stock.

2015 Financings. In the first quarter of fiscal year 2015, we raised $2,200,000 and issued warrants to acquire an aggregate of up to 61,600,000 shares of common stock including the warrants we issued pursuant to the restructuring of the 2015 financings.

Warrant Exercises

Between June 16, 2015 and December 9, 2015, 37,080,000 shares were issued upon exercise of certain warrants we issued in connection with our 2015 financings, providing $9.22 million in proceeds. The following table reflects the remaining outstanding warrants from the August 2014, January and March 2015 Financings (including placement agent warrants):

Series	Outstanding Warrants	Exercise Price	Expiration
A	2,573,200	$ 0.10	01/13/2020
C	12,093,200	$ 0.50	01/13/2020
D	7,320,000	$ 0.75	Between 07/16/2020 and 08/13/2020 and 08/19/2020 and 09/09/2020
E	7,393,200	$ 1.25	Between 10/01/2020 and 11/12/2020 and 11/30/2020 and 12/09/2020
A-1	5,025,000	$ 0.10	03/09/2020
C-1	5,025,000	$ 0.50	03/09/2020
D-1	5,000,000	$ 0.75	Between 08/19/2020 and 09/09/2020
E-1	5,025,000	$ 1.25	06/16/2020

Future Capital Requirements

Our capital requirements for 2016 will depend on numerous factors, including the success of our research and development, the resources we devote to develop and support our technologies and our success in pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to raise additional capital including through possible joint ventures and/or partnerships, we expect to incur substantial expenditures to further develop our technologies including continued increases in costs related to research, nonclinical testing and clinical studies, as well as costs associated with our capital raising efforts and being a public company. We will require substantial funds to conduct research and development and nonclinical and Phase II clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase II and III clinical testing. Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

Our current available cash and cash equivalents are insufficient to satisfy our liquidity requirements. We believe our existing cash and cash equivalents will allow us to fund our operating plan through the end of 2016. We expect to continue to seek additional funding for our operations. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned clinical testing and research and development activities, which could harm our business. The sale of additional equity or debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We also will require additional capital beyond our currently forecasted amounts.

Because of the numerous risks and uncertainties associated with research, development and commercialization of our product candidates, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting nonclinical and clinical trials including the research and development expenditures we expect to make in connection with our license agreements with Mayo Foundation;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- our ability to maintain current research and development licensing agreements and to establish new strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to achieve our milestones under our licensing arrangements and the payment obligations we may have;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

We have based our estimates on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our shares or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

Going Concern

We have no sources of revenue to provide incoming cash flows to sustain our future operations. As outlined above, our ability to pursue our planned business activities is dependent upon our successful efforts to raise additional equity financing. These factors raise substantial doubt regarding our ability to continue as a going concern. Our consolidated financial statements have been prepared on a going concern basis, which implies that we will continue to realize our assets and discharge our liabilities in the normal course of business. As at December 31, 2015, we had accumulated losses of $133,508,000 since inception. Our financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes of financial condition, revenues, expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Tax Loss and Credit Carryforwards

As of December 31, 2015 and 2014, we have approximately $24,123,000 of federal and $4,336,000 of state NOLs that may be available to offset future taxable income, if any. The federal net operating loss carryforwards, if not utilized, will expire between 2029 and 2035. The state net operating loss carryforwards, if not utilized, will expire in 2035. Any greater than 50% change in ownership under Section 382 of the Internal Revenue Code, or the Code, places significant annual limitations on the use of such net operating loss carryforwards.

At December 31, 2015 and 2014, we recorded a 100% valuation allowance against our deferred tax assets of approximately $10,826,000 and $12,471,000, respectively, as our management believes it is uncertain that they will be fully realized. If we determine in the future that we will be able to realize all or a portion of our net operating loss carryforwards, an adjustment to our net operating loss carryforwards would increase net income in the period in which we make such a determination.

Inflation

Inflation affects the cost of raw materials, goods and services that we use. In recent years, inflation has been modest. However, fluctuations in energy costs and commodity prices can affect the cost of all raw materials and components. The competitive environment somewhat limits our ability to recover higher costs resulting from inflation by raising prices. Although we cannot precisely determine the effects of inflation on our business, it is management's belief that the effects on revenues and operating results will not be significant. We do not believe that inflation has had a material impact on our results of operations for the periods presented, except with respect to payroll-related costs and other costs arising from or related to government imposed regulations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

ITEM 8. FINANCIAL STATEMENTS

The Financial Statements are incorporated herein by reference to pages F-1 to F-18 at the end of this report and the supplementary data is not applicable.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

We have had no disagreements with our principal independent accountants.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer and Principal Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this report. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is accumulated and communicated to management, including our Principal Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer has concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are not effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by us in the reports that we file or submit under the Exchange Act.

It should be noted that any system of controls is based in part upon certain assumptions designed to obtain reasonable (and not absolute) assurance as to its effectiveness, and there can be no assurance that any design will succeed in achieving its stated goals.

Management's Report on Internal Control Over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as required by Sarbanes-Oxley (SOX) Section 404 A. The Company's internal control over financial reporting is a process designed under the supervision of the Company's Principal Executive Officer and Principal Financial Officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external purposes in accordance with United States generally accepted accounting principles ("US GAAP").

As of December 31, 2015, management has not completed a proper evaluation, risk assessment and monitoring of the Company's internal control over financial reporting based on the criteria for effective internal control over financial reporting established in the 2013 Internal Control -Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and SEC guidance on conducting such assessments. Based on that evaluation, they concluded that, as at December 31, 2015 such internal controls and procedures were not effective to detect the inappropriate application of US GAAP rules as more fully described below.

The matters involving internal controls and procedures that the Company's management considered to be material weaknesses under the standards of the Public Company Accounting Oversight Board were:

(1) inadequate entity level controls due to an ineffective audit committee resulting from the presence of only one of independent member on the current audit committee and the presence of only one outside director on our board of directors;

(2) inadequate segregation of duties consistent with control objectives;

(3) insufficient written policies and procedures for accounting and financial reporting with respect to the requirements and application of US GAAP and SEC disclosure requirements;

(4) ineffective controls over period end financial disclosure and reporting processes; and

(5) Non- performance of an evaluation, risk assessment or monitoring of our internal controls over financial reporting.

Management believes that none of the material weaknesses set forth above had a material adverse effect on the Company's financial results for the fiscal year ended December 31, 2015, but management is concerned that the material weakness in entity level controls set forth in item (1) results in ineffective oversight in the establishment and monitoring of required internal controls and procedures, it could result in a material misstatement in our financial statements in future periods.

We are committed to improving our financial organization. As part of this commitment, we intend to continue to enhance our internal control over financial reporting by: i) expanding our personnel, ii) improving segregated duties consistent with control objectives, iii) appointing more outside directors to our board of directors who shall be appointed to our audit committee resulting in a fully functioning audit committee who will undertake the oversight in the establishment and monitoring of required internal controls and procedures such as reviewing and approving estimates and assumptions made by management; and iv) preparing and implementing sufficient written policies and checklists which will set forth procedures for accounting and financial reporting with respect to the requirements and application of US GAAP and SEC disclosure requirements.

Management believes that the appointment of one or more outside directors, who were appointed to a fully functioning audit committee, remedied the ineffective audit committee. To this end, David Laskow-Pooley was appointed to our audit Committee in 2015. In addition, management believes that preparing and implementing sufficient written policies and checklists will remedy the following material weaknesses (i) insufficient written policies and procedures for accounting and financial reporting with respect to the requirements and application of US GAAP and SEC disclosure requirements; and (ii) ineffective controls over period end financial close and reporting processes. Further, management believes that the hiring of additional personnel will result in improved segregation of duties and provide more checks and balances within the financial reporting department.

We will continue to monitor and evaluate the effectiveness of our internal controls and procedures over financial reporting on an ongoing basis and are committed to taking further action by implementing additional enhancements or improvements, or deploying additional human resources as may be deemed necessary.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal controls over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to the temporary rules of the SEC that permit the Company to provide only management's report in this annual report.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during our fourth fiscal quarter of our fiscal year ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Our directors and executive officers and their respective ages as of the date of this annual report are as follows:

Name	Age	Position with the Company
Dr. Glynn Wilson	68	Chairman of the Board, Chief Executive Officer, Principal Executive Officer and a Director
Mark Reddish	60	Director
Sherry Grisewood	62	Director
Dr. John Bonfiglio	61	Director
David Laskow-Pooley	61	Independent Director
Frederick Wasserman	61	Independent Director

The following describes the business experience of each of our directors and executive officers, including other directorships held in other public companies:

Glynn Wilson, Ph. D., Chief Executive Officer and Chairman

Dr. Wilson was appointed to the Board in February 2005. Prior to joining the Board he was President and Chief Scientific Officer of Auriga Pharmaceuticals, a public specialty pharmaceutical company. Dr. Wilson was the Worldwide Head of Drug Delivery at SmithKline Beecham from 1989 to 1994, and the Chief Scientific Officer at Tacora Corporation from 1994 to 1997. Dr. Wilson was the Vice-President, R&D, at Access Pharmaceuticals from 1997 to 1998, and the President and CEO of PharmaSpec Corporation from 1999 to 2000. Most recently Dr. Wilson is President and Chief Scientific Officer of Auriga Pharmaceuticals, a public specialty pharmaceutical company. He has been an adjunct professor, Pharmaceutics and Pharmaceutical Chemistry, at the University of Utah since 1994, and was a faculty member at Rockefeller University, New York, in the laboratory of the Nobel Laureates, Sanford Moore and William Stein, from 1974 to 1979. He is a recognized leader in the development of drug delivery systems and has been involved in taking lead products & technologies from concept to commercialization. Dr. Wilson has a Ph. D. in Biochemistry and conducted medical research at The Rockefeller University, New York.

Dr. Wilson brings an extensive background of success in corporate management and product development with tenures in both major multinational pharmaceutical companies and start-up pharmaceutical/biotech organizations.

Mark Reddish, Director

Mr. Reddish joined the Company as Vice-President of Product Development in November 2011, and was appointed to the Board in April 2012. Mr. Reddish previously served as Vice President of Product Development and Principal Investigator, Biodefense at ID Biomedical, Bothell, WA, where he was employed from 1998 to 2005. At Biomira Inc, (renamed Oncothyreon), where he was employed from 1991 to 1998, He was responsible for preclinical development of their cancer vaccines program where he led the early research and clinical development of Stimuvax, which is currently in late Stage 3 clinical trials under a partnership with Merck KGa.

Mr. Reddish brings thirty years of biomedical experience ranging from clinical and academic research to industrial product development and has already brought significant value and insight to TapImmune as a member of the scientific advisory board. He has over 50 publications and a number of issued and pending patents in the area of vaccine technologies.

Sherry Grisewood, Director

Ms. Grisewood, CFA, joined the Board in March 2013. She has over 25 years securities industry experience in a range of investment banking, advisory and research-related activities. Since December 2012 she was been associated with Dawson James Securities Inc., first as Managing Director, Corporate Finance until September 2015 and now as Managing Partner, Life Science Research. Prior to joining Dawson James, she inaugurated a Lifesciences specialty investment banking practice as Managing Director, Lifesciences and Technology Banking, for Tripoint Global Equities where she was employed from December 2010 to December 2012. Prior to that, she was an investment banker, independent strategic advisor and consultant in life sciences for several investment banks over the prior 12 year period. Prior to consulting for investment banks, Ms. Grisewood served as Director of Research for a mid-tier brokerage company and a leading independent investment research company. Ms. Grisewood holds a Bachelor of Science degree

(Highest Honors) in Life Science from Ramapo College of New Jersey. She is a member of the American Society of Gene and Cell Therapy, the Tissue Engineering and Regenerative Medicine Society International, the Society of Biomaterials, and the CFA Institute.

Ms. Grisewood brings a wealth of knowledge about the securities and biomedical industries to TapImmune. She has participated in over 70 transaction-related projects involving initial public offerings, secondary offerings, PIPE's, private equity, M&A and licensing transactions. These deals and projects represented US, Canadian, Scandinavian, UK, Chinese and Australian clients with advanced therapeutic technologies and delivery systems in the life sciences such as those addressing nucleic acid therapeutics, regenerative medicine, immune-therapy, CNS diseases, or leading edge device technologies for lifescience special situations.

Dr. John Bonfiglio, Director

Dr. Bonfiglio joined the Board in July 2015. Dr. Bonfiglio served as President, Chief Executive Officer and Director of Oragenics, Inc. (a public company: NYSE MKT: OGEN) from May 2011 through October 2014. Dr. Bonfiglio also served as the Chief Executive Officer, President and Director of Transdel Pharmaceuticals (a public company: TDLPE. OB) between October 2010 and May 13, 2011. Previously Dr. Bonfiglio served as the President and Chief Executive Officer of Argos Therapeutics from January 2007 to February 2010. From November 2005 to December 2006, he served as an independent consultant to two medical device companies, a therapeutic company and a medical communications company. From January 2003 to October 2005, he served as the Chief Executive Officer of The Immune Response Corporation, a public company and immuno-pharmaceutical company focused on developing products to treat autoimmune and infectious diseases. From 2001 to 2002, he was the Chief Operating Officer and Executive Vice President of Cypress Biosciences, a public company (NASDAQ: CYPB) providing therapeutics and personalized medicine services. From 1997 to 2001, he served as the Chief Executive Officer and President of Peregrine Pharmaceuticals, Inc., a public biopharmaceutical company (NASDAQ: PPHM) developing first-in-class monoclonal antibodies for the treatment of cancer and viral infections. Dr. Bonfiglio has also held senior management positions with Baxter Healthcare and Allergan, Inc. Dr. Bonfiglio received his bachelor of sciences degree in chemistry from State University of New York at Stony Brook in 1976, later earning his masters degree and a doctorate in synthetic organic chemistry from University of California at San Diego in 1978 and 1980 respectively. He later went on to serve as a postdoctoral fellow in organometallic chemistry at the University of California at Berkeley in 1981, earning his masters in business administration from Pepperdine University in 1992.

We believe that Dr. Bonfiglio's qualifications to serve as a director include his 30 years of executive experience in the pharmaceutical, medical device and healthcare businesses, his experience in raising funds and completing licensing transactions for his prior companies and his experience on other company boards.

David Laskow-Pooley, Director

Mr. Laskow-Pooley joined the Board in March 2015. He is currently CEO of LondonPharma Ltd, a clinical stage company re-purposing approved drugs through novel drug delivery technologies, where he has been employed since April 2012. He is also a Co-founder of Pharmafor Ltd, a small company incubator. He was formerly Managing Director (UK) of Nasdaq- listed drug discovery platform company, OSI, where he was employed from 2002 to 2004. He also was part of the corporate team that developed and launched Tarceva for the treatment of lung cancer with marketing partners Roche and Genentech. He is a pharmacist with more than 30 years of experience in the Pharmaceutical, Diagnostic and Device sectors, and has had a distinguished career in multinational pharmaceutical companies including Glaxo SmithKline and Abbott, in addition to InVitrogen (Biotech Life Sciences) and Amersham, now GE Healthcare (Diagnostic Imaging). He currently serves as a non-executive director and Chairman of OBN Ltd, an industry representative for small to medium enterprises (SME's) in the UK.

Mr. Laskow-Pooley brings a wealth of experience in the pharmaceutical industry and with start-up and early stage pharmaceutical/biotech organizations.

Frederick Wasserman, Director

Mr. Wasserman joined the Board in January 2016. He is a business executive with over 35 years of business experience, having served at various companies in roles including Chief Executive Officer, President, Chief Operating Officer and Chief Financial Officer. He is currently the President of FGW Partners LLC, Pennington, NJ, where he has been employed since 2007. He currently serves on the boards of directors of DHL Holdings Corp, Breeze-Eastern Corporation, MAM Software Group, Inc. SMTC Corporation and National Holdings Corporation. Mr. Wasserman was employed as a certified public accountant from 1976 to 1989. He earned a Bachelor of Science degree from The Wharton School at The University of Pennsylvania in 1976.

Mr. Wasserman brings to our Board an extensive array of business and industry experience as well as experience as a director of public companies.

Term of Office

Our directors are appointed for a one-year term to hold office until the next annual general meeting of our stockholders or until they resign or are removed from the board in accordance with our bylaws. Our officers are appointed by our Board of Directors and hold office until they resign or are removed from office by the Board of Directors.

Audit Committee

Our Board of Directors has established an Audit Committee which functions pursuant to a written charter last amended by our Board of Directors in November 2015. The members of the Committee were Dr. Wilson, Mr. Reddish and Ms. Grisewood from the beginning of 2015 until November 6, 2015, when Dr. Wilson was replaced by Mr. Laskow-Pooley. Ms. Grisewood serves as Chair of the Committee. Our Board of Directors has determined that Ms. Grisewood qualifies as an “audit committee financial expert” as defined in Item 407(d)(5)(ii) of Regulation S-K. The Board has determined that Ms. Grisewood is not independent under the Nasdaq listing standards, due to the fact that she was paid $10,000 in 2013 for consulting work performed for the Company. The Committee met four times during 2015.

Compensation Committee

Our Board of Directors has established a Compensation Committee which functions pursuant to a written charter last amended by our Board of Directors in November 2015. The members of the Committee were Dr. Wilson and Ms. Grisewood from the beginning of 2015 until November 6, 2015, when Dr. Wilson was replaced by Mr. Laskow-Pooley. Dr. Bonfiglio was also appointed to the Committee on November 6, 2015. Mr. Laskow-Pooley serves as Chair of the Committee. The Board has determined that Dr. Bonfiglio is not independent under the Nasdaq listing standards, due to the fact that he serves as a consultant to the Company. See “Certain Relationships and Related Transactions and Director Independence.” The Committee met or acted by written consent twice during 2015.

Nominating and Corporate Governance Committee

Our Board of Directors has established a Nominating and Corporate Governance Committee which functions pursuant to a written charter adopted by our Board of Directors in November 2015. The members of the Committee are Dr. Wilson, Mr. Laskow-Pooley and Mr. Reddish. Dr. Wilson serves as Chair of the Committee. The Committee met once during 2015.

A copy of the charter of each of the foregoing committees of the Board can be viewed on our website at the following URL:

http://www. tapimmune. com/wp-content/uploads/2016/03/TapImmune-Audit-Committee-Charter. pdf
http://www. tapimmune. com/wp-content/uploads/2016/03/TapImmune-Nominating-Committee-Charter. pdf
http://www. tapimmune. com/wp-content/uploads/2016/03/TapImmune-Audit-Committee-Charter. pdf

Code of Ethics and Business Conduct

We have adopted a Code of Ethics and Business Conduct that applies to all directors and officers. The code describes the legal, ethical and regulatory standards that must be followed by the directors and officers of the Company and sets forth high standards of business conduct applicable to each director and officer. A copy of the code can be viewed on our website at the following URL:

http://www. tapimmune. com/wp-content/uploads/2016/04/TapImmune-Inc-Code-of-Ethics. pdf

Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Exchange Act requires our directors and officers, and the persons who beneficially own more than 10% of our common stock, to file reports of ownership and changes in ownership with the SEC. Copies of all filed reports are required to be furnished to us pursuant to Rule 16a-3 promulgated under the Exchange Act. Based solely on the reports received by us and on the representations of the reporting persons, we believe that these persons have complied with all applicable filing requirements during the years ended December 31, 2014 and December 31, 2015, except as noted below:

Dr. Glynn Wilson. On November 13, 2015, a Form 4 was filed to disclose: (i) 513,319 shares of common stock issued on February 26, 2014 at a price of $0.80 per share for cancellation of debt;(ii) 120,000 share of common stock issued on December 2, 2014 at a price of $1.00 per share for compensation owed in the amount of $120,000; and (iii) 1,600 stock options at issued on February 11, 2011 at a price of $17.00 per share.

Mark Reddish. On November 13, 2015, a Form 4 was filed to disclose**:** (i) 225,000 share issued on February 26, 2014 at price per share of $0.80 in connection with cancellation of debt; (ii) 2,000 stock options issued on February 16, 2011 at a price of $17.00 per share-these shares have vested; and (iii) 2,500 stock options issued on February 16, 2011 at a price of $17.00 per share-these shares have vested.

Sherry Grisewood. On November 13, 2015, a Form 3 was filed to disclose: that (i) Ms. Grisewood joined Board on March 20, 2013; and (ii) 205 shares of common stock issued for consulting services on a post-split basis prior to becoming a director. On November 13, 2015, a Form 4 was filed to disclose: 28,125 shares of common stock issued on February 16, 2014 at a price of $0.80 per share for cancellation of amounts owed.

David Laskow-Pooley. On November 13, 2015, a Form 3 was filed to disclose that Mr. Laskow-Pooley joined Board on Mach 19, 2015. On November 13, 2015, a Form 4 was filed to disclose 150,000 stock options issued on 3/19/15 at a price of $0.21 per share.

Dr. John Bonfiglio. On November 9, 2015, a Form 3 was filed to disclose**:** that (i) Dr. Bonfiglio joined the Board on July 23, 2015; and (ii) 250,000 shares of common stock issued on February 10, 2015 at a price of $0.145 in connection with a consulting agreement. On November 9, 2015, a Form 4 was filed to disclose that 150,000 stock options issued on July 23, 2015 at a price of $0.57 per share issued in connection with appointment as a director.

(b) *Board meetings and committees; annual meeting attendance.*

(1) The Company held four meetings of the board of directors during 2015.

(2) The Company did not hold an annual meeting of security holders in 2015.

ITEM 11. EXECUTIVE COMPENSATION

Compensation Discussion and Analysis

The following table sets forth the compensation paid to our executive officers for their services as executive officers during our fiscal years ended December 31, 2015 and December 31, 2014:

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Glynn Wilson							
Chairman, CEO and Principal Executive Officer and	2015	204,000	Nil	Nil	605,000	11,000	820,000
Acting Principal Accounting Officer	2014	180,000	Nil	Nil	Nil	Nil	180,000
Patrick Yeramian	2015	186,000	Nil	Nil	4,000	11,000	201,000
Chief Medical Officer	2014	Nil	Nil	Nil	Nil	Nil	Nil

The amounts represent fees paid or accrued by us to the executive officers during the past year pursuant to various employment and consulting services agreements, as between us and the executive officers, which are described below. Our executive officers are also reimbursed for any out-of-pocket expenses incurred in connection with corporate duties. We presently have no pension, health, annuity, insurance, profit sharing or similar benefit plans.

The following table sets forth information as at December 31, 2015 relating to outstanding equity awards for each Named Executive Officer:

Outstanding Equity Awards at Year End Table

Name	Number of Securities Underlying Unexercised Options (exercisable)	Number of Securities Underlying Unexercised Options (unexercisable)	Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date
Glynn Wilson	1,000,000	1,000,000	Nil	$ 0.61	12/11/25
Chairman, CEO and Principal Executive Officer	400	Nil	Nil	$ 17.00(2)	07/06/17
	16,000(1)	Nil	Nil	$ 17.00(2)	10/14/19
	1,600(1)	Nil	Nil	$ 17.00	02/16/21
	20,000(1)	Nil	Nil	$ 19.00	03/16/16

(1) The plan under which these shares were issued was approved by the Board of Directors and the shareholders in 2009 but did not come into effect until February 22, 2010.

(2) Effective February 16, 2011, the option exercise price was reduced to $17.00.

The following table sets forth information relating to compensation earned or paid to our directors for their services as directors in the fiscal year ended December 31, 2015, and excludes compensation paid to our directors for their services as executive officers:

Director Compensation Table

Name	Fees Earned or Paid in Cash	Stock Awards ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Glynn Wilson	Nil	Nil	Nil	Nil	Nil
David Laskow-Pooley	$ 2,000	Nil	13,000	Nil	$ 15,000
Sherry Grisewood	$ 6,000	Nil	91,000	Nil	$ 97,000
John Bonfiglio	$ 4,000	Nil	119,000	145,000*	$ 268,000
Mark Reddish	$ 6,000	Nil	96,000	Nil	$ 102,000

* Represents fees paid to Dr. Bonfiglio for consulting services during the year pursuant to a consulting agreement we entered into with Dr. Bonfiglio and subsequently amended. See discussion below of the terms of the consulting agreement.

At its meeting on November 6, 2015 the Non-Employee Director Compensation Plan was ratified and approved and provided for the following:

- An initial grant upon joining the Board of 150,000 stock options under the 2014 Omnibus Stock Ownership Plan;
- In person meeting fees of $2,000, with the anticipation that four in person board meetings would be held each year;
- No fees for telephonic meetings (board and committee);
- No annual fees;
- No committee meeting fees;
- No committee chair fees; and
- Reimbursement of reasonable expenses incurred.

Employment, Consulting and Services Agreements

Dr. Wilson

On November 12, 2015, the Company entered into a new employment agreement with Dr. Glynn Wilson, the Company's Chief Executive Officer, President and Chairman, the material terms and conditions of which are summarized below.

The employment agreement provides that Dr. Wilson will serve as the Chief Executive Officer, President and Chairman of the Company. The initial term of the agreement ends November 11, 2017, but it will automatically be extended for 12-months unless terminated by the Company or Dr. Wilson by written notice to the other not later than 12 months prior to the end of such initial term. It will thereafter be further extended for an additional 12 months after the end of each such extended term unless terminated by the Company or Dr. Wilson by written notice no later than 90 days prior to the end of such term, subject to early termination for cause or good reason by Dr. Wilson. Under the agreement, Dr. Wilson's annual base salary is to be $280,000, and he is entitled to a performance-based bonus ranging of up to 50% of his base salary based on goals and other conditions as the Board determines on an annual basis, which may be paid in cash or equity awards as the Board determines.

Dr. Wilson will be entitled to 21 days paid vacation per calendar year plus such sick leave as he may reasonably and actually require, and he will be entitled to participate in all group insurance, vacation, retirement and other employee benefits established by Company for its full time employees generally, on terms comparable to those provided to such employees from time to time by the Company.

In connection with entering into the new agreement, Dr. Wilson received equity awards under the Company's 2014 Omnibus Stock Ownership Plan consisting of (i) an award of 315,000 shares of unregistered common stock, which immediately vested, and (ii) an award of stock options to purchase 2 million shares of Company common stock, prior to November 12, 2025, for $0.605 per share (the closing price of the common stock on November 12, 2015). One-half of the stock options immediately vested, and the remaining 1 million shares will vest ratably over the following 24 months.

If the agreement is terminated by the Company without cause (as defined in the agreement), or if the agreement is terminated by Dr. Wilson for good reason (as defined in the agreement), the Company is required to pay Dr. Wilson a severance payment in an amount equal to 2/3 of his annual base salary, plus any amount of his annual performance bonus that was earned as of the date of termination but not yet paid.

If the agreement is terminated either by the Company without cause or by Dr. Wilson for good reason during the period of ninety (90) days following a change in control (as defined in the agreement), then in lieu of the severance payment described above, the Company is required to pay Dr. Wilson severance equal to the sum of (i) 2/3 of his annual base salary and (ii) his Annual Performance Bonus for the year which includes the effective date of the change in control, payable at the target level of performance. In addition, the Company will also be required to pay Dr. Wilson the amount of any annual performance bonus that, as of the date of termination, has been earned by him but not yet paid. If Dr. Wilson holds any stock options or other stock awards granted under the Company's equity plans which are not fully vested at the time his employment with the Company is terminated either by the Company without Cause or by him for good reason during the period of ninety (90) days following a change in control, such equity awards shall become fully vested as of the termination date.

The agreement provides that Dr. Wilson may not solicit any of the Company's employees or compete directly or indirectly with the Company during the term of the agreement and for one year after its expiration anywhere in the United States. The agreement contains customary confidentiality provisions.

Dr. Bonfiglio

On February 10, 2015, we entered into a Consulting Agreement with Dr. Bonfiglio. Pursuant to that Agreement, Dr. Bonfiglio was to (a) review our strategy, technology differentiation and development; (b) identify and implement new strategies to increase our financing opportunities; (c) present our company at external meetings and conferences; (d) develop and implement improved an investors' relations program; and (e) upgrade our management team and Board of Directors. The Agreement provided that Dr. Bonfiglio would perform such services for up to 80 hours per month, and in exchange for these services, he would be paid $10,000 per month and receive 250,000 options to purchase shares of our common stock for $0.145 per share. The stock options vested as follows: 33,333 options vested at the end of each of the first three months and 16,666 options vested at the end of each of the following nine months. The term of the Agreement was originally one year, and provided for termination by either party with 30 days' notice. The Agreement was amended in June 2015 to increase the monthly cash payment to $15,000 per month, and increase the number of hours during which Dr. Bonfiglio would perform services to up to 120 hours per month. The Agreement was amended again in February 2016 to extend the term until August 10, 2016.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth, as of the date of this Annual Report certain information regarding the ownership of our common stock by (i) each person known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock, (ii) each of our directors, (iii) our Chief Executive Officer and (iv) all of our directors and our Chief Executive Officer as a group. Unless otherwise indicated, the address of each person shown is c/o TapImmune Inc., 50 N. Laura Street, Suite 2500, Jacksonville, Florida 32202. Beneficial ownership, for purposes of this table, includes options and warrants to purchase common stock that are either currently exercisable or will be exercisable within 60 days of the date of this annual report.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Owner(1)	Percent of Class
Directors and Officers:		
Dr. Glynn Wilson, Chairman and Chief Executive Officer (2)	2,911,675	4.1%
Mark Reddish, Director (3)	381,167	*
Sherry Grisewood, Director (4)	178,330	*
Dr. John Bonfiglio, Director (5)	400,000	*
David Laskow-Pooley, Director (6)	150,000	*
Frederick Wasserman, Director (7)	150,000	*
All executive officers and directors as a group (6 persons)	4,171,172	5.9%
Major Stockholders:		
Eastern Capital Limited (8)	40,000,000	49.9%
Iroquois Capital Management L. L. C. (9)	8,481,124	9.9%
Brio Capital Master Fund(11)	4,711,239	6.9%
Empery Asset Management LP(10)	4,963,792	4.99%
American Capital Management L. L. C. (12)	5,250,000	4.9%

* Less than one percent (1%)

(1) Under Rule 13d-3, a beneficial owner of a security includes any person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise has or shares: (i) voting power, which includes the power to vote, or to direct the voting of shares; and (ii) investment power, which includes the power to dispose or direct the disposition of shares. Certain shares may be deemed to be beneficially owned by more than one person (if, for example, persons share the power to vote or the power to dispose of the shares). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire the shares (for example, upon exercise of an option) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person, the amount of shares outstanding is deemed to include the amount of shares beneficially owned by such person (and only such person) by reason of these acquisition rights. As a result, the percentage of outstanding shares of any person as shown in this table does not necessarily reflect the person's actual ownership or voting power with respect to the number of shares of common stock actually outstanding as of the date of this Annual Report. As of March 1, 2016 there were 70,400,762 shares of common stock issued and outstanding.

(2) This figure includes 2,038,000 shares subject to purchase under stock options, 1,329,662 of which have vested.

(3) This figure includes 150,000 shares subject to purchase under stock options.

(4) This figure includes 150,000 shares subject to purchase under stock options.

(5) This figure includes 400,000 shares subject to purchase under stock options, 318,750 of which have vested.

(6) This figure includes 150,000 shares subject to purchase under stock options, 93,750 of which have vested.

(7) This figure includes 150,000 shares subject to purchase under stock options, 25,000 of which have vested.

(8) All information is based upon the Schedule 13D jointly filed with the Securities and Exchange Commission by Eastern Capital Limited, Portfolio Services LTD. and Kenneth B. Dart, on September 29, 2015. Eastern Capital Limited's address is 10 Market St. #773, Camana Bay, Grand Cayman KY1-1206 Cayman Islands. Eastern Capital beneficially owns 20,000,000 shares of Common Stock and 20,000,000 shares of Common Stock issuable upon

exercise of the Series A-1 Warrant, Series D-1 Warrant, Series E-1 Warrant or the remainder of the Series C-1 Warrant. All warrants are subject to a limit of exercise to the extent (and only to the extent) that Eastern Capital Limited or any of its affiliates would beneficially own in excess of 49.9% (the "Maximum Percentage") of the Common Stock after giving effect to such exercise.

(9) All information is based upon the Schedule 13G jointly filed with the Securities and Exchange Commission by Iroquois Capital Management L. L. C., Joshua Silverman and Richard Abbe on February 8, 2016. The Series A, D and E Warrants are subject to a limit of exercise to the extent (and only to the extent) that Iroquois Capital Management L. L. C., or any of its affiliates would beneficially own in excess of 4.9% (the "Maximum Percentage") of the Common Stock after giving effect to such exercise. The Series C Warrants are subject to a limit of exercise to the extent (and only to the extent) that Iroquois Capital Management L. L. C., or any of its affiliates would beneficially own in excess of 9.9% of the Common Stock after giving effect to such exercise.

Pursuant to the terms of the warrants, the reporting persons cannot exercise (i) any of the warrants that are Series A, Series D or Series E warrants if the reporting persons would beneficially own, after any such exercise, more than 4.9% of the outstanding shares of Common Stock or (ii) any of the warrants that are Series C warrants if the reporting persons would beneficially own, after any such exercise, more than 9.9% of the outstanding shares of Common Stock (the applicable "Blockers"). The reporting persons are not able to exercise all of the warrants due to the applicable Blockers.

Mr. Abbe and Mr. Silverman are the members of Iroquois who have the authority and responsibility for the investments made on behalf of the Fund. As such, Mr. Abbe and Mr. Silverman may be deemed to be the beneficial owner of all shares of Common Stock held by, and underlying the warrants (subject to the applicable Blockers) held by, the Fund. In addition, by virtue of his position as a custodian or trustee of certain Accounts (The Merav Abbe Irrevocable Trust, The Samantha Abbe Irrevocable Trust, The Talia Abbe Irrevocable Trust and The Bennett Abbe Irrevocable Trust), Mr. Abbe may be deemed to be the beneficial owner of the shares of Common Stock held by, and underlying the warrants (subject to the applicable Blockers) held by, such Accounts. The foregoing should not be construed in and of itself as an admission by any reporting person as to beneficial ownership of shares of Common Stock owned by another reporting person. Each of the reporting individuals disclaims any beneficial ownership of any such shares of Common Stock except to the extent of their pecuniary interest therein.

(10) All information is based upon the Schedule 13G filed with the Securities and Exchange Commission by Brio Capital Master Fund Ltd. on January 29, 2016. The Series C Warrants are are subject to a limit of exercise to the extent (and only to the extent) that Brio Capital Master Fund Ltd. or any of its affiliates would beneficially own in excess of 9.9% (the "Maximum Percentage") of the Common Stock after giving effect to such exercise. The warrants acquired in 2014are are subject to a limit of exercise to the extent (and only to the extent) that Brio Capital Master Fund Ltd. or any of its affiliates would beneficially own in excess of 4.9% of the Common Stock after giving effect to such exercise.

Pursuant to the terms of (i) the Series C Warrants, the reporting persons cannot exercise any of such warrants if the reporting persons would beneficially own, after any such exercise, more than 9.9% of the outstanding shares of Common Stock, and (ii) the warrants issued in 2014, the reporting persons cannot exercise any of such warrants if the reporting persons would beneficially own, after any such exercise, more than 4.99% of the outstanding shares of Common Stock (the "Blockers"). Consequently, the reporting persons were not able to exercise all of the warrants due to the Blockers.

(11) All information is based upon the Schedule 13G jointly filed with the Securities and Exchange Commission by Empery Asset Management LP, Ryan M. Lane and Martin D. Hoe on January 19, 2016. Assumes exercise of all Class C Warrants, are subject to a limit of exercise to the extent (and only to the extent) that Empery Asset Management LP or any of its affiliates would beneficially own in excess of 9.9% (the "Maximum Percentage") of the Common Stock after giving effect to such exercise.

The Investment Manager, which serves as the investment manager to the Empery Funds, may be deemed to be the beneficial owner of all shares of Common Stock held by, and underlying the reported warrants (subject to the Blockers) held by, the Empery Funds. Each of the reporting individuals, as managing members of the general partner of the Investment Manager with the power to exercise investment discretion, may be deemed to be the beneficial owner of all shares of Common Stock held by, and underlying the warrants (subject to the Blockers) held by, the Empery Funds. The foregoing should not be construed in and of itself as an admission by any reporting person as to beneficial ownership of shares of Common Stock owned by another reporting person. Each of the reporting individuals disclaims any beneficial ownership of any such shares of Common Stock.

(12) All information is based upon the Schedule 13G jointly filed with the Securities and Exchange Commission by American Capital Management L. L. C. and Kimberly Page on February 8, 2016. The Series A, D and E Warrants are subject to a limit of exercise to the extent (and only to the extent) that American Capital Management L. L. C. or any of its affiliates would beneficially own in excess of 4.9% (the "Maximum Percentage") of the Common Stock after giving effect to such exercise. The Series C Warrants are subject to a limit of exercise to the extent (and only to the extent) that American Capital Management L. L. C., or any of its affiliates would beneficially own in excess of 9.9% of the Common Stock after giving effect to such exercise.

Pursuant to the terms of the warrants, the reporting persons cannot exercise (i) any of the warrants that are Series A, Series D or Series E Warrants if the reporting persons would beneficially own, after any such exercise, more than 4.9% of the outstanding shares of Common Stock or (ii) any of the warrants that are Series C Warrants if the reporting persons would beneficially own, after any such exercise, more than 9.9% of the outstanding shares of Common Stock (the applicable "Blockers").

Ms. Page has the authority and responsibility for the investments made on behalf of ACM and accordingly, has voting and dispositive power over the shares of Common Stock held by ACM. As such, Ms. Page may be deemed to be the beneficial owner of all shares of Common Stock held by, and underlying the warrants (subject to the applicable Blockers) held by, ACM.

There are no arrangements or understanding among the parties set out above or their respective associates or affiliates concerning election of directors or any other matters which may require shareholder approval.

Changes in Control

Other than the changes in stock ownership by our major shareholders who hold warrants to acquire additional shares of our common stock (as reflected in the footnotes to the table above), we are unaware of any contract, or other arrangement or provision, the operation of which may at a subsequent date result in a change of control of our Company.

Equity Compensation Plan Information

The following table summarizes the equity compensation plans under which the equity securities of the Company may be issued as of December 31, 2015:

	(a) Number of Securities to be Issued Upon Exercise of Options	(b) Weighted Average Exercise Price of Outstanding Options	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by shareholders(1)	44,150	$ 17. 94	55,850
Equity compensation plans not approved by shareholders(2)	3,540,000	$ 0. 55	3,460,000
Totals	3,584,150	$ 0. 77	3,515,850

(1) Includes shares of common stock authorized for awards under the 2009 Stock Incentive Plan.
(2) Represents shares of common stock authorized for issuance under the 2014 Omnibus Stock Option Plan.

On October 14, 2009, the Company adopted the 2009 Stock Incentive Plan (the “2009 Plan”). The 2009 Plan allows for the issuance of up to 100,000 common shares. Options granted under the Plan shall be at prices and for terms as determined by our Board of Directors, and may have vesting requirements as determined by our Board of Directors. The foregoing summary of the 2009 Stock Incentive Plan is not complete and is qualified in its entirety by reference to the 2009 Stock Incentive Plan, a copy of which has been filed with the SEC. To date, 44,150 options have been issued under the 2009 Plan.

On March 19, 2014, the Board adopted the 2014 Omnibus Stock Option Plan (“2014 Plan”). The 2014 Plan allowed for grants of stock options, restricted shares, stock bonuses and other equity based awards to employees and non-employee directors of the Company. Awards under the 2014 Plan may be at prices and for terms as determined by the Board of Directors, and may have vesting requirements as determined by the Board, provided that the exercise price for any stock option must be at least equal to the fair market value (as defined in the 2014 Plan) of a share of the stock on the grant date. Once granted, the exercise price of an option may not be reduced without the approval of the Company’s shareholders, other than under certain limited circumstances such as a stock split, or take any other action with respect to a stock option that would be treated as a repricing under the rules and regulations of the New York Stock Exchange. Under the 2014 as originally approved, stock could be issued under the 2014 Plan as a bonus to any employee, other than executive officers of the Company and 2.0 million shares of common stock were reserved for issuance under the 2014 Plan. The 2014 Plan was amended in February 2015 to provide for grants to consultants, and again in November 2015 to (i) increase the number of shares reserved for issuance under the Plan by 5.0 million shares to 7.0 million shares; (ii) provide the Board and Committee administering the Plan with full discretion on the vesting period for Service-Vesting Awards under the Plan, including the grant of Awards with less than the Minimum Vesting Requirement (as such terms are defined in the Plan), and (iii) provide the Board and Committee administering the Plan with the ability to grant stock bonuses to executive officers. To date, 3,540,000 options have been issued under the 2014 Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The Board affirmatively determines the independence of each director and nominee for election as a director in accordance with guidelines it has adopted, which include all elements of independence set forth in the NASDAQ listing standards. Based upon these standards, at its meeting held on November, 2015, the Board determined that David Laskow-Pooley was independent and had no relationship with the Company, except as a director and shareholder of the Company. At the time of appointment in January 2016 the Board determined that Frederick G. Wasserman was an independent Director.

Review and Approval of Related Person Transactions. In order to ensure that material transactions and relationships involving a potential conflict of interest for any executive officer or director of the Company are in the best interests of the Company, under the Code of Ethics and Business Conduct ("Code of Ethics") adopted by the Board of Directors for all of our employees and directors, all such conflicts of interest are required to be reported to the Audit Committee of the Board of Directors, and the approval of the Audit Committee must be obtained in advance for the Company to enter into any such transaction or relationship. Pursuant to the Code of Ethics, no officer or employee of the Company may, on behalf of the Company, authorize or approve any transaction or relationship, or enter into any agreement, in which such officer, director or any member of his or her immediate family, may have a personal interest without such Audit Committee approval. Further, no officer or employee of the Company may, on behalf of the Company, authorize or approve any transaction or relationship, or enter into any agreement, if they are aware that an executive officer or a director of the Company, or any member of any such person's family, may have a personal interest in such transaction or relationship, without such Audit Committee approval.

The Company's Audit Committee reviews all conflict of interest transactions involving executive officers and directors of the Company, pursuant to its charter.

In the course of their review of a related party transaction, the Audit Committee considers:

- the nature of the related person's interest in the transaction;
- the material terms of the transaction, including, without limitation, the amount and type of transaction;
- the importance of the transaction to the Company;
- the importance of the transaction to the related person;
- whether the transaction would impair the judgment of the director or executive officer to act in the best interests of the Company; and
- any other matters the Audit Committee deems appropriate.

Any member of the Audit Committee who has a conflict of interest with respect to a transaction under review may not participate in the deliberations or vote respecting approval of the transaction, provided, however, that such director may be counted in determining the presence of a quorum.

During the years ended December 31, 2014 and December 31, 2015, we entered into transactions with certain of our officers and directors as follows:

The Dr. Bonfiglio Consulting Agreement. On July 23, 2015, Dr. John Bonfiglio became a director. Prior to that time, on February 10, 2015, we entered into a Consulting Agreement with Dr. Bonfiglio. Pursuant to that Agreement, Dr. Bonfiglio was to (a) review our strategy, technology differentiation and development; (b) identify and implement new strategies to increase our financing opportunities; (c) present our company at external meetings and conferences; (d) develop and implement improved an investors' relations program; and (e) upgrade our management team and Board of Directors. The Agreement provided that Dr. Bonfiglio would perform such services for up to 80 hours per month, and in exchange for these services, he would be paid $10,000 per month and receive 250,000 options to purchase shares of our common stock for $0.145 per share. The stock options vested as follows: 33,333 options vested at the end of each of the first three months and 16,666 options vested at the end of each of the following nine months. The term of the Agreement was originally one year, and provided for termination by either party with 30 days' notice. The Agreement was amended in June 2015 to increase the monthly cash payment to $15,000 per month, and increase the number of hours during which Dr. Bonfiglio would perform services to up to 120 hours per month. The Agreement was amended again in February 2016 to extend the term until August 10, 2016. Because Dr. Bonfiglio was a director at the time of the most recent amendment, the amendment was approved by our audit committee.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Marcum LLP served as our independent registered public accounting firm and audited our financial statements for the fiscal years ended December 31, 2014 and December 31, 2014. Aggregate fees for professional services rendered to us by our auditor are set forth below:

	Year Ended December 31, 2014	Year Ended December 31, 2015
Audit Fees	$ 125,000	$ 95,000
Audit Related Fees	—	—
Tax Fees	—	60,000
All Other Fees	—	—
	$ 125,000	$ 155,000

Audit Fees

Audit fees are the aggregate fees billed for professional services rendered by our independent auditors for the audit of our annual financial statements, the review of the financial statements included in each of our quarterly reports and services provided in connection with statutory and regulatory filings or engagements.

Audit Related Fees

Audit related fees are the aggregate fees billed by our independent auditors for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not described in the preceding category.

Tax Fees

Tax fees are billed by our independent auditors for tax compliance, tax advice and tax planning.

All Other Fees

All other fees include fees billed by our independent auditors for products or services other than as described in the immediately preceding three categories.

Policy on Pre-Approval of Services Performed by Independent Auditors

It is our Audit Committee’s policy to pre-approve all audit and permissible non-audit services performed by the independent auditors. The Audit Committee approved all services that our independent accountants provided to us in the past two fiscal years.

TAPIMMUNE INC.

CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2015

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Audit Committee of the
Board of Directors and Shareholders
of TapImmune, Inc.

We have audited the accompanying consolidated balance sheets of TapImmune, Inc. (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity (deficit) and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of TapImmune, Inc. as of December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered losses from operations and will require identifying new sources of capital to fund operations. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans concerning these matters are also discussed in Note 2 to the consolidated financial statements. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Marcum LLP
New York, NY
April 14, 2016

TAPIMMUNE INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2015	December 31, 2014
ASSETS		
Current Assets		
Cash	$ 6,576,564	$ 141,944
Prepaid expenses and deposits	68,803	82,504
	$ 6,645,367	$ 224,448
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities		
Accounts payable and accrued liabilities	$ 967,358	$ 693,362
Research agreement obligations	492,365	492,365
Derivative liability – warrants	26,493,000	9,415
Promissory notes	30,000	29,942
Promissory note, related party	23,000	23,000
	28,005,723	1,248,084
COMMITMENTS AND CONTINGENCIES		
Stockholders' Equity (Deficit)		
Convertible preferred stock, $0.001 par value — 5,000,000 shares authorized:		
Series A, $0.001 par value, 1,250,000 shares designated, -0- shares issued and outstanding as of December 31, 2015 and December 31, 2014	—	—
Series B, $0.001 par value, 1,500,000 shares designated, -0- shares issued and outstanding as of December 31, 2015 and December 31, 2014	—	—
Common stock, $0.001 par value, 500,000,000 shares authorized 70,550,763 shares issued and outstanding (2014 – 20,318,815)	70,551	20,319
Additional paid-in capital	112,077,520	85,265,776
Accumulated deficit	(133,508,427)	(86,309,731)
Accumulated other comprehensive loss	—	—
	(21,360,356)	(1,023,636)
	$ 6,645,367	$ 224,448

The accompanying notes are an integral part of these consolidated financial statements.

TAPIMMUNE INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31, 2015	Year Ended December 31, 2014
Operating expenses:		
General and administrative	$ 4,447,781	$ 3,181,927
Research and development	1,711,177	189,000
Loss from Operations	(6,158,958)	(3,370,927)
Other Income (Expense)		
Foreign exchange (loss) gain	775	(52,976)
Changes in fair value of derivative liabilities	(27,872,585)	581
Accretion of discount on convertible notes	—	(492,296)
Interest and financing charges	(10,925)	(83,247)
Loss on extinguishment of debt	—	(26,884,231)
Loss on settlement agreement	(24,697)	—
Net Loss for the Period	(34,066,390)	(30,883,096)
Other comprehensive income		
Foreign exchange translation adjustment	—	58,334
TOTAL COMPREHENSIVE LOSS	$(34,066,390)	$(30,824,762)
Basic and Diluted Net Loss per Share	$ (0.78)	$ (2.00)
Weighted Average Number of Common Shares Outstanding	43,947,067	15,465,213

The accompanying notes are an integral part of these consolidated financial statements.

TAPIMMUNE INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Additional Paid In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Number of shares	Amount $	$	$	$	$
Balance, December 31, 2013	1,465,712	1,466	46,715,500	(55,426,635)	(58,334)	(8,768,003)
Convertible notes, promissory notes, loan payable-related party, due to related parties and accrued interest converted into Series A and B preferred stock and immediately converted into commons stock	14,048,701	14,049	30,937,029			30,951,078
Conversion of accounts payable to common stock	1,836,361	1,836	4,347,592	—	—	4,349,428
Private placement (net of finders' fee)	2,157,042	2,157	1,875,343	—	—	1,877,500
Foreign exchange translation adjustment	—	—	—	—	58,334	58,334
Stock- based compensation	811,000	811	1,390,312	—	—	1,391,123
Net loss	—	—	—	(30,883,096)	—	(30,883,096)
Balance, December 31, 2014	20,318,816	20,319	85,265,776	(86,309,731)	—	(1,023,636)
Accounts payable settled in shares	118,450	118	21,795	—	—	21,913
Private placement (net of finders' fee)	12,363,447	12,321	2,313,694	—	—	2,326,015
Fair value of warrants recognized as derivative liabilities in January and March 2015 Financing	—	—	(2,313,694)	(6,999,306)	—	(9,313,000)
Fair value of warrants issued on May 28, 2015	—	—	—	(6,133,000)	—	(6,133,000)
Exercise of warrants	37,079,990	37,122	9,182,876	—	—	9,219,998
Reclassification of Derivative Warrant Liabilities to Equity at exercise date	—	—	16,835,000	—	—	16,835,000
Finders' fee on exercise of warrants	—	—	(767,995)	—	—	(767,995)
Shares issued in settlement	49,950	50	26,423	—	—	26,473
Stock- based compensation	620,110	621	1,513,645	—	—	1,514,266
Net loss	—	—	—	(34,066,390)	—	(34,066,390)
Balance, December 31, 2015	70,550,763	70,551	112,077,520	(133,508,427)	—	(21,360,356)

The accompanying notes are an integral part of these consolidated financial statements.

TAPIMMUNE INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2015	Year Ended December 31, 2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(34,066,390)	$(30,883,096)
Adjustments to reconcile net loss to net cash from operating activities:		
Changes in fair value of derivative liabilities	27,872,585	(581)
Loss on extinguishment of debt	—	26,884,231
Loss on settlement agreement	24,697	—
Accretion of discount on convertible notes	—	492,296
Non-cash interest and finance charges	10,925	83,247
Stock based compensation	1,705,067	1,391,123
Foreign exchange loss	—	58,334
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	13,701	(67,500)
Accounts payable and accrued liabilities	96,018	(145,199)
NET CASH USED IN OPERATING ACTIVITIES	(4,343,397)	(2,187,145)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of shares, net of finders' fee	2,326,015	1,877,500
Convertible notes issuance	—	418,000
Proceeds from exercise of warrants	9,219,998	—
Finders' fee on exercise of warrants	(767,996)	—
Repayment of promissory notes	—	(15,000)
NET CASH PROVIDED BY FINANCING ACTIVITIES	10,778,017	2,280,500
INCREASE IN CASH	6,434,620	93,355
CASH, BEGINNING OF YEAR	141,944	48,589
CASH, END OF YEAR	$ 6,576,564	$ 141,944

The accompanying notes are an integral part of these consolidated financial statements.

TAPIMMUNE INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2015	Year Ended December 31, 2014
SUPPLEMENTAL SCHEDULE OF NON-CASH ACTIVITIES		
Accounts payable settled in common stock	$ 22,000	$2,415,000
Fair value of issuance of warrants in January and March 2015 financing	9,313,000	—
Issuance of additional warrants in May 28, 2015 transaction	6,133,000	—
Reclassification of Derivative Warrant Liabilities to Equity at exercise date	16,835,000	—
Conversion of debt obligations into common stock:		
Accrued interest	—	525,000
Convertible notes payable	—	4,116,000
Loans payable, related party	—	42,000
Promissory notes, related party	—	210,000
Due to related parties	—	369,000
Fair value derivative liability – conversion option at conversion	—	708,000

The accompanying notes are an integral part of these consolidated financial statements.

TAPIMMUNE INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2015

NOTE 1: NATURE OF OPERATIONS

TapImmune Inc. (the "Company"), a Nevada corporation incorporated in 1992, is a biotechnology Company focusing on immunotherapy specializing in the development of innovative peptide and gene-based immunotherapeutics and vaccines for the treatment of oncology and infectious disease. Unlike other vaccine technologies that narrowly address the initiation of an immune response, TapImmune's approach broadly stimulates the cellular immune system by enhancing the function of killer T-cells and T-helper cells and by restoring antigen presentation in tumor cells allowing their recognition and killing by the immune system.

A Phase I study at the Mayo Clinic, Rochester, MN, evaluating the safety and immune responses of a set of proprietary HER2/neu+ antigens has been successfully completed and the results led to the decision to proceed with Phase II clinical studies in 2016.

A separate Phase I study has also been conducted at Mayo Foundation ("Mayo") in Ovarian and breast cancer (Folate Receptor Alpha). Folate Receptor Alpha is expressed in nearly 50% of breast cancers and in addition, over 95% of ovarian cancers, for which the only treatment options are surgery and chemotherapy, leaving a very important and urgent clinical need for a new therapeutic. Time to recurrence is relatively short for this type of cancer and survival prognosis is extremely poor after recurrence. In the USA alone, there are approximately 30,000 ovarian cancer patients newly diagnosed every year. These Folate Receptor Antigens are applicable to Ovarian and Triple Negative Breast Cancer. Both of these diseases have few treatment options if any beyond surgery and chemotherapy and therefore the Company is hopeful that it might be an ideal candidate for orphan drug status in these indications. This study has been successfully completed and the results led to the decision to proceed with multiple Phase II studies in 2016.

In addition, enhancing the visibility of cancer or infected cells to a patient's immune system is a critical aspect of an effective vaccine. In this regard, TapImmune's PolyStart nucleic acid-based technology provides a four-fold increase in target cell specific naturally processed antigenic epitopes on a cells surface. This increased cell surface presentation corresponding increases activated Helper and/or long-lived Killer T-cell populations that then effectively seek out and work to destroy a patient's cancer cells.

These consolidated financial statements have been prepared on the basis of a going concern which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As at December 31, 2015, the Company had a working capital deficiency and has incurred significant losses since inception in the development of its business. The ability of the Company to continue as a going concern is dependent on raising additional capital to fund clinical trials, ongoing research and development, maintenance and protection of patents, accommodation from certain debt obligations and ultimately on generating future profitable operations. Planned expenditures relating to current and future clinical trials of the Company's immunotherapy vaccine will require significant additional funding. The Company is dependent on future financings to fund ongoing research and development as well as working capital requirements. The Company's future capital requirements will depend on many factors including the rate and extent of scientific progress in its research and development programs, the timing, cost and scope involved in clinical trials, obtaining regulatory approvals, pursuing further patent protections and the timing and costs of commercialization activities.

Management is addressing going concern remediation through seeking new sources of capital, restructuring and retiring debt through conversion to equity and debt settlement arrangements with creditors, cost reduction programs and seeking possible joint venture participation. Management's plans are intended to return the Company to financial stability and improve continuing operations. The Company is continuing initiatives to raise capital through private placements, related party loans and other institutional sources to meet immediate working capital requirements.

Historically the Company has raised capital through issuances of various financial instruments and the Company recently completed significant restructuring of outstanding debt and equity instruments into equity. Additional capital is required to expand programs including pre-clinical work and to progress clinical trials for the lead vaccine candidates. Strategic partnerships will be needed to continue the product development portfolio and fund development costs. These measures, if successful, may contribute to reduce the risk of going concern uncertainties for the Company over the next twelve months.

There is no certainty that the Company will be able to arrange sufficient funding to satisfy current debt obligations or to continue development of products to marketability.

NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

These financial statements are presented in United States dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”).

Principles of Consolidation

These financial statements include the accounts of the Company and its wholly-owned subsidiary GeneMax Pharmaceuticals Inc. (“GPI”). All significant intercompany balances and transactions are eliminated upon consolidation.

Use of Estimates

Preparation of the Company’s financial statements in conformity with GAAP requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ materially from those estimates. Significant areas requiring management’s estimates and assumptions include valuation allowance on deferred tax assets, determining the fair value of stock-based compensation and stock based transactions, the fair value of the components of the derivative liabilities - warrants and accrued liabilities.

Fair Value Measurements

The fair value of certain of the Company’s financial instruments, including cash and cash equivalents, accrued compensation, and other accrued liabilities, approximate cost because of their short maturities. The Company measures the fair value of certain of its financial assets and liabilities on a recurring basis. A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value will be classified and disclosed in one of the following three categories:

- Level 1-Quoted prices (unadjusted) in active markets for identical assets and liabilities.
- Level 2-Inputs other than Level 1 that are observable, either directly or indirectly, such as unadjusted quoted prices for similar assets and liabilities, unadjusted quoted prices in the markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3-Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Financial Instruments and Concentration of Credit Risk.

The fair values of cash, accounts payable, and other current monetary liabilities approximate their carrying values due to the immediate or short-term maturity of these financial instruments. The Company’s operations and financing activities are conducted primarily in United States dollars, and as a result the Company is not subject to significant exposure to market risks from changes in foreign currency rates. Unless otherwise noted, it is management’s opinion that the Company is not exposed to significant interest or credit risks arising from assets and liabilities classified as financial instruments.

Prior Period Reclassifications

Certain prior period amounts that were combined in the December 31, 2014 consolidated financial statements have been reclassified for comparability with the December 31, 2015 presentation. These reclassifications had no effect on previously reported net loss.

Stock-Based Compensation

Stock-based compensation is measured at the grant date based on the fair value of the award. The fair value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. The expense recognized for the portion of the award that is expected to vest has been reduced by an estimated forfeiture rate. The forfeiture rate is determined at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Expected Term — The expected term of options represents the period that the Company's stock-based awards are expected to be outstanding based on the simplified method, which is the half-life from vesting to the end of its contractual term.

Expected Volatility — The Company computes stock price volatility over expected terms based on its historical common stock trading prices.

Risk-Free Interest Rate — The Company bases the risk-free interest rate on the implied yield available on U. S. Treasury zero-coupon issues with an equivalent remaining term.

Expected Dividend — The Company has never declared or paid any cash dividends on its common shares and does not plan to pay cash dividends in the foreseeable future, and, therefore, uses an expected dividend yield of zero in its valuation models. The Company recognizes fair value of stock options granted to nonemployees as stock-based compensation expense over the period in which the related services are received.

Research and Development Costs

The Company has acquired development and marketing rights to certain technologies. The rights and licenses acquired are considered rights to unproven technology which may not have alternate future uses and therefore, have been expensed as incurred as research and development costs. The Company spent $1,711,000 on research and development in the year ended December 31, 2015 compared to $189,000 during the prior fiscal year.

Income Taxes

The Company follows the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax balances. Potential deferred tax assets and liabilities are measured using enacted tax rates expected to apply to the taxable income in the years in which those differences are expected to be recovered or settled. The effect on potential deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the date of allowances against deferred tax assets.

Derivative Liability

The Company evaluates its convertible debt, options, warrants or other contracts to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for. This accounting treatment requires that the carrying amount of embedded derivatives be marked-to-market at each balance sheet date and carried at fair value. In the event that the fair value is recorded as a liability, the change in fair value during the period is recorded in the Statement of Operations as either income or expense. Upon conversion, exercise or modification to the terms of a derivative instrument, the instrument is marked to fair value at the conversion date and then the related fair value is reclassified to equity.

In circumstances where the embedded conversion option in a convertible instrument is required to be bifurcated and there are also other embedded derivative instruments in the convertible instrument that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument.

The classification of financial instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period. Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities will be classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is expected within 12 months of the balance sheet date.

Management must determine whether an instrument (or an embedded feature) is indexed to the Company's own stock. An entity should use a two-step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. This exercise affects the accounting for (i) certain freestanding warrants that contain exercise price adjustment features and (ii) convertible notes containing full-ratchet and anti-dilution protections (iii) certain free standing warrants that contain contingently puttable cash settlement.

Loss per Common Share

Basic loss per share is computed by dividing loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. If applicable, diluted earnings per share reflect the potential dilution of securities that could share in the earnings (loss) of the Company. The common shares potentially issuable on conversion of outstanding convertible debentures, warrants and stock options are anti-dilutive and have not been included in the calculation.

Recently Issued Accounting Pronouncements

Accounting Standard Update No. ASU 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The amendments in this update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company is currently evaluating the impact of this update on its consolidated financial statements.

NOTE 3: NET LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDER

Net Loss per Share Applicable to Common Stockholders

Options, warrants, and convertible debt outstanding were all considered anti-dilutive for the years ended December 31, 2015 and 2014, due to net losses.

The following securities were not included in the diluted net loss per share calculation because their effect was anti-dilutive as of the periods presented:

	December 31,	
	2015	2014
Common stock options	3,584,150	65,430
Common stock warrants - equity treatment	2,548,632	2,556,133
Common stock warrants - liability treatment	49,557,865	103,284
Excluded potentially dilutive securities	55,690,647	2,724,847

NOTE 4: RESEARCH AGREEMENTS

Crucell Holland B. V. ("Crucell") – Research License and Option Agreement

In 2003 and further amended in 2008 the Company acquired a research license and option agreement from Crucell for use of an adenoviris technology. The Company has not made use of the technology in its current work and has not asked for nor received any work product from Crucell. Crucell was acquired by Johnson and Johnson in 2010.

As of December 31, 2015, the Company has accrued $492,000 as amounts owed under the amended agreement.

NOTE 5: DERIVATIVE LIABILITY

A summary of quantitative information with respect to valuation methodology and significant unobservable inputs used for the Company's common stock purchase warrants that are categorized within Level 3 of the fair value hierarchy for the years ended 2015 and 2014 is as follows:

Stock Purchase Warrants	Weighted Average Inputs for the Period	
Date of valuation	For the Year Ending December 31, 2015	For the Year Ending December 31, 2014
Strike price	$ 0.74	$ 10.70
Volatility (annual)	155%	166%
Risk-free rate	1.8%	1.00%
Contractual term (years)	4.2	2. 25
Dividend yield (per share)	0%	0%

The foregoing assumptions are recalculated every reporting period and are subject to change based primarily on management's assessment of the probability of the events described occurring. Accordingly, changes to these assessments could materially affect the valuations.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

Financial assets and liabilities measured at fair value on a recurring basis are summarized below and disclosed on the balance sheet under Derivative liability – warrants:

	As of December 31, 2015				
	Fair Value Measurements				
	Fair Value	Level 1	Level 2	Level 3	Total
Derivative liability - warrants	$26,493,000	—	—	$26,493,000	$26,493,000
Total	$26,493,000	—	—	$26,493,000	$26,493,000

	As of December 31, 2014				
	Fair Value Measurements				
	Carrying Value	Level 1	Level 2	Level 3	Total
Derivative liability - warrants	$ 9,000	—	—	$ 9,000	$ 9,000
Total	$ 9,000	—	—	$ 9,000	$ 9,000

There were no transfers between Level 1, 2 or 3 during the year ended December 31, 2015.

The following table presents changes in Level 3 liabilities measured at fair value for the year ended December 31, 2015:

	Derivative liability – warrants
Balance – December 31, 2014	$ 9,000
Additions during the period	15,446,000
Settlement of debt	(16,835,000)
Change in fair value of warrant liability	27,873,000
Balance – December 31, 2015	$ 26,493,000

The valuation of warrants is subjective and is affected by changes in inputs to the valuation model including the price per share of common stock, the historical volatility of the stock price, risk-free rates based on U. S. Treasury security yields, the expected term of the warrants and dividend yield. Changes in these assumptions can materially affect the fair value estimate. The Company could ultimately incur amounts to settle the warrant at a cash settlement value that is significantly different than the carrying value of the liability on the financial statements. The Company will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire, or are amended in a way that would no longer require these warrants to be classified as a liability. Changes in the fair value of the common stock warrants liability are recognized as a component of other income (expense) in the Statements of Operations.

The net cash settlement value at the time of any future transactions, where the Company consolidates or merges with another entity, will depend upon the value of the following inputs at that time: the consideration value per share of the Company’s common stock, the volatility of the Company’s common stock, the remaining term of the warrant from announcement date, the risk-free interest rate based on U. S. Treasury security yields, and the Company’s dividend yield. The warrant requires use of a volatility assumption equal to the greater of 100% and the 100-day volatility function determined as of the trading day immediately following announcement of a Fundamental Transaction.

NOTE 6: PROMISSORY NOTES

The Company has outstanding promissory notes in the amount of $30,000 (December 31, 2014 - $30,000). The promissory notes bear 10% annual interest and were due in 2012. As of December 31, 2015, the notes are in default and there has been no request for payment.

NOTE 7: PROMISSORY NOTE, RELATED PARTY

The Company has an outstanding promissory note in the amount of $23,000 (December 31, 2014 - $23,000) owed to an officer and a director of the Company. The promissory note bears no interest charges and has no fixed repayment terms.

NOTE 8: CAPITAL STOCK

Stock Split and increase in authorized shares

On February 18, 2014, the Company completed a reverse stock split thereby issuing 1 new share for each 100 outstanding shares of the Company's common stock and amended the Company's Articles of Incorporation to increase the authorized shares of common stock from 150,000,000 shares of common stock to 500,000,000 shares.

Share Capital

Series A Convertible Preferred Stock

The Company has designated 1,250,000 Series A Convertible preferred shares (Series A) par value $0.001. Each share of Series A is automatically converted into five shares of the Company's common stock upon the occurrence of the 1:100 reverse stock split.

Series B Convertible Preferred Stock

The Company has designated 1,500,000 Series B Convertible preferred shares (Series B), par value $0.001. The terms of the Series B are as follows:

- rank pari passu to the common stock with respect to rights on liquidation, winding up and dissolution;
- have no dividend rights except as may be declared by the Board in its sole and absolute discretion;
- shall have the right to cast one thousand (1,000) votes for each share held of record on all matters submitted to a vote of holders of the Corporation's common stock; and
- shall automatically convert into seven (7) shares of common upon the occurrence of a 1:100 reverse stock split.

There are no shares outstanding under preferred shares as of December 31, 2015.

2015 Share Transactions

Private placements

In January, 2015, the Company entered into a Securities Purchase Agreement with certain investors for the sale of 7,320,000 units at a purchase price of $0.20 per unit, for a total purchase price of approximately $1,250,000, net of finders' fee and offering expenses of approximately $214,000. Each unit consisting of (i) one share of the Company's Common Stock, (ii) one Series A warrant to purchase one share of common stock, (iii) one Series B warrant to purchase one share of common stock (iv) one Series C warrant to purchase one share of common stock, (v) one Series D warrant to purchase one share of common stock, and (vi) one Series E warrant to purchase one share of common stock (the Series A, B, C, D and E warrants are hereby collectively referred to as the "January 2015 Warrants"). Series A warrants are exercisable at $1.50 per share, with a five year term. Series B warrants are exercisable at $0.40 per share, with a six month term. Series C warrants are exercisable at $1.00 per share, with a five year term. Series D warrants are exercisable at $0.75 per share only if and to the extent that the Series B warrants are exercised, with a five year term from the date that the Series B warrants are exercised. Series E warrants are exercisable at $1.25 per share, only if and to the extent that the Series C warrants are exercised, with a five year term from the date that the Series C warrants are exercised.

Pursuant to a placement agent agreement, the Company agreed to issue warrants to purchase 366,000 common shares with substantially the same terms as the January 2015 Warrants and pay a 7% finders fee on gross proceeds from the sale of securities.

In March, 2015, the Company entered into a Securities Purchase Agreement with certain accredited investors for the sale of 5,000,000 units at a purchase price of $0.20 per unit, for a total purchase price of approximately $950,000, net of finders' fee and offering expenses of approximately $50,000. Each unit consisting of (i) one share of the Company's Common Stock, (ii) one Series A warrant to purchase one share of common stock, (iii) one Series B warrant to purchase one share of common stock (iv) one Series C warrant to purchase one share of common stock, (v) one Series D warrant to purchase one share of common stock, and (vi) one Series E warrant to purchase one share of common stock (the Series A, B, C, D and E warrants are hereby collectively referred to as the "March 2015 Warrants"). The March 2015 Warrants have substantially the same terms as the January 2015 Warrants.

Pursuant to a placement agent agreement, the Company agreed to issue warrants to purchase 125,000 common shares with substantially the same terms as the March 2015 Warrants and pay a 3.5% finders fee on gross proceeds from the sale of securities.

Initial Fair Value of Warrants Issued

Pursuant to ASC 480-10 Distinguishing liabilities from equity and ASC 815-40 Contracts in an Entity's Own Equity, the common stock purchase warrants are classified as a derivative liability as the Company cannot control their ability to gross settle the financial instruments with registered securities. The fair value of the warrants issued pursuant to the January and March 2015 stock purchase agreement was $9,313,000. The weighted average inputs include contractual term of 5.0 years, volatility of 158% and risk free rate of 1.2%.

May 2015 Restructuring agreement

In May 2015, the Company entered into a restructuring agreement with the investors of the January 2015 and March 2015 private placements, where:

- The exercise price of the Series A warrants was changed from $1.50 per warrant to $0.10 per warrant,
- The exercise price of Series B warrants was changed from $0.40 per warrant to $0.20 per warrant,
- Each warrant of Series B existing prior to the restructuring agreement was replaced with two warrants of such series,
- The exercise price of the Series C warrants was changed from $1.00 per warrant to $0.50 per warrant, and
- Each warrant of Series C existing prior to the restructuring agreement was replaced with two warrants of such series.

As a result of the restructuring agreement, the Company issued an additional 12,320,000 Series B warrants and 12,320,000 Series C Warrants. The fair value of the warrants issued pursuant to the May 2015 restructuring agreement was $6,133,000. The weighted average inputs include contractual term of 2.46 years, volatility of 141% and risk free rate of 1.5%.

Management Compensation

In November, 2015, the Company entered into an employment agreement with Dr. Glynn Wilson, the Company's Chief Executive Officer, President and Chairman of the Company. As part of the agreement, the Company granted Dr. Wilson 315,000 shares of unregistered common stock, fully vested. As of December 31, 2015, the shares have not been issued. Accordingly, the fair value of the common stock of approximately $191,000 was accounted for as an accrued liability.

Share Purchase Warrants

A summary of the Company's share purchase warrants as of December 31, 2015 and changes during the period is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life
Balance, December 31, 2014	2,659,417	1.83	4.15
Issued	86,730,975	0.54	4.30
Exercised	(37,079,990)	0.25	—
Extinguished or expired	(203,905)	2.39	—
Balance, December 31, 2015	52,106,497	$ 0.74	4.24

During the year ended December 31, 2015, a warrant holder exercised 4,820,000 of Series A warrants at $0.10 per warrant for a total of $482,000.

During the year ended December 31, 2015, warrant holders exercised 24,639,995 of Series B warrants at $0.20 per warrant for a total of $4,928,000.

During the year ended December 31, 2015, warrant holders exercised 7,620,000 of Series C warrants at $0.50 per warrant for a total of $3,810,000.

The fair value of derivative liabilities associated with these warrants in the amount of $16,835,000 were credited to additional paid-in capital.

Stock Compensation Plan

On March 19, 2014, the Company adopted the 2014 Omnibus Stock Option Plan ("2014 Plan"). The 2014 Plan was amended in February 2015 to provide for grants to consultants, and again in November 2015 to (i) increase the number of shares reserved for issuance under the Plan by 5.0 million shares to 7.0 million shares. Options granted under the Plan shall be at prices and for terms as determined by the Board of Directors.

Share purchase options

A summary of the Company's stock options as of December 31, 2015 and 2014 and changes during the years is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life	Intrinsic Value
Outstanding at January 1, 2014	65,430	18.00	5.04	$ —
Issued	—	—	—	—
Cancelled/Forfeited	—	—	—	—
Outstanding at January 1, 2015	65,430	18.00	4.04	—
Issued	3,540,000	0.55	4.39	—
Cancelled/Forfeited	(21,280)	17.00	—	—
Outstanding at December 31, 2015	3,584,150	$ 0.77	9.69	$ 177,000
Exercisable at December 31, 2015	1,987,000	$ 0.92	9.59	$ 132,000

The following weighted average assumptions were used for the Black-Scholes option-pricing model to value stock options granted in 2015:

	2015
Expected life of options in years	9.08
Weighted-average volatility	230%
Risk-free rate	2.10%
Expected dividend rate	0%

Stock based compensation costs of $945,000 are expected to be recognized over the next 1.86 years.

NOTE 9: INCOME TAXES

The company has no income tax expense due to operating losses incurred for the years ended December 31, 2015 and 2014. Approximately $1.6 million in non-qualified stock options were cancelled during 2015 due to terminations that resulted in a reversal of the deferred tax asset of approximately $0.52 million. The cancellations did not result in a book income for December 31, 2015.

The effects of temporary differences that give rise to significant portions of the deferred tax assets as of December 31, 2015 and 2014 are as follows:

	Year Ended December 31, 2015	Year Ended December 31, 2014
Deferred tax assets:		
Net operating loss carryforwards	$ 8,359,000	$ 10,433,000
Stock-based compensation	1,897,000	1,871,000
License agreements	268,000	—
Research and development	117,000	—
Technology licensing fee	185,000	167,000
Total deferred tax assets	10,826,000	12,471,000
Valuation allowance	(10,826,000)	(12,471,000)
Deferred tax assets, net of valuation allowance	$ —	$ —

The Company assesses the likelihood that deferred tax assets will be realized. To the extent that realization is not likely, a valuation allowance is established. Based upon the history of losses, management believes that it is more likely than not that future benefits of deferred tax assets will not be realized and has established a full valuation allowance for the years ended December 31, 2015 and 2014. The valuation allowance decreased by $1.6 million as of December 31, 2015. The Company has research and development tax credit carryforwards of $117,000 to offset future federal income taxes. The research and development tax credit carryforwards begin to expire in 2029.

The Company has approximately $24,123,000 of federal and $4,336,000 of state NOLs that may be available to offset future taxable income, if any. The federal net operating loss carryforwards, if not utilized, will expire between 2029 and 2035. The state net operating loss carryforwards, if not utilized, will expire in 2035.

In accordance with Section 382 of the Internal Revenue code, the usage of the Company’s net operating loss carryforwards may be limited in the event of a change in ownership. A full Section 382 analysis has not been prepared and NOLs could be subject to limitation under Section 382.

For the years ended December 31, 2015 and 2014, the expected tax expense (benefit) based on the U. S. federal statutory rate is reconciled with the actual tax provision (benefit) as follows:

	Year Ended December 31, 2015	Year Ended December 31, 2014
U. S. federal statutory rate	$ (11,582,000)	$ (10,449,000)
State taxes, net of federal benefit	$ (199,000)	—
Permanent differences		
- Non-cash loss on extinguishment of debt	—	9,122,000
- Change in fair value of derivative liabilities	9,477,000	—
- Write off of net operating loss	3,591,000	—
-Other permanent differences	12,000	62,000
Change in valuation allowance	(1,645,000)	1,265,000
Other	346,000	—
Income tax provision (benefit)	$ —	$ —

ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. As of December 31, 2015 and 2014, there were no unrecognized tax benefits. The Company recognizes accrued interest and penalties as income tax expense. No amounts were accrued for the payment of interest and penalties at December 31, 2015 and 2014. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position in the next year.

NOTE 10: CONTINGENCIES AND COMMITMENTS

The Company has entered into an office property lease for one year expiring in July 2016. The minimum rental payments due under the agreement as at December 31, 2015 are $17,500.

Durin the year ended December 31, 2015, the Company exercised its option to license certain intellectual property rights from Mayo Foundation under a license and assignment agreement. Under the agreement, the Company has agreed to:

1. Make upfront license fee payments of $100,000 and $350,000 as partial consideration by March 21, 2016 and June 21, 2016, respectively;
2. Pay annual license maintenance fees of $50,000 beginning on July 21, 2017 and every year thereafter until the Company starts paying 6% royalty on sales of the licensed product.
3. Pay milestone fees for each licensed product developed by the Company on achievement of certain events.

Contingencies:

In the case of a fundamental transaction investors in the January and March 2015 financings could require the Company to pay them the Black Scholes value of their remaining warrants.

ITEM 15. EXHIBITS

The following exhibits are filed as part of this registration statement. Exhibit numbers correspond to the exhibit requirements of Regulation S-K.

Exhibit No.	Description
3.1	Amended Articles of Incorporation dated February 3, 2009 as filed as Exhibit 3. 1 to Form 8-K filed on February 6, 2009 and incorporated herein by reference.
3.2	Amended Articles of Incorporation dated May 19, 1999 as filed as Exhibit 2. 1 to the Registration Statement filed on Form 10-SB on September 3, 1999 and incorporated herein by reference.
3.3	Amended and Restated Bylaws of the Company dated May 10, 2004 as filed as Exhibit 3. 1 to the Company's Quarterly Report on Form 10-QSB as filed on May 20, 2004 and incorporated herein by reference.
4.1	Securities Purchase Agreement, dated May 17, 2010, as filed as Exhibit 10. 1 to our Current Report on Form 8-K as filed on May 18, 2010 and incorporated herein by reference.
4.2	Registration Rights Agreement, dated May 24, 2010, as filed as Exhibit 10. 4 to our Current Report on Form 8-K as filed on May 18, 2010 and incorporated herein by reference.
4.3	Security Agreement, dated May 24, 2010, as filed as Exhibit 10. 3 to our Current Report on Form 8-K as filed on May 18, 2010 and incorporated herein by reference.
4.4	Form of Senior Secured Convertible Note, as filed as Exhibit 10. 2 to our Current Report on Form 8-K as filed on May 18, 2010 and incorporated herein by reference.
4.5	Form of Series A Warrants, as filed as Exhibit 10. 5 to our Current Report on Form 8-K as filed on May 18, 2010 and incorporated herein by reference.
4.6	Form of Series B Warrants, as filed as Exhibit 10. 6 to our Current Report on Form 8-K as filed on May 18, 2010 and incorporated herein by reference.
4.7	Form of Series C Warrants, as filed as Exhibit 10. 7 to our Current Report on Form 8-K as filed on May 18, 2010 and incorporated herein by reference.
4.8	Securities Purchase Agreement, dated February 24, 2011, as filed as Exhibit 10. 1 to our Current Report on Form 8-K as filed on March 2, 2011 and incorporated herein by reference.
4.9	Form of Convertible Note, as filed as Exhibit 10. 2 to our Current Report on Form 8-K as filed on March 2, 2011 and incorporated herein by reference.
4.10	Security Agreement, dated February 24, 2011, as filed as Exhibit 10. 3 to our Current Report on Form 8-K as filed on March 2, 2011 and incorporated herein by reference.
4.11	Form of Warrant, as filed as Exhibit 10. 4 to our Current Report on Form 8-K as filed on March 2, 2011 and incorporated herein by reference.
4.12	Form of Convertible Note in connection with the sale of same on April 12, 2011 filed as an Exhibit to the Company's Annual Report on Form 10-K as filed on April 18, 2011 and incorporated by reference herein.
4.13	Security Agreement, dated April 12, 2011 filed as an Exhibit to the Company's Annual Report on Form 10-K as filed on April 18, 2011 and incorporated by reference herein.
4.14	Form of Securities Purchase Agreement in connection with the sale of Units on April 14, 2011 filed as an Exhibit to the Company's Annual Report on Form 10-K as filed on April 18, 2011 and incorporated by reference herein.
4.15	Form of Warrant in connection with Securities Purchase Agreement dated April 14, 2011 filed as an Exhibit to the Company's Annual Report on Form 10-K as filed on April 18, 2011 and incorporated by reference herein.
4.16	Form of Common Stock Purchase Warrant, as filed as Exhibit 4. 1 to our Current Report on Form 8-K as filed on August 14, 2014 and incorporated herein by reference.
4.17	Form of Placement Agent Warrant, as filed as Exhibit 4. 2 to our Current Report on Form 8-K as filed on August 14, 2014 and incorporated herein by reference.
4.18	Form of Common Stock Purchase Warrants-Series A, as filed as Exhibit 4. 1 to our Current Report on Form 8-K as filed on January 12, 2015 and incorporated herein by reference.
4.19	Form of Common Stock Purchase Warrants-Series B, as filed as Exhibit 4. 2 to our Current Report on Form 8-K as filed on January 12, 2015 and incorporated herein by reference.

Exhibit No.	Description
4.20	Form of Common Stock Purchase Warrants-Series C, as filed as Exhibit 4. 3 to our Current Report on Form 8-K as filed on January 12, 2015 and incorporated herein by reference.
4.21	Form of Common Stock Purchase Warrants-Series D, as filed as Exhibit 4. 4 to our Current Report on Form 8-K as filed on January 12, 2015 and incorporated herein by reference.
4.22	Form of Common Stock Purchase Warrants-Series E, as filed as Exhibit 4. 5 to our Current Report on Form 8-K as filed on January 12, 2015 and incorporated herein by reference.
4.23	Form of Placement Agent Common Stock Purchase Warrants-Series A, as filed as Exhibit 4. 6 to our Current Report on Form 8-K as filed on January 12, 2015 and incorporated herein by reference.
4.24	Form of Placement Agent Common Stock Purchase Warrants-Series B, as filed as Exhibit 4. 7 to our Current Report on Form 8-K as filed on January 12, 2015 and incorporated herein by reference.
4.25	Form of Placement Agent Common Stock Purchase Warrants-Series C, as filed as Exhibit 4. 8 to our Current Report on Form 8-K as filed on January 12, 2015 and incorporated herein by reference.
4.26	Form of Placement Agent Common Stock Purchase Warrants-Series D, as filed as Exhibit 4. 9 to our Current Report on Form 8-K as filed on January 12, 2015 and incorporated herein by reference.
4.27	Form of Placement Agent Common Stock Purchase Warrants-Series E, as filed as Exhibit 4. 10 to our Current Report on Form 8-K as filed on January 12, 2015 and incorporated herein by reference.
4.28	Form of Common Stock Purchase Warrants-Series A-1, as filed as Exhibit 4. 1 to our Current Report on Form 8-K as filed on March 10, 2015 and incorporated herein by reference.
4.29	Form of Common Stock Purchase Warrants-Series B-1, as filed as Exhibit 4. 2 to our Current Report on Form 8-K as filed on March 10, 2015 and incorporated herein by reference.
4.30	Form of Common Stock Purchase Warrants-Series C-1, as filed as Exhibit 4. 3 to our Current Report on Form 8-K as filed on March 10, 2015 and incorporated herein by reference.
4.31	Form of Common Stock Purchase Warrants-Series D-1, as filed as Exhibit 4. 4 to our Current Report on Form 8-K as filed on March 10, 2015 and incorporated herein by reference.
4.32	Form of Common Stock Purchase Warrants-Series E-1, as filed as Exhibit 4. 5 to our Current Report on Form 8-K as filed on March 10, 2015 and incorporated herein by reference.
4.33	Form of Placement Agent Common Stock Purchase Warrants-Series A-1, as filed as Exhibit 4. 6 to our Current Report on Form 8-K as filed on March 10, 2015 and incorporated herein by reference.
4.34	Form of Placement Agent Common Stock Purchase Warrants-Series B-1, as filed as Exhibit 4. 7 to our Current Report on Form 8-K as filed on March 10, 2015 and incorporated herein by reference.
4.35	Form of Placement Agent Common Stock Purchase Warrants-Series C-1, as filed as Exhibit 4. 8 to our Current Report on Form 8-K as filed on March 10, 2015 and incorporated herein by reference.
4.36	Form of Placement Agent Common Stock Purchase Warrants-Series D-1, as filed as Exhibit 4. 9 to our Current Report on Form 8-K as filed on March 10, 2015 and incorporated herein by reference.
4.37	Form of Placement Agent Common Stock Purchase Warrants-Series E-1, as filed as Exhibit 4. 10 to our Current Report on Form 8-K as filed on March 10, 2015 and incorporated herein by reference.
10.1	Executive Services Agreement with Denis Corin as filed as Exhibit 10. 1 to our Quarterly Report on Form 10-QSB as filed on November 14, 2007 and incorporated herein by reference.
10.2	Amended Executive Services Agreement with Denis Corin as filed as Exhibit 10. 2 to our Quarterly Report on Form 10-QSB as filed on November 14, 2007 and incorporated herein by reference.
10.3	License Agreement made March 6, 2000 between GeneMax Pharmaceuticals, UBC and Dr. Jefferies as filed as an Exhibit to our Annual Report on Form 10-KSB for the year ended December 31, 2004 as filed on April 15, 2005 and incorporated by reference herein.

Exhibit No.	Description
10.4	Collaborative Research Agreement made September 1, 2000 between GeneMax Pharmaceuticals, GeneMax Pharmaceuticals Inc. and UBC as filed as an Exhibit to our Annual Report on Form 10-KSB for the year ended December 31, 2004 as filed on April 15, 2005 and incorporated by reference herein.
10.5	Production Services Agreement made March 18, 2003 between the Company and Molecular Medicine as filed as an Exhibit to our Annual Report on Form 10-KSB for the year ended December 31, 2004 as filed on April 15, 2005 and incorporated by reference herein.
10.6	Biological Materials Transfer Agreement made October 21, 2003 between the Company and National Institutes of Health as filed as an Exhibit to our Annual Report on Form 10-KSB for the year ended December 31, 2004 as filed on April 15, 2005 and incorporated by reference herein.
10.7	Option and Settlement Agreement made January 23, 2006 between GeneMax Pharmaceuticals, GeneMax Pharmaceuticals Inc., UBC and Dr. Jefferies as filed as an Exhibit to the Company's Current Report on Form 8-K as filed on January 24, 2006 and incorporated by reference herein.
10.8	2009 Stock Incentive Plan as filed as Exhibit B to our Information Statement filed on Definitive Schedule 14-C on January 29, 2010 and incorporated herein by reference.
10.9	Technology Option Agreement, dated June 1, 2010, between TapImmune Inc. and Mayo Foundation for Education and Research as filed as an Exhibit to the Company's Current Report on Form 8-K as filed on June 4, 2010 and incorporated by reference herein.
10.10	Form of Securities Purchase Agreement, dated as of August 11, 2014, by and among the Company and the Purchasers, as filed as Exhibit 10. 1 to our Current Report on Form 8-K as filed on August 14, 2014 and incorporated herein by reference.
10.11	Placement Agency Agreement, dated as of July 29, 2014, by and between the Company and H. C. Wainwright & Co., LLC, as filed as Exhibit 10. 2 to our Current Report on Form 8-K as filed on August 14, 2014 and incorporated herein by reference.
10.12	Form of Securities Purchase Agreement, dated as of January 12, 2015, by and among the Company and the Purchasers, as filed as Exhibit 10. 1 to our Current Report on Form 8-K as filed on January 12, 2015 and incorporated herein by reference.
10.13	Placement Agency Agreement, dated as of July 29, 2014 and Amended on January 12, 2015, by and between the Company and H. C. Wainwright & Co., LLC, as filed as Exhibit 10. 2 to our Current Report on Form 8-K as filed on January 12, 2015 and incorporated herein by reference.
10.14	Finders Agreement, dated as of January 12, 2015, by and between the Company and Olympus Securities LLC, as filed as Exhibit 10. 3 to our Current Report on Form 8-K as filed on January 12, 2015 and incorporated herein by reference.
10.15	Securities Purchase Agreement, dated as of March 9, 2015, by and among the Company and Eastern Capital Limited, as filed as Exhibit 10. 1 to our Current Report on Form 8-K as filed on March 10, 2015 and incorporated herein by reference.
10.16	Placement Agency Agreement, dated as of July 29, 2014, Amended on January 12, 2015, by and between the Company and H. C. Wainwright & Co., LLC and Amended on March 9, 2015, by and between the Company and H. C. Wainwright & Co., LLC, as filed as Exhibit 10. 2 to our Current Report on Form 8-K as filed on March 10, 2015 and incorporated herein by reference.
10.17	Form of Restructuring Agreement dated May 28, 2015 as filed as an Exhibit to the Company's Current Report on Form 8-K as filed on June 3, 2015 and incorporated by reference herein.
10.18	Amended and Restated Restructuring Agreement, dated as of June 2, 2015 as filed as an Exhibit to the Company's Current Report on Form 8-K as filed on June 5, 2015 and incorporated by reference herein.
10.19	Consulting Agreement, dated February 10, 2015, between TapImmune Inc. and John Bonfiglio as filed as an Exhibit to the Company's Current Report on Form 8-K as filed on, July 30, 2015 and incorporated by reference herein. **
10.20	License and Assignment Agreement, dated July 21, 2015, with The Mayo Foundation for Medical Education and Research filed as an Exhibit to the Company's Quarterly Report on Form 10-Q as filed on August 14, 2015 and incorporated by reference herein.
10.21	2014 Omnibus Stock Ownership Plan filed as an Exhibit to the Company's Quarterly Report on Form 10-Q as filed on November 16, 2015 and incorporated by reference herein. **

Exhibit No.	Description
10.22	Amendment to 2014 Omnibus Stock Ownership Plan (February 10, 2015) filed as an Exhibit to the Company's Quarterly Report on Form 10-Q as filed on November 16, 2015 and incorporated by reference herein. **
10.23	Amendment to 2014 Omnibus Stock Ownership Plan (November 6, 2015) filed as an Exhibit to the Company's Quarterly Report on Form 10-Q as filed on November 16, 2015 and incorporated by reference herein. **
10.24	Form of Stock Option Award Agreement – Key Employee filed as an Exhibit to the Company's Quarterly Report on Form 10-Q as filed on November 16, 2015 and incorporated by reference herein. **
10.25	Form of Stock Option Award Agreement – Non-employee Director filed as an Exhibit to the Company's Quarterly Report on Form 10-Q as filed on November 16, 2015 and incorporated by reference herein. **
10.26	Form of Stock Option Award Agreement – Consultant filed as an Exhibit to the Company's Quarterly Report on Form 10-Q as filed on November 16, 2015 and incorporated by reference herein. **
10.27	Form of Restricted Stock Award Agreement – Consultant filed as an Exhibit to the Company's Quarterly Report on Form 10-Q as filed on November 16, 2015 and incorporated by reference herein. **
10.28	Employment Agreement between TapImmune, Inc. and Dr. Glynn Wilson, dated November 12, 2015 filed as an Exhibit to the Company's Quarterly Report on Form 10-Q as filed on November 16, 2015 and incorporated by reference herein. **
10.29	Amendment to Consulting Agreement between TapImmune Inc. and John Bonfiglio dated as of June 12, 2015 as filed as an Exhibit to the Company's Current Report on Form 8-K as filed on, February 16, 2016 and incorporated by reference herein. **
10.30	Second Amendment to the Consulting Agreement by and between TapImmune Inc. and John Bonfiglio dated as of February 10, 2016 as filed as an Exhibit to the Company's Current Report on Form 8-K as filed on, February 16, 2016 and incorporated by reference herein. **
14	Code of Ethics and Business Conduct filed as an Exhibit to the Company's Quarterly Report on Form 10-Q as filed on November 16, 2015 and incorporated by reference herein.
21.1	Subsidiaries of TapImmune Inc. filed as an Exhibit to the Company's Annual Report on Form 10-K as filed on April 18, 2011 and incorporated by reference herein.
31.1	Certification of Principal Executive Officer and Acting Principal Accounting Officer pursuant to Securities Exchange Act of 1934 Rule 13a-14(a) or 15d-14(a). *
32.1	Certification of Principal Executive Officer and Acting Principal Accounting Officer pursuant to 18 U. S. C. Section 1350. *
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*

* Filed herewith
** Executive management contract or compensatory plan or arrangement.
*** Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been submitted separately with the SEC.

SIGNATURES

Pursuant to the requirements of Section 13 and 15 (d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TAPIMMUNE INC.

By: */s/ Glynn Wilson*
Glynn Wilson
Chairman, Chief Executive Officer,
Principal Executive Officer and Acting Principal Accounting Officer

Date: April 14, 2016

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

By: /s/ Glynn Wilson
Glynn Wilson, Director
April 14, 2016

By: /s/ Sherry Grisewood
Sherry Grisewood, Director
April 14, 2016

By: /s/ David Laskow-Pooley
David Laskow-Pooley, Director
April 14, 2016

By: /s/ Mark Reddish
Mark Reddish, Director
April 14, 2016

By: /s/ John Bonfiglio
John Bonfiglio, Director
April 14, 2016

By: /s/ Frederick Wasserman
Frederick Wasserman, Director
April 14, 2016

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Glynn Wilson, certify that:

1. I have reviewed this annual report on Form 10-K of TapImmune Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurances regarding the reliability of financial reporting in the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 14, 2016

By: */s/ Glynn Wilson*
Glynn Wilson
Chief Executive Officer, Principal Executive Officer and
Acting Principal Accounting Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of TapImmune, Inc. (the "Company") on Form 10-K for the period ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Glynn Wilson, Principal Executive Officer and Acting Principal Accounting Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written certification has been provided to the company and will be retained by the company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: April 14, 2016

By: */s/ Glynn Wilson*
Glynn Wilson
Chief Executive Officer, Principal Executive Officer and
Acting Principal Accounting Officer