TAPIMMUNE INC
Form 10-K
March 14, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-K

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

For the Fiscal Year Ended December 31, 2016

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

For the transition period from _____ to _____.

TAPIMMUNE INC.

(Exact name of registrant as specified in its charter)

Nevada	**001-37939**	**45-4497941**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

50 N. Laura Street, Suite 2500	**32202**

Jacksonville, FL
(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:

Common Stock, Par Value $0. 001

(Title of class)

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

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

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 x

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 x 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 x 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 x

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

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, 2016 (the last day of the registrant's most recently completed second fiscal quarter) at a price per share of $6.12 and was approximately $36,554,500.

The registrant had 8,439,166 shares of common stock outstanding as of March 13, 2017.

TABLE OF CONTENTS

ITEM
16.

i

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”, “anticipat “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;

- 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 and clinical trial 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, other than Eastern Capital Limited, 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 can be located in Part III, Item 12 of this Annual Report on Form 10-K.

Note Regarding Reverse Stock Splits

On February 18, 2014, we filed a 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 100. On September 15, 2016, we filed another 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 12. All historical share and per share amounts reflected in this report have been adjusted to reflect the reverse stock splits.

PART I

ITEM 1. BUSINESS

Company Overview

We are a clinical-stage immuno-oncology company specializing in the development of innovative peptide and gene-based immunotherapeutics and vaccines for the treatment of cancer & metastatic disease. We are also developing a proprietary technology to improve the ability of the cellular immune system to recognize and destroy diseased cells. This DNA expression technology named Polystart is in preclinical development.

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 overexpresses Human Epidermal Growth Factor Receptor 2 (HER2/neu) (TPIV 100/110),

(2) an exclusively licensed vaccine for treating breast and ovarian cancers that overexpress Folate Receptor Alpha (TPIV 200), and

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

To enhance stockholder 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
TPIV 100/110 HER2/neu+ Breast Cancer Vaccine	Peptide Vaccine	Treatment of HER2/neu+ Breast Cancer	Phase I trial completed Phase I/II to start in 2017(TPIV 110)
TPIV 200 Folate Receptor Alpha Vaccine	Peptide Vaccine	Treatment of Folate Alpha/Triple-Negative Breast and Ovarian Cancer	Phase I trial completed Multiple Phase II trials started 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.

1

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, Minnesota for clinical development of a new HER2/neu+ breast cancer vaccine technology. An Investigational New Drug ("IND") application for Phase I human clinical trial on the HER2/neu+ cancer vaccine in collaboration with the Mayo Foundation was allowed by the Food and Drug Administration ("FDA") in July 2011 and the Mayo Institutional Review Board 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 effects. In addition, 19 out of 20 evaluable patients showed robust T-cell immune responses to the antigens in the vaccine composition (Source: The Journal of Immunology: January 1, 2013 190:479-488). These results provided the rationale for advancement into Phase II during 2016**.** An additional secondary endpoint incorporated into this Phase I Trial was 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 Clinic (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 2017.

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

Folate Receptor Alpha ("FRA") is overexpressed in over 80% of breast cancers and in addition, over 90% of ovarian cancers, for which the only treatment options are surgery, radiation therapy 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 24-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 one cycle of cyclophosphamide (given days 1-7 and 15-22 of 28). Following this, patients were vaccinated intradermally at three sites with a mixture of the five FRA peptides on day one of a 28-day cycle for a maximum of six vaccination cycles. The vaccine showed to be well-tolerated and safe and 20 out of 21 evaluable patients showed positive immune responses, providing a strong rationale for progressing to Phase II trials. Further, the data showed that 16 out of 16 patients in the observation stage still showed immune responses (Source: Data published in Journal of Clinical Oncology at ASCO in Chicago May 2015). We have developed a commercial quality lyophilized formulation of the vaccine in a single vial for reconstitution and injection. Good Manufacturing Practice ("GMP") manufacturing of initial

batch for initial Phase II trials has been completed.

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.

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. This Phase II study of TPIV 200 in the treatment of triple-negative breast cancer will begin enrolling patients in early 2017.

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 seven-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.

On February 3, 2016, we announced that the U.S. FDA designated the investigation of multiple-epitope Folate Receptor Alpha Peptide Vaccine (TPIV 200) with GM-CSF adjuvant for maintenance therapy in subjects with platinum-sensitive advanced ovarian cancer who achieved stable disease or partial response following completion of standard-of-care chemotherapy, as a Fast Track Development Program. We initiated a Phase II study in this indication at the end of 2016 in one clinical site. The remainder of the planned clinical sites are expected to be open during 2017.

We have opened ten clinical sites and have begun enrolling and treating patients in a Phase II trial of our Folate Receptor Alpha cancer vaccine, TPIV 200, in the treatment of triple-negative breast cancer, one of the most difficult-to-treat cancers representing a clear unmet medical need. The open-label, 80-patient clinical trial is designed to evaluate dosing regimens, efficacy, and immune responses in women with triple-negative breast cancer. Key data from the trial is expected to be included in a future New Drug Application submission to the FDA for marketing clearance. This trial is sponsored and conducted by TapImmune.

On April 21, 2016, we announced our participation in an ovarian cancer study sponsored by Memorial Sloan Kettering Cancer Center in New York City in collaboration with AstraZeneca Pharmaceuticals in ovarian cancer patients who are not responsive to platinum, a commonly used chemotherapy for ovarian cancer. This study, a Phase II study of TPIV 200 is currently enrolling ovarian cancer patients and is designed to look at the effects of combination therapy with AstraZeneca's checkpoint inhibitor "durvalumab". The study will enroll 40 patients and is open-label. Because they are unresponsive to platinum, these patients have no real options left. If the combination therapy proves effective, we believe it would address a critical unmet need. TPIV 200 has received Orphan Drug designation for use in the treatment of ovarian cancer. Although we have no business relationship with AstraZeneca, we are paying for one-half of the costs of the clinical study in addition to providing our TPIV 200 for the study.

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. 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 deoxyribonucleic acid ("DNA") or incorporated into a viral delivery system via ribonucleic acid ("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. On February 7, 2017, we announced that we received a Notice of Allowance from the U.S. Patent and Trademark Office of our patent application titled, "Chimeric nucleic acid molecules with non-AUG initiation sequences and uses thereof," which represents our first patent on our Polystart program. We anticipate additional patent filings in connection with our research and development in this area.

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 transporter associated with antigen processing ("TAP") expression vectors was shown to be encouraging. However, due to 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 in Rochester, Minnesota, 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, we executed a Sponsored Research Agreement with the Mayo Foundation for the clinical trial.

Mayo HER2/neu License

On March 25, 2012, we entered into a Patent & Know-How Agreement with the Mayo Foundation in Rochester, Minnesota, 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 option for a worldwide license to use the patent rights related to U.S. 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 had the right to exercise this option after Phase I clinical trials had been reported. We may sublicense the technology with the approval of Mayo Foundation, which approval may not be unreasonably withheld.

On May 4, 2016, we exercised the option and entered into a license and assignment agreement with Mayo Foundation. The Mayo Foundation granted this license in exchange for an initial payment of $300,000, which was required to be paid by June 3, 2016**.** Upon the payment, the Mayo Foundation assigned to us IND # 14749, and we assumed all responsibility and liability for this investigative new drug application. In addition to the initial payment, we are to pay 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).

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 any other cancers that overexpress HER2/neu antigens. 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 numbers12/740,562 and 14/480,365, divisionals, continuations and continuations in part, and (ii) U.S. provisional application 60/984,646 and PCT/US2008/081799.

Under the agreement, 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 agreement) 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 agreement) and Materials (as defined in the agreement).

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 agreement by or on behalf of us or any sub-licensee; (ii) research, development, design, manufacture, distribution, use, sale, importation, exportation or other disposition of Licensed Products; (iii) our or any sub-licensee's act or omission, including negligence or willful misconduct; and (iv) third party suits for patent infringement.

The term of this agreement runs from May 4, 2016 until the date of our last obligation to make payments under the agreement, provided that Mayo Foundation may terminate the 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 second anniversary of the agreement 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 fifth anniversary of the agreement, (iii) we fail to make a sale of a Licensed Product by May 4, 2026, and (iv) we cease to conduct business in the normal event of operations or become insolvent or bankrupt. We may voluntarily terminate the agreement at any time upon written notice to Mayo Foundation.

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 sub-licensee; (ii) research, development, design, manufacture, distribution, use, sale, importation, exportation or other disposition of Licensed Products; and (iii) our or any sub-licensee’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.

5

HER2/neu License Agreement

On June 7, 2016, we announced that we exercised our option agreement with Mayo Clinic and signed a worldwide license agreement to a proprietary HER2/neu vaccine technology. The license gives us the right to develop and commercialize the technology in any cancer indication in which the HER2/neu antigen is overexpressed.

General

Company History

We were incorporated under the laws of the State of Nevada in 1991. We have one wholly-owned and dormant subsidiary named GeneMax Pharmaceuticals Inc. ("GeneMax Pharmaceuticals"). Our common stock is currently listed for trading on the Nasdaq Capital Market under the symbol "TPIV."

We operated offices and laboratories at 1551 Eastlake Avenue, Seattle, Washington 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, Florida to be in closer proximity to our collaborators at Mayo Clinic in Jacksonville, Florida and our strategic and medical advisors who live in Florida. We continue to lease a single office at Eastlake Avenue in Seattle, Washington for the purposes of continuing to develop and patent our Polystart technology.

Over the past two years, 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 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 Histocompatibility Class ("MHC") 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. One of our strategic visions 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 market for cancer immunotherapy is estimated to grow to more than $80 billion by 2020 according to ResearchandMarkets.com. There exists 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 http://jutiagroup.com/20120412-vaccine-therapies-hold-promise-for-investors-stephen-dunn/). 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. 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.

Intellectual Property

We rely upon a combination of licenses, patents, trade secrets, know-how, and licensing opportunities to develop our business. Our future prospects depend on our ability to protect our intellectual property. We also need to operate without infringing the proprietary rights of third parties.

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. As of December 2016, we held four U.S. issued patents (one owned, three licensed or option to license), seven patent applications pending (three owned, four licensed or option to license), three foreign issued/allowed patents, and seventeen foreign patent applications pending (eight owned, nine licensed or option to license). Our policy is to seek appropriate patent protection both in the United States and abroad for our proprietary technologies and product candidates. 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 the information disclosed elsewhere in this annual report under “Risk Factors”. We reassess the value of each patent at the time maintenance fees are due, and in cases where maintaining the patent is judged to be of no significant strategic value we decline to pay the maintenance fee.

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.

We currently have 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 December 31, 2016 on each issued patent currently held or licensed by us:

Patent No.	Expiration	Title	Ownership	Jurisdiction Where Granted/Filed
Peptide Based Vaccine (Folate Receptor Alpha, Breast and Ovarian Cancer)				
Patent No. 8,486,412	Expires 2030	Immunity To Folate Receptors	Exclusive License	USA
Patent No. 9,243,033	Expires 2027	Immunity To Folate Receptors	Exclusive License	USA
Not yet assigned (allowed 9-19-2016)	Expires 2027	Immunity to Folate Receptors	Exclusive License	Canada
Peptide Based Vaccine (HER2/neu+ Breast Cancer)				
Patent No. 8,858,952	Expires 2031	Methods and Materials for Generating T Cells	Exclusive License	USA
Nucleic Acid Based Vaccine (Polystart; infectious disease, breast and ovarian Cancer)				
Patent No. 9,364,523	Expires 2035	Nucleic Acid Molecule Vaccine Compositions And Uses Thereof	Exclusive License	USA
HLA DR Peptide Vaccines				

Patent No. 6,006,265	Expires 2028	HLA-DR Binding Peptides And Their Uses	Exclusive License	Japan
Patent No. 2,215,111	Expires 2028	HLA-DR Binding Peptides And Their Uses	Exclusive License	Europe (DE, FR, GB, IE)

On February 7, 2017, we announced that we received a Notice of Allowance from the U.S. Patent and Trademark Office of our patent application titled, “Chimeric nucleic acid molecules with non-AUG initiation sequences and uses thereof.”

We have exclusively licensed the intellectual property for our TPIV 100/110 HER2/neu+ breast cancer vaccine and TPIV 200 folate receptor alpha vaccine product candidates from Mayo Foundation for Medical Education and Research. See “Mayo Foundation for Medical Education and Research Relationships.”

The effect of the issued patents is that they provide us with patent protection for the claims covered by the patents. While the expiration of a product patent normally results in a loss of market exclusivity for the covered product or product candidate, commercial benefits may continue to be derived from: (i) later-granted patents on processes and intermediates related to the most economical method of manufacture of the active ingredient of such product; (ii) patents relating to the use of such product; (iii) patents relating to novel compositions and formulations; and (iv) in the United States and certain other countries, market exclusivity that may be available under relevant law. The effect of patent expiration on our product candidates also depends upon many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

Our pending patent applications cover a range of technologies, including specific embodiments and applications for treatment of various medical indications, improved application methods and adjunctive utilization with other therapeutic modalities. The coverage claimed in a patent application can be significantly reduced before the patent is issued. Accordingly, we do not know whether any of the applications we acquire or license will result in the issuance of patents, or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because unissued U.S. patent applications are maintained in secrecy for a period of eighteen months and U.S. patent applications filed prior to November 29, 2000 are not disclosed until such patents are issued, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in opposition proceedings in a foreign patent office, or for United States patent applications filed before March 16, 2013, in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, or in United States *inter partes* review or post-grant review procedures, any of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued, would be held valid by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology.

We have patents and patent applications in other countries, as well as in the European Patent Office that we believe provide equivalent or comparable protection for our product candidates in jurisdictions internationally that we consider to be key markets. Because of the differences in patent laws and laws concerning proprietary rights, the

extent of protection provided by U.S. patents or proprietary rights owned by us may differ from that of their foreign counterparts.

We believe that our patents, the protection of discoveries in connection with our development activities, our proprietary products, technologies, processes and know-how and all of our intellectual property are important to our business. To achieve a competitive position, we rely on trade secrets, non-patented proprietary know-how and continuing technological innovation, where patent protection is not believed to be appropriate or attainable. In addition, as outlined above, we have a number of patent licenses from third parties, some of which important to our business. See “Mayo Foundation for Medical Education and Research Relationships”. There can be no assurance that any of our patents, licenses or other intellectual property rights will afford us any protection from competition.

Trademarks

Our trademarks are of material importance to our business. We currently have pending with the U.S. PTO, an application for registration of the mark of POLYSTART. We recently received notice of the registration of the mark TAPIMMUNE from the U.S. PTO. We also have rights to use other names essential to our business. Federally registered trademarks have a perpetual life, as long as they are maintained and renewed on a timely basis and used properly as trademarks, subject to the rights of third parties to seek cancellation of the trademarks if they claim priority or confusion of usage. We regard our trademarks and other proprietary rights as valuable assets and believe they have significant value to us.

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 Inc., Genzyme Molecular Oncology, Immune Design, Oncothyreon, Celldex, BN Immunotherapeutics, Immunocellular, Galena BioPharma, 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 and 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 ("GLP") and Good Manufacturing Practice ("GMP") 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 a New Drug Application ("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 through 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 ("GMP"), 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 GMP 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 ("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 payors 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. Payors also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. Payors 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 payors 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 ("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 that 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, 2016 and 2015, we incurred research and development expenses of approximately $3,800,000, and $1,700,000, 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. Management maintains products and clinical trial liability insurance policies. There can be no assurance that 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 eight full-time employees. The management team is comprised of Dr. Glynn Wilson (Chief Executive Officer), John Bonfiglio (President and Chief Operating Officer), Michael J. Loiacono (Chief Financial Officer), Dr. Robert Florkiewicz (Sr. Research Director) and a Director of Administration. Additionally, we employ a Director of Manufacturing, a Clinical Trials Manager and an Executive Assistant.

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. Patrick Yeramian serves as our medical director in a consulting capacity.

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, 2016, we had cash of approximately $7,851,000. We believe that our cash resources can be sufficient to fund our research efforts and operations through the end of 2017. 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 us, 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, 2016 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. We believe our current capital resources are sufficient to support our operations through the end of 2017. Management intends to continue our research efforts and to finance our operations through debt and/or equity financings. Management plans to seek additional debt and/or equity financing through private or public offerings or through a business combination or strategic partnership. There can be no assurance that we will be successful in obtaining additional financing on favorable terms, or at all. These matters raise substantial doubt about our ability to continue as 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 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, 2016, we had an accumulated deficit of approximately $146,000,000 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.

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 and 2016 financings upon exercise of such outstanding warrants, we have filed registration statements with the SEC to register such shares. The registration statements permit 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 useable 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 have filed such amendments to our registration statements, there can be no assurance that we will be able to have the post-effective amendments to our registration statements declared effective in a timely manner. 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 Food and Drug Administration ("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 at least five 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 not be able to establish or maintain the third-party relationships that are necessary to develop or potentially commercialize some or all of our product candidates.

We expect to depend on collaborators, partners, licensees, clinical research organizations and other third parties to support our discovery efforts, to formulate product candidates, to manufacture our product candidates, and to conduct clinical trials for some or all of our product candidates. We cannot guarantee that we will be able to successfully negotiate agreements for or maintain relationships with collaborators, partners, licensees, clinical investigators, vendors and other third parties on favorable terms, if at all. Our ability to successfully negotiate such agreements will depend on, among other things, potential partners' evaluation of the superiority of our technology over competing technologies and the quality of the preclinical and clinical data that we have generated, and the perceived risks specific to developing our product candidates. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidates.

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. The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may initiate or become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or we may become subject to proceedings initiated by our competitors or other third parties or the United States Patent and Trademark Office ("USPTO") or applicable foreign bodies to reexamine the patentability of our licensed or owned patents. In addition, litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of other.

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 have world-wide exclusive licenses on (1) a novel set of Class II HER2/neu peptide antigens, (ii) a novel Class I HER2/neu antigen, and (iii) a novel set of Class II Folate Receptor Alpha peptide antigens. 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 rely upon patents and licensed technologies 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 positions, 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.

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 seven-year market exclusivity upon receiving marketing approval. Even though we were granted orphan drug designation, 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 European Medicines Evaluation Agency ("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.

New regulatory pathways for biosimilar competition could reduce the duration of market exclusivity for our products.

Under the federal PPACA, enacted in 2010, there is an abbreviated path in the United States for regulatory approval of products that are demonstrated to be “biosimilar” or “interchangeable” with an FDA-approved biological product. The PPACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to (but not generic copies of) innovative drugs on the basis of less extensive data than is required by a full BLA. Under this regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. However, the term of regulatory exclusivity may not remain at 12 years in the United States and could be shortened.

A number of jurisdictions outside of the United States have also established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier versions of biological products. For example, the EU has had an established regulatory pathway for biosimilars since 2005.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our late-stage product candidates or other clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

We have limited 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 (“CMOs”). To meet our projected needs for preclinical 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 Current Good Manufacturing Practice ("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 preclinical study or clinical trial could considerably delay completion of such preclinical 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 December 31, 2016, we had eight full-time employees and a number of management and scientific consultants and advisors. 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 biotechnology 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 Chief Executive Officer Dr. Glynn Wilson, our President and Chief Operating Officer Dr. John Bonfiglio and our Sr. Research Director, Dr. Robert Florkiewicz, as well as the services of several key consultants. 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 cybersecurity/information systems risk.

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 some of 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 those Phase II clinical trials started in 2016 and those planned to commence in 2017.

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 ("BLA") 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 payors, including government payors 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 payors 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 payors 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 carry products and clinical trial liability insurance. There can be no assurance that future 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.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

As described above, the PPACA and potential regulations thereunder easing the entry of competing follow-on biologics into the marketplace, other new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

The current U.S. administration and Congress could carry out significant changes in legislation, regulation, and government policy (including with respect to the possible repeal of all or portions of the PPACA, possible changes in the existing treaty and trade relationships with other countries, and tax reform), as evidenced by statements and recent actions of the current president. While it is not possible to predict whether and when any such changes will occur, changes in the laws, regulations, and policies governing the development and approval of our product candidates and the commercialization, importation, and reimbursement of our product candidates could adversely affect our business.

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;

- results of our preclinical studies and clinical trials or delays in anticipated timing;
- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- announcements of new collaboration agreements with strategic partners or developments by our existing collaboration partners;
- announcements of acquisitions, mergers or business combinations;
- announcements of technological innovations, new commercial products, failures of products, or progress toward commercialization by our competitors or peers;
- general economic conditions and trends;
- positive and negative events relating to healthcare and the overall pharmaceutical and biotechnology sectors;
- major catastrophic events;
- sales of large blocks of our stock;
- 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 maintain listing requirements on the Nasdaq Capital Market;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

33

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

The listing of our common stock on the Nasdaq Capital Market does not assure that a meaningful, consistent and liquid trading market currently exists or will exist in the future. In recent years, the stock 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 stockholders 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 thus causing large swings in price. 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;
- 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 Nasdaq Capital Market which would limit the ability of broker-dealers to sell our securities and the ability of stockholders to sell their securities in the secondary market.

Companies listed for trading on the Nasdaq Capital Market 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 listed on the Nasdaq Capital Market, 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 stockholders to sell their securities in the secondary market.

Our internal control over financial reporting and our disclosure controls and procedures have been determined to be ineffective in the past, and may be determined to be ineffective again in the future, and failure to improve them 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.

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 stockholders 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 41,666,667 shares of our common stock. As of December 31, 2016, we had 8,421,185 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 a minority of our authorized shares, meaning that the ownership position of the current stockholders could be diluted significantly were we to issue a large number of additional shares. For example, as of December 31, 2016, we had outstanding warrants and options to purchase an aggregate of approximately 5,492,000 shares of our common stock with exercise prices ranging between $1.20 and $240.00 per share that will result in dilution if and when exercised.

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 contained prior to being amended, or may be deemed to contain from time to time, embedded derivative rights in accordance with U.S. Generally Accepted Accounting Principles, or GAAP. 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. 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, 2016, the fair value of the derivative liability – warrants was $14,500. 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.

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 stockholders. These provisions may discourage certain types of coercive takeover practices and inadequate takeover bids and encourage persons seeking to acquire control of our company to first negotiate with our 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 office 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 31, 2017. The rent is approximately $3,500 per month. We also rent a single office at 2815 Eastlake Avenue East in Seattle, Washington. The monthly rent is approximately $1,100. Additionally, we rent an office at the Florida Atlantic Research and Development Authority at 3651 FAU Blvd, Boca Raton, Florida on a month by month agreement. The monthly rent for the Boca Raton space is $1,550 per month. Lastly, we rent a 100 square-foot office in the Innovation Bio Business Center at Mayo Clinic Jacksonville at 4500 San Pablo Road, Jacksonville, Florida 32224. The term is for six months ending May 14, 2017, and the monthly rent is $275.

ITEM 3. LEGAL PROCEEDINGS

We are not aware of any legal proceedings contemplated 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 averse to us in any legal proceeding, or (ii) has an adverse interest to us in any legal proceeding.

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 listed for trading on the Nasdaq Capital Market under the symbol "TPIV". The following table sets forth, for the periods indicated, the high and low sales prices for the common stock since January 1, 2015, as reported on Nasdaq.com.

	High	Low
Fiscal Year 2016		
Fourth Quarter	$6.69	$3.32
Third Quarter	$7.15	$4.80
Second Quarter	$9.82	$5.52
First Quarter	$8.34	$5.04
Fiscal Year 2015		
Fourth Quarter	$11.64	$6.30
Third Quarter	$14.04	$3.69
Second Quarter	$20.52	$1.98
First Quarter	$4.32	$1.45

As of February 28, 2017, we had 458 stockholders 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.

Options and Warrants

As of December 31, 2016, there were an aggregate of approximately 5,492,000 common stock purchase warrants and stock options issued and outstanding, with exercise prices ranging between $1.20 and $240.00 per share.

Recent Sales of Unregistered Securities

We recorded the issuances of the following securities during the fourth quarter of 2016 to the named individual pursuant to exemptions under the Securities Act of 1933, including Section 4(2):

In December 2016, Dr. John Bonfiglio exercised 10,417 shares of common stock pursuant to stock options at an exercise price equal to $1.74 per share.

In December 2016, 15,000 shares of common stock were awarded to Omnicor Media, LLC pursuant to a vendor 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, 2016 and December 31, 2015 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.

Our Cancer Vaccines

We are a clinical-stage immuno-oncology company specializing in the development of innovative peptide and gene-based immunotherapeutics and vaccines for the treatment of cancer & metastatic disease. We are also developing a proprietary technology to improve the ability of the cellular immune system to recognize and destroy diseased cells. This DNA expression technology named Polystart is in preclinical development.

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 cancer 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 & Co.) together with the development of CAR T-cell therapies (Juno Therapeutics, Kite Pharma) 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 Clinic**

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, radiation therapy 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.

TPIV 200 Folate Receptor Alpha

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 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, TapImmune exercised its option agreement with Mayo Clinic 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 for the Folate Receptor Alpha Phase I trial was transferred from Mayo to TapImmune for amendment for our Phase II Clinical Trials on our lead product.

On September 15, 2015, we announced that our collaborators at the Mayo Clinic 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. TapImmune will work closely with Mayo Clinic 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 seven-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.

On February 3, 2016, we announced that the U.S. Food & Drug Administration ("FDA") has designated the investigation of multiple-epitope Folate Receptor Alpha Peptide Vaccine (TPIV 200) with GM-CSF adjuvant for maintenance therapy in subjects with platinum-sensitive advanced ovarian cancer who achieved stable disease or partial response following completion of standard of care chemotherapy, as a Fast Track Development Program. A Phase II study in this indication was ready for initiation at the end of 2016.

We are currently enrolling a Company-sponsored triple-negative breast cancer study at eight clinical sites nation-wide. The study will enroll 80 patients. It is open-label and designed to look at dosing regimens, immune responses and efficacy.

We also announced the start of an ovarian cancer study sponsored by Memorial Sloan Kettering Cancer Center in New York City in collaboration with AstraZeneca Pharmaceuticals. This study is currently enrolling platinum resistant ovarian cancer patients and is designed to look at the effects of combination therapy with AstraZeneca's checkpoint inhibitor "durvalumab". The study will enroll 40 patients and is open label. Although we have no business relationship with AstraZeneca, we are paying for half of the clinical study plus providing our TPIV 200 for the study.

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

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 2015. 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 Clinic (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 2017.

Products and Technology-Preclinical

Polystart

We converted the previously filed U.S. Provisional Patent Application on Polystart into a full Patent Application, and in February 2016 we received a Notice of Allowance from the U.S. Patent and Trademark Office ("USPTO") for a patent application entitled, "A chimeric nucleic acid molecule with non-AUG initiation sequences." The term of this patent extends to March 17, 2034. Additional patent filings are in progress. We plan to develop Polystart as both a stand-alone therapy and as a 'boost strategy' to be used synergistically with our peptide-based vaccines for breast and 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 is totally funded by a $13.3 million grant from the U.S. Department of Defense to our collaborators at the Mayo Clinic in Jacksonville, Florida. A Company-sponsored trial in triple-negative breast cancer started during the second quarter of 2016 with recruitment at multiple sites and treatment of first patients. We believe that our development pipeline is strong and provides us the opportunity to continue to expand on collaborations with leading institutions and corporations.

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

We expect to 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 TapImmune to capitalize on the acceptance of immunotherapy as a leading therapeutic strategy in cancer and infectious disease.

TapImmune's Pipeline

Clinical Program

We have a pipeline of potential immunotherapies under development. Phase I clinical programs on HER2/neu for 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 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.

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). We announced the allowance of this patent in February 2016.

40

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 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, and Polystart expression system. 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 vaccine in its own right but also to enhance the efficacy of other immunotherapy approaches such as CAR-T and PD1 inhibitors for example.

Recent Developments and Company Highlights

Research Programs

HER2/neu License Agreement

On June 7, 2016, we announced that we exercised our option agreement with Mayo Clinic and signed a worldwide license agreement to a proprietary HER2/neu vaccine technology. The license gives us the right to develop and commercialize the technology in any cancer indication in which the HER2/neu antigen is overexpressed.

Phase II Trials Started

On April 26, 2016, we announced plans to participate in a Phase II trial of our cancer vaccine, TPIV 200, a multi-epitope anti-Folate Receptor vaccine (FR), in combination with AstraZeneca's durvalumab (MEDI4736), an anti-PD-L1 antibody, in patients with platinum-resistant ovarian cancer. The study started with the enrollment and treatment of patients in the second quarter of 2016 at Memorial Sloan Kettering Cancer Center in New York and is being led by Jason Konner, M.D. as Principal Investigator. On June 21, 2016, we announced the treatment of the first patient in a company-sponsored Phase II trial in triple-negative breast cancer as part of a multi-center study.

Manufacturing

On April 7, 2016, we announced that we have successfully completed formulation development, scale-up, GMP (Good Manufacturing Practice) manufacturing, and the release of TPIV 200, our multi-epitope folate receptor peptide vaccine for breast and ovarian cancer. The manufactured product contains five peptide antigens freeze dried in a single vial, ready for injection after reconstitution and addition of granulocyte-macrophage colony-stimulating factor (GM-CSF). TPIV 200 doses are now available for the upcoming Phase II clinical trials in both triple-negative breast cancer and ovarian cancer.

Recent Developments

Enrolling Patients: Phase II TPIV 200 Trial in Triple-Negative Breast Cancer

We have opened ten clinical sites (with another two more sites anticipated in 2017) and have begun treating patients in a Phase II trial of our Folate Receptor Alpha cancer vaccine, TPIV 200, in the treatment of triple-negative breast cancer, one of the most difficult cancers to treat, representing a clear unmet medical need. The open-label, 80-patient clinical trial is designed to evaluate dosing regimens, adjuvants, efficacy, and immune responses in women with triple-negative breast cancer. Key data from the trial is expected to be included in a future New Drug Application submission to the FDA for marketing clearance. This trial is sponsored and conducted by TapImmune. Details regarding this trial can be found at *www.clinicaltrials.gov* under identifier numbers NCT02593227 and FRV-002.

Enrolling Patients: Phase II Trial at Memorial Sloan Kettering of TPIV 200 in Ovarian Cancer

A Phase II study of TPIV 200 in ovarian cancer patients who are not responsive to platinum, a commonly used chemotherapy for ovarian cancer, sponsored by Memorial Sloan Kettering Cancer Center, and in collaboration with AstraZeneca and TapImmune, has begun enrollment for a 40-patient study. The open-label study is designed to evaluate a combination therapy which includes our TPIV 200 T-cell vaccine and AstraZeneca's checkpoint inhibitor, durvalumab. Because they are unresponsive to platinum, these patients have no real remaining options. If the combination therapy proves effective, we believe it would address a critical unmet need. TPIV 200 has received Orphan Drug designation for use in the treatment of ovarian cancer. Details regarding this trial can be found at *www.clinicaltrials.gov* under identifier numbers NCT02764333.

Enrolling Patients: Phase II TPIV 200 Trial in Platinum-Sensitive Ovarian Cancer

We have opened one clinical site (with at least another 10 sites anticipated in 2017) in a Phase II trial of TPIV 200 in 80 ovarian cancer patients who are responsive to platinum. We have received the FDA's Fast Track designation to develop TPIV 200 as a maintenance therapy in combination with platinum, in platinum responsive ovarian cancer patients. This multi-center, double-blind efficacy study is sponsored and conducted by TapImmune. Details regarding this trial can be found at *www.clinicaltrials.gov* under identifier numbers NCT02978222 and FRV-004.

Patient Enrollment to Commence in the First Quarter of 2017: Phase II Mayo Clinic-U.S. DOD Trial of TPIV 200 in Triple-Negative Breast Cancer

We anticipate this Phase II study of TPIV 200 in the treatment of triple-negative breast cancer, conducted by the Mayo Clinic and sponsored by the U.S. Department of Defense ("DOD"), will begin to enroll patients in the first quarter of 2017. The anticipated 280-patient study will be led by Dr. Keith Knutson of the Mayo Clinic in Jacksonville, Florida. Dr. Knutson is the inventor of the technology and in the Scientific Advisory Board at TapImmune. While TapImmune is supplying doses of TPIV 200 for the trial, and being reimbursed for the costs associated with manufacturing, the remaining costs associated with conducting this study will be funded by a $13.3 million grant made by the DOD to the Mayo Clinic.

Open IND with FDA for TPIV 110 Early 2017: Phase II Protocol Now in Preparation

We have reformulated our second cancer vaccine product, TPIV 110, following very strong safety and immune responses from a Phase I Mayo Clinic study. TPIV 110 targets HER2/neu, which makes it applicable to breast, ovarian and colorectal cancer. The reformulated product adds a fifth antigen which should produce an even more robust immune response activating both CD4+ and CD8+ T-cells. We have participated in a pre-Investigational New Drug (pre"IND") meeting with the FDA and are now in discussions with the FDA as to requirements for filing the amended IND containing the fifth peptide. Although we cannot know for sure, we anticipate having an open IND in early 2017 pending comments from FDA. The protocol for a Phase II trial of TPIV 110 in the treatment of HER2/neu positive breast cancer patients has been designed and is now being reviewed by our Scientific Advisory Board and collaborators.

TPIV Products Are Off-the-Shelf, Commercially Viable, with Excellent Potential Margins

We are continuously working on improving our product formulation and supply. We believe TPIV 200 and TPIV 110 are both very stable, off-the-shelf, lyophilized products that only require reconstitution at the clinical site before injection. We believe the investments we have made in the formulation work we have performed will result in a commercially viable product with excellent potential profit margins.

Robust Product Data & Independent Vetting Key to High-Value Collaborations

We believe the Phase I data produced for both TPIV 200 and TPIV 100 in collaboration with the Mayo Clinic are the driving force behind the high-value collaborations we have been able to maintain and establish with organizations including Mayo Clinic, AstraZeneca, Sloan Kettering, and the U.S. Department of Defense. As we move forward into advancing the Phase II studies, some of which are represent collaboration with prestigious third-party organizations, we believe this represents further independent validation of the potential of our technology.

Company Highlights

Reverse Stock Split

On September 16, 2016, we effected a one-for-twelve reverse split of our common shares. The common shares began trading on a split-adjusted basis on September 16, 2016. The reverse stock split was effected in connection with our intention to apply to list our common stock on the Nasdaq Capital Market. On November 2, 2016, we received notification that our common stock was approved for listing on The Nasdaq Capital Market and it began trading on Tuesday, November 8, 2016 under the ticker symbol “TPIV.”

Our historical financial results have been adjusted to reflect a reduction in the number of shares of our outstanding common stock from 70,550,763 shares to 5,882,955 shares at December 31, 2015. In addition, effective upon the reverse stock split, the number of authorized shares of our common stock was reduced from 500 million shares to 41,666,667 shares. All fractional shares resulting from the reverse stock split were rounded up to the nearest whole share. All share data herein has been retroactively adjusted for the reverse stock split. The par value was not adjusted as a result of the one for twelve reverse stock split.

August 2016 Private Placement Transaction

On August 10, 2016 and August 26, 2016, we completed private placements of units with certain accredited investors. The units consisted of (i) one share of our common stock, par value $0.001 per share and (ii) one five-year warrant to purchase one share of our common stock for $6.00. We issued and sold an aggregate of 653,187 units at a purchase price per unit of $4.80 for an aggregate of approximately $3,100,000. We incurred approximately $0.8 million in agency fees and legal costs.

In addition, we issued five-year warrants to the placement agent in the offering providing for the purchase of up to 65,327 shares of our common stock for $4.80 per share.

Pursuant to the registration rights agreements entered into in connection with the private placements, we were required to file a registration statement with the Securities and Exchange Commission registering for resale (a) the common stock issued in the private placement offering; (b) the shares of common stock issuable upon the exercise of the five-year warrants; and (c) the shares of common stock issuable upon the exercise of the warrants issued to the placement agent. We were required to file the registration statement within 120 days of the August 26, 2016 closing, or by December 27, 2016. We were also required to ensure that the registration statement is declared effective within 90 calendar days after filing with the Securities and Exchange Commission.

We filed the registration statement on December 22, 2016 and it was subsequently declared effective by the Securities and Exchange Commission on January 18, 2017, meeting the contractual deadlines.

August 2016 Warrant Exercises

On August 11, 2016, holders of an aggregate of 583,333 outstanding Series C Warrants and 416,667 Series C-1 Warrants, each providing for the purchase of one share of our common stock for $6.00 per share, exercised their warrants for an aggregate exercise price of $6,000,000.

August 2016 Warrant Amendments

Simultaneous with the exercise of the Series C and Series C-1 Warrants, we and holders of an aggregate of 3,096,665 outstanding Series A Warrants, Series A-1 Warrants, Series C Warrants, Series C-1 Warrants, Series D Warrants, Series D-1 Warrants, Series E Warrants and Series E-1 Warrants (the "Outstanding Series Warrants") entered into Warrant Amendment Agreements (the "Amendment Agreement"), in which they agreed to amend the terms of the Outstanding Series Warrants to remove provisions from the Outstanding Series Warrants that had previously caused them to be classified as a derivative liability as opposed to equity on our balance sheet. In consideration for such amendment and the exercise of the Series C Warrants and Series C-1 Warrants, we issued an aggregate of 750,000 additional shares of common stock to such warrant holders and new five-year warrants to purchase one million shares of our common stock at an exercise price of $7.20 per share (the "Series F and F-1 Warrants").

The following table reflects the status of the outstanding warrants from the January 2015, March 2015, and August 2016 private placement financings (including placement agent warrants) following the Amendment Agreement and private placement:

Series	Outstanding Warrants	Exercise Price	Expiration
A	214,433	$ 1.20	01/13/2020
C	424,433	$ 6.00	01/13/2020
D	610,000	$ 9.00	Between 07/16/2020 and 08/13/2020 and 08/19/2020 and 09/09/2020
E	616,100	$ 15.00	Between 10/01/2020 and 11/12/2020 and 11/30/2020 and 12/09/2020
A-1	418,750	$ 1.20	03/09/2020
C-1	2,083	$ 6.00	01/13/2020
D-1	416,667	$ 9.00	Between 08/19/2020 and 09/09/2020
E-1	418,750	$ 15.00	06/16/2020
F	583,333	$ 7.20	08/11/2021
F-1	416,667	$ 7.20	08/11/2021
PIPE Warrants	653,187	$ 6.00	08/11/2021
Broker Warrants	65,327	$ 4.80	08/11/2021

Financial Overview

Critical Accounting Policies

The condensed consolidated financial statements are prepared in conformity with U.S. GAAP, which require the use of estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of expenses in the periods presented. We believe that the accounting estimates employed are appropriate and resulting balances are reasonable; however, due to inherent uncertainties in making estimates, actual results could differ from the original estimates, requiring adjustments to these balances in future periods. The critical accounting estimates that affect the consolidated financial statements and the judgments and assumptions used are consistent with those described under Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2016.

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 twelve 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, 2016 Compared to the Year Ended December 31, 2015

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 $2,455,000 or ($0.36) basic per share and ($0.72) diluted per share during the year ended December 31, 2016 compared to a net loss of $34,066,000 or ($9.30) basic and diluted per share for the year ended December 31, 2015.

Operating Expenses

Operating expenses incurred during the fiscal year ended December 31, 2016 were $8,492,000 compared to $6,159,000 in the prior year. Significant changes and expenditures are outlined as follows:

- Research and development costs during the fiscal year ended December 31, 2016 were $3,800,000 compared to 1,711,000 during the prior fiscal year. This was due to our exercising our option to acquire Mayo Clinic technology as part of an agreement entered into in March 2014 and increased in-house research activity in the current period.
- General and administrative expenses increased to $4,692,000 during the year ended December 31, 2016 from $4,448,000 during the prior period. was due to generally increased expenses relating to consulting, general and administrative, investor relations and professional fees as our operating activities increased substantially.
- The changes in fair value of derivative liabilities for the year ended December 31, 2016 was $5,940,000 as compared to ($27,873,000) for the year ended December 31, 2015. The variance from the previous year was due to the following factor : the revaluation of the Series A and A-1, Series C and C-1, Series D and D-1 and Series E and E-1 warrants issued by us in January and March 2015, from December 31, 2015 through August 10, 2016, when on

August 10, 2016 we amended warrant agreements to remove the clause that caused the warrants to be classified as derivative liabilities. We revalue the derivative liabilities at each balance sheet date to fair value and record with a corresponding gain in the consolidated statement of operations. The most significant change in the revaluation was the difference in the stock price used at August 10, 2016 of $6.00 compared to $7.20 at December 31, 2015. Of the $5,940,000 change in fair value of derivative liabilities for fiscal 2016, $5,937,000 was due to the revaluation between December 31, 2015 and August 10, 2016. The remaining change was due to the revaluation of the remaining derivative warrants through December 31, 2016.

- During the year ended December 31, 2016, we received $231,000 of a grant awarded to Mayo Foundation from the U.S. Department of Defense for the Phase II Clinical Trial of TPIV 200. The grant paid for the clinical supplies purchased by us.
- During the year ended December 31, 2016, we incurred $136,000 loss on debt settlement agreements relating to an outstanding debt agreement from previous years. This compares to $25,000 loss on debt settlement agreements for the year ended December 31, 2015.

The weighted average number of shares outstanding were approximately 6,890,000 basic and 7,421,000 diluted for the year ended December 31, 2016 compared to approximately 3,662,000 basic and diluted for the year ended December 31, 2015.

Liquidity and Capital Resources

We have not generated any 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, 2016 and 2015:

	December 31, 2016	December 31, 2015
Cash	$ 7,851,000	$ 6,577,000
Working capital (deficit)	$ 6,185,000	$ (21,360,000)

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2016 and 2015:

	Years Ended December 31,	
	2016	2015
Net cash provided by (used in):		
Operating activities	$(6,510,000)	$(4,343,000)
Financing activities	7,785,000	10,778,000
Net increase in cash	$1,275,000	$6,435,000

Financings

Our current available funding has come from financings that we conducted in January and March of 2015 and from the exercise of warrants issued in connection with our January and March, 2015 financings as well as our recent August 2016 private placement.

2015 Financings

January 2015 Financing

In January 2015, we entered into a Securities Purchase Agreement with certain investors for the sale of 610,000 units at a purchase price of $2.40 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 our 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 were exercisable at $18.00 per share, with a five-year term. Series B warrants were exercisable at $4.80 per share, with a six-month term. Series C warrants were exercisable at $12.00 per share, with a five-year term. Series D warrants were exercisable at $9.00 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 were exercisable at $15.00 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 30,500 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 416,667 units at a purchase price of $2.40 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 our 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 10,417 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 $18.00 per share to $1.20 per share,
- The exercise price of Series B and Series B-1 warrants was changed from $4.80 per share to $2.40 per share,
- 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 $12.00 per share to $6.00 per share, 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 1,026,667 Series B and B-1 warrants and 1,026,667 Series C and C-1 Warrants.

2016 Financings

August 2016 Private Placement Transaction

On August 10, 2016 and August 26, 2016, we completed private placements of units with certain accredited investors. The units consisted of (i) one share of our common stock, par value $0.001 per share and (ii) one five-year warrant to purchase one share of our common stock for $6.00. We issued and sold an aggregate of 653,187 units at a purchase price per unit of $4.80 for an aggregate of approximately $3,100,000. We incurred approximately $0.8 million in agency fees and legal costs.

In addition, we issued five-year warrants to the placement agent in the offering providing for the purchase of up to 65,327 shares of our common stock for $4.80 per share.

Pursuant to the registration rights agreements entered into in connection with the private placements, we were required to file a registration statement with the Securities and Exchange Commission registering for resale (a) the common stock issued in the private placement offering; (b) the shares of common stock issuable upon the exercise of the five-year warrants; and (c) the shares of common stock issuable upon the exercise of the warrants issued to the placement agent. We were required to file the registration statement within 120 days of the August 26, 2016 closing, or by December 27, 2016. We were also required to ensure that the registration statement is declared effective within 90 calendar days after filing with the Securities and Exchange Commission. We met all of the foregoing requirements.

Warrant Exercises

Between June 16, 2015 and December 9, 2015, 3,090,000 shares were issued upon exercise of certain warrants we issued in connection with our 2015 financings, providing $9.22 million in proceeds. In August 2016, holders of an aggregate of 583,333 outstanding Series C Warrants and 416,667 Series C-1 Warrants, each providing for the purchase of one share of our common stock for $6.00 per share, exercised their warrants for an aggregate exercise price of $6,000,000.

Future Capital Requirements

Our capital requirements through 2017 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 believe our existing cash and cash equivalents will allow us to fund our operations over the next twelve months. 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.

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.

Various conditions outside of our control may detract from our ability to raise additional capital needed to execute our plan of operations, including overall market conditions in the international and local economies. We recognize that the United States economy has suffered through a period of uncertainty during which the capital markets have been impacted, and that there is no certainty that these levels will stabilize or reverse despite the optics of an improving economy. Any of these factors could have a material impact upon our ability to raise financing and, as a result, upon our short-term or long-term liquidity.

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 capital.

While 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. 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, 2016, we have approximately $31,000,000 of federal and $11,200,000 of state Net Operating Loss (“NOL”s) 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 2036. The state net operating loss carryforwards, if not utilized, will expire in 2036. 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, 2016 and 2015, we recorded a 100% valuation allowance against our deferred tax assets of approximately $13,792,000 and $10,826,000, 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 valuation allowance against our deferred tax assets 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-24 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 have 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

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting, as such term is defined in Exchange Act Rule 13a15(f). Under the supervision and with the participation of our management, including our principal executive, financial and accounting officer, we conducted an evaluation of the effectiveness of our internal controls over financial reporting as of December 31, 2016. This evaluation was based on the framework in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Based on management's evaluation as of December 31, 2016, our management identified the following material weaknesses set forth below in our internal control over financial reporting:

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

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

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

(4) non-performance of an evaluation, risk assessment or monitoring of our internal controls over financial reporting; and

(5) the lack of an effective anti-fraud program designed to detect and prevent fraud relating to (i) an effective whistle-blower program or other comparable mechanism and (ii) an ongoing program to manage identified fraud risks.

Management believes that none of the material weaknesses set forth above had a material adverse effect on our financial results for the fiscal year ended December 31, 2016, but management concluded that in light of the material weaknesses described above, we did not maintain effective internal control over financial reporting as of December 31, 2016 based on the criteria set forth in Internal Control-Integrated Framework (2013) issued by the COSO.

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; and iii) 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 and Frederick Wasserman were appointed to our audit Committee in 2015 and all audit committee members are considered outside directors as of the date of this filing. 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 our registered public accounting firm regarding internal controls over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the temporary rules of the SEC that permit us to provide only management's report in this annual report.

Changes in Internal Control Over Financial Reporting

We hired an experienced Chief Financial Officer effective August 25, 2016 to manage our finance-related functions and to take primary responsibility for preparing the various filings required under the rules of the Securities and Exchange Commission.

As of December 31, 2016, our finance and accounting review functions were supplemented by an external firm on a contract services basis. This firm specializes in providing finance and accounting functions for biotech companies, and the founders and senior managers are highly experienced former partners of national accounting firms. In addition, during the quarter ended December 31, 2016, we engaged a national accounting and consulting firm to provide assistance in complying with the requirements of Sarbanes-Oxley and help us improve its disclosure controls and procedures. Together with these two external firms, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended.

During the year ended December 31, 2016 and as of the date of this filing, we have completed remediation of one of the five material weaknesses identified in our Annual Report on Form 10-K, filed in April 2016:

- 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 and Frederick Wasserman were appointed to our audit Committee in 2015, such that the audit committee, together with Audit Chair Sherry Grisewood, as of December 31, 2016 consists entirely of outside directors.

We have made substantial progress towards remediation of the remaining four continuing material weaknesses identified above. Since the quarter ended December 31, 2016, we have:

- prepared a comprehensive entity-wide risk assessment to evaluate and ultimately report on risks to financial reporting throughout the organization. Following this assessment, we undertook an action plan to strengthen internal controls and procedures;

- prepared comprehensive documentation of our internal controls over financial reporting and tested key financial reporting controls for operating effectiveness;

- further segregated duties within our finance and accounting functions, to ensure that incompatible duties are segregated;

- implemented a new process in connection with our year-end financial close to more fully document our identification of related parties and related party transactions, to ensure that all material transactions and developments impacting the financial statements are reflected and properly recorded;

- implemented a new process to more fully document and test our accounting operations throughout the organization, including the review, supervision and monitoring taking place;

- expanded the personnel resources allocated to our internal controls over financial reporting, and the activities performed for us, by the two external firms referred to above; and

- implemented a whistleblower policy, with a hotline number allowing for anonymous communications, to encourage open and effective channels of information in order to help ensure the accuracy and reliability of our financial statements and disclosures and identification of possible fraudulent activities.

There have been no additional changes in our internal control over financial reporting during our fourth fiscal quarter of our fiscal year ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On March 9, 2017 the Board of Directors approved changes to the Director Compensation Program for non-employee directors. In lieu of any per board or committee meeting fees (including telephonic meetings), or committee chair fees, the Board approved an annual retainer in the amount of $80,000 for each non-employee director. The annual retainer is payable as follows:

(i) half in cash ($40,000) to be paid in four equal quarterly payments at the end of each calendar quarter, provided such director is still serving as a director, and

(ii) half ($40,000) to be paid in restricted common stock under the 2014 Omnibus Stock Ownership Plan (the "Plan") at the time of the Company's annual shareholder meeting in which directors are elected, with such shares determined based on the closing price for the Company's shares on the day preceding the annual meeting and which shall be immediately vested.

To the extent any per meeting fees were paid in 2017 to our non-employee directors under the prior non-employee director compensation plan, such fees are to be deducted from the cash portion of the quarterly payments until fully accounted for. The following components of the Director Compensation Program applicable to non-employee directors remain in place:

- An initial grant upon joining the Board of 12,500 stock options under the Plan;
- Reimbursement of reasonable expenses incurred; and
- Eligibility for discretionary awards under the Plan.

The disclosure set forth below is provided in lieu of a separate Form 8-K filing.

Compensatory Arrangements of Certain Officers.

Bonus Awards 2016

On March 9, 2017 the Board of Directors approved a discretionary 2016 bonus award for Dr. Wilson, our Chief Executive Officer in the amount of $110,000 payable, (i) half in cash ($55,000), and (ii) half ($55,000) in restricted, immediately vested, common stock under the Company's Plan. The restricted share portion of the 2016 bonus award for Dr. Wilson resulted in the issuance of 12,761 shares of restricted common stock based on the closing price or our common stock of $4.31 per share on the day immediately preceding the date the 2016 bonus award was approved by the Board.

On March 9, 2017 the Compensation Committee approved discretionary 2016 bonus awards for each of Dr. Bonfiglio, our President and Chief Operating Officer and Mr. Loiacono, our Chief Financial Officer for their performance during 2016. Dr. Bonfiglio was awarded a 2016 bonus of $45,000 payable, (i) half in cash ($22,500), and (ii) half ($22,500) in restricted, immediately vested, common stock under the Company's Plan. The restricted share portion of the 2016 bonus award for Dr. Bonfiglio resulted in the issuance of 5,220 shares of restricted common stock based on the closing price or our common, of $4.31 per share, on the day immediately preceding the date the 2016 bonus award was approved by the Committee. Mr. Loiacono was awarded a 2016 bonus of $10,000 payable in cash.

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	69	Chairman of the Board, Chief Executive Officer, Principal Executive Officer and a Director
Dr. John Bonfiglio	62	President, Chief Operating Officer and a Director
Michael J. Loiacono	51	Chief Financial Officer and Chief Accounting Officer
Sherry Grisewood	64	Independent Director
David Laskow-Pooley	62	Independent Director
Mark Reddish	62	Independent Director
Joshua Silverman	46	Independent Director
Frederick Wasserman	62	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 and as Chief Executive Officer and President in November 2015. On July 18, 2016, Dr. Wilson relinquished the office of President when we hired Dr. John Bonfiglio as President and Chief Operating Officer. 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.

Dr. John Bonfiglio, Director, President and Chief Operating Officer

Dr. John Bonfiglio joined the Board in July 2015 and serves as President, Chief Operating Officer and a Director. Dr. Bonfiglio served as President, Chief Executive Officer and Director of Oragenics, Inc. (NYSE MKT: OGEN) from May 2011 through October 2014. Dr. John 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. John 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. John Bonfiglio has also held senior management positions with Baxter Healthcare and Allergan, Inc. Dr. John Bonfiglio received his bachelor of sciences degree in chemistry from State University of New York at Stony Brook in 1976, later earning his master’s 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 master’s in business administration from Pepperdine University in 1992.

We believe that Dr. John 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.

Michael J. Loiacono, Chief Financial Officer

Michael J. Loiacono has more than 25 years of financial management experience. At his previous company, FCTI, Inc., Michael was responsible for the company's strategic development to include new products and services, new market penetration and maximizing gross and net revenues. In 2013, FCTI, Inc. acquired Global Axcess Corp, a publicly-traded company, where Michael served as CFO since 2006. At Global Axcess, Michael oversaw the overall financial strategy of the company, including capital raises, mergers & acquisitions, corporate finance, treasury, financial planning and analysis, accounting, investor relations, external auditing and was responsible for Global Axcess' corporate strategy function. In 2009, Michael was named a Jacksonville Florida Ultimate CFO of the year. Prior to FCTI/Global Axcess, Michael held various positions of increasing responsibility in finance management through several private and publicly-traded organizations.

Sherry Grisewood, CFA, Director

Ms. Grisewood joined the Board in March 2013. She has over 25 years of securities industry experience in a range of investment banking, advisory and research-related activities. Since December 2012 she was 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 life science special situations.

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 35 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 on the boards of directors of Pharmafor Ltd, LondonPharma Ltd and OBN Ltd, all UK private companies in addition to Neurovive AB, a Swedish and US public company.

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

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, MAM Software Group, Inc., and SMTC 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.

Joshua Silverman, Director

Mr. Silverman joined the board in November 2016. Mr. Silverman is currently and has been the Co–founder and Managing Member of Parkfield Funding LLC, an investment and consulting firm, since August 1, 2016. Mr. Silverman was a former Principal and Managing Partner of Iroquois Capital Management, LLC (“Iroquois”), where he served as Co–Chief Investment Officer of Iroquois from 2003 until August 1, 2016. From 2000 to 2003, Mr. Silverman served as Co–Chief Investment Officer of Vertical Ventures, LLC, a merchant bank. Prior to forming Iroquois, Mr.

Silverman was a Director of Joele Frank, a boutique consulting firm specializing in mergers and acquisitions. Previously, Mr. Silverman served as Assistant Press Secretary to the President of the United States. Mr. Silverman received his B.A. from Lehigh University in 1992. In the past five years, Mr. Silverman has served on the boards of directors of Neurotrope, Inc., MGT Capital Investments Inc., National Holdings Corporation, Alanco Technologies Inc., Protagenic Therapeutics, Inc. and WPCS International Incorporated.

CORPORATE GOVERNANCE AND BOARD MATTERS

Leadership Structure of the Board of Directors

In 2009, our board of directors elected Glynn Wilson as our Chairman. In addition to his role as Chief Executive Officer, focusing on the day-to-day business and strategic decisions, as Chairman Mr. Wilson leads our board in its fundamental role of providing advice to and oversight of management. Our board of directors recognizes the time, effort and energy that the Chief Executive Officer role is required to devote to the current business environment, as well as the commitment that is required to serve as our Chairman, particularly as the board's oversight responsibilities continue to grow. Our bylaws and corporate governance guidelines do not require that our Chairman and Chief Executive Officer positions be separate. In addition, the independent members of our board meet during every board meeting in separate executive session without any member of management present.

Meetings of the Board of Directors

In 2016, our board of directors met six times. Our board of directors adopted various resolutions pursuant to one unanimous written consent in lieu of a meeting during the year ended December 31, 2016. All but one board member attended 100% of the aggregate of (i) meetings of our board of directors during the year and (ii) the total number of meetings of all committees on our board of directors on which the incumbent directors served. The other remaining directors attended 83% of the aggregate of (i) the meetings of our board of directors during the year and (ii) the total number of meetings of all committees of our board of directors on which the incumbent directors served, due to joining the board during the year.

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.

Board 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 Capital Market listing standards. Based upon these standards, the Board determined that Mark Reddish, Sherry Grisewood, David Laskow-Pooley and Frederick G. Wasserman were independent and had no relationships with the Company, except as a director and stockholder of the Company. At the time of his appointment in November 2016, the Board determined that Josh Silverman also was an Independent Director.

Shareholder Communications with the Board of Directors

Our Corporate Governance Guidelines provide that our Chairman and Chief Executive Officer are responsible for establishing effective communications with our shareholders. Our board of directors has implemented a process for shareholders to send communications to our board of directors and to specific individual directors. Any shareholder desiring to communicate with our board of directors, or with specific individual directors, may do so by writing to our Secretary at 50 N. Laura Street, Suite 2500, Jacksonville, Florida 32202. Our Secretary will promptly forward all such sealed communications to our board of directors or such individual directors, as applicable.

Committees of the Board of Directors

Our board of directors has three standing committees – the audit committee, the compensation committee, and the nominating and corporate governance committee. Each of our committees operates pursuant to a written charter which, as in effect from time to time, may be found on our website at *www.tapimmune.com/investors/briefcase.* Each of the committees is composed of independent directors, consistent with the independence standards defined by the SEC and NASDAQ. Each committee has the right to retain its own legal and other advisors.

The following table reflects the current membership of each Board committee:

	Committee Membership		
Name	**Audit Committee**	**Compensation Committee**	**Nominating and Corporate Governance Committee**
Sherry Grisewood	Chair	√	
David Laskow-Pooley	√	Chair	√
Mark Reddish		√	√
Joshua Silverman(1)			
Frederick Wasserman	√		Chair

(1) Joined the Board on November 28, 2016.

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 July 2016. The members of the Committee consist of Sherry Grisewood, David Laskow-Pooley and Frederick Wasserman. 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 Audit Committee met six times during 2016.

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 July 2016. The members of the Committee are David Laskow-Pooley, Mark Reddish and Sherry Grisewood. Mr. Laskow-Pooley serves as Chair of the Committee. The Compensation Committee met or acted by written consent three times during 2016.

Nominating and Corporate Governance Committee

Our Board of Directors has established a Nominating and Corporate Governance Committee which functions pursuant to a written charter last amended by our Board of Directors in July 2016. The members of the Committee are David Laskow-Pooley, Mark Reddish and Frederick Wasserman. Mr. Wasserman serves as Chair of the Committee. The Nominating and Corporate Governance Committee met or acted by written consent twice during 2016.

Role in Risk Oversight

Our board of directors oversees our stockholders' and other stakeholders' interest in our long-term health and overall success and financial strength. Risk is inherent with every business, and how well a business manages risk can ultimately determine is success. We face a number of risks, including economic risks, environmental and regulatory risks, and others, such as the impact of competition. Management is responsible for the day-to-day management of risks, while our board of directors, as a whole and through its committees, has the responsibility of satisfying itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

Our board of directors believes that establishing the right “tone at the top” and that full and open communication between management and our board of directors are essential for effective risk management and oversight. Our Chairman and Chief Executive Officer meets with our senior officers on a monthly basis to discuss strategy and risks facing us. In addition, senior management regularly attends board meetings and is available to address any questions or concerns raised by our board on risk management-related and other matters. Our board also holds strategic planning sessions with senior management to discuss strategies, key challenges, and risks and opportunities.

While our entire board of directors is ultimately responsible for risk oversight, our board committees assist our board of directors in fulfilling its oversight responsibilities in certain areas of risk. Our audit committee assists our board in the areas of financial reporting, internal controls and compliance with legal and regulatory requirements and discusses policies with respect to risk assessment and risk management. Risk assessment reports are provided annually by management to our audit committee. Our compensation committee assists our board with respect to the management of risk arising from our compensation policies and programs. Our nominating and corporate governance committee assists our board with respect to the management of risk associated with board organization, membership and structure, succession planning for our directors and executive officers, and corporate governance.

Shareholder Nominations

Our nominating and corporate governance committee will consider candidates recommended by shareholders. To recommend director candidates, shareholders should submit their suggestions in writing to the chairman of the nominating and corporate governance committee, c/o our Secretary, providing the candidate’s name, biographical data and other relevant information, together with consent from the suggested candidate to serve on our board of directors if nominated and elected.

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 our directors and officers 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 *http://tapimmune.com/investors/briefcase/*

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

During the year ended December 31, 2016, the executive officers and directors of the Company filed with the Securities and Exchange Commission (the "Commission") on a timely basis, all required reports relating to transactions involving equity securities of the Company beneficially owned by them. The Company has relied solely on the written representation of its executive officers and directors and copies of the reports they have filed with the Commission in providing this information.

ITEM 11. EXECUTIVE COMPENSATION

Compensation Discussion and Analysis

The following table sets forth the compensation earned by our executive officers for their services as executive officers during our fiscal years ended December 31, 2016 and December 31, 2015:

Summary Compensation Table(6)

Name and Principal Position	Year	Salary ($)(1)	Bonus ($)(2)	Stock Awards ($)(3)	Option Awards ($)(4)	All Other Compensation ($)(5)	Total ($)
Glynn Wilson	2016	276,200	110,000	191,000	-	49,200	626,400
Chairman, CEO and Principal Executive Officer	2015	204,000	-	-	605,000	11,000	820,000
John Bonfiglio	2016	115,000	45,000	102,500	374,900	100,600	738,000
President and Chief Operating Officer	2015	-	-	-	-	-	-
Michael J. Loiacono	2016	66,900	10,000	-	308,700	21,600	407,200
Chief Financial Officer, Chief Accounting Officer and Principal Accounting Officer	2015	-	-	-	-	-	-

(1) Represents the salary paid to Dr. Glynn Wilson, Dr. John Bonfiglio and Michael J. Loiacono in accordance with the terms of their employment agreement with us. In the case of Dr. John Bonfiglio and Mr. Michael J. Loiacono the salary reflects the portion of the year they served us in the capacity as an officer from the time their employment became effective.

(2) Represents bonus awards of $110,000 earned by Dr. Glynn Wilson for fiscal year 2016, of which $55,000 is to be paid in cash and $55,000 is to be paid in stock. Dr. John Bonfiglio earned $45,000 of bonus for fiscal year 2016, of which $22,500 is to be paid in cash and $22,500 is to be paid in stock. Michael J. Loiacono earned $10,000 bonus for fiscal year 2016 which is to be paid in cash.

(3) Represents awards of restricted common stock under our 2014 Omnibus Stock Ownership Plan awarded to Dr. Glynn Wilson of 26,250 shares and Dr. John Bonfiglio of 20,833 shares. Such share awards were granted in connection with Dr. Glynn Wilson’s amended and restated employment agreement and in the case of Dr. John Bonfiglio in connection with his initial employment agreement with us. The shares issued to Dr. Glynn Wilson and Dr. John Bonfiglio were issued at a fair value of $7.32 per share and $4.92 per share, respectively.

(4) Represents option awards made to Dr. John Bonfiglio and Michael J. Loiacono in connection with their employment with us. Dr. John Bonfiglio was awarded options to acquire 62,500 shares, with 20,833 shares vesting immediately and the remaining options vesting in 24 equal monthly installments of 1,737. The exercise price for the option is $5.70 per share which was based on the fair market value on the date of the grant. Michael J. Loiacono was awarded an option to acquire 54,167 with 6,251 shares vesting immediately and the remaining shares vesting in 36 equal monthly installments of 1,331 shares on the last day of each of the 36 months following the grant date, at an exercise price of $5.70 per share based upon the fair market value on the date of the grant. See Note 12 of the Notes to the Consolidated Financial Statements contained in this Annual Report on Form 10-K for a discussion of all assumptions made by us in the valuation of the equity awards.

(5) Amounts under the Other column for 2016 reflected for Dr. Glynn Wilson include payroll taxes paid by the Company on behalf of Dr. Glynn Wilson in connection with the 26,250 shares of restricted stock awarded to Dr. Glynn Wilson. Amounts reflected under the Other column for Dr. John Bonfiglio include (i) compensation he was paid as a consultant up to the time he became employed as an officer, and (ii) payroll taxes paid by the Company on behalf of Dr. John Bonfiglio in connection with the 20,833 shares of restricted stock awarded to Dr. John Bonfiglio. Mr. Loiacono’s amount under the Other column reflects payments made to Mr. Loiacono as a consultant prior to his joining the Company as an officer.

(6) Share amounts reflected in the notes to this table have been adjusted to reflect the one for twelve reverse split that occurred on September 15, 2016 unless such share awards occurred after the date of the reverse split.

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, annuity, life insurance, profit sharing or similar benefit plans.

The following table sets forth information as at December 31, 2016 relating to outstanding equity awards for each named executive officer:

	Outstanding Equity Awards at Year End Table(3)				
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					
Chairman, CEO and Principal Executive Officer	125,000	41,667	-	$7.26	12/11/25
	33	-	-	$204.00 (2)	07/06/17
	1,334 (1)	-	-	$204.00 (2)	10/14/19
	134 (1)	-	-	$204.00	02/16/21
John Bonfilgio					
President and Chief Operating Officer	10,416	-	-	$1.74	02/10/25
	9,375	3,125	-	$6.84	07/23/25
	29,514	32,986	-	$5.70	07/18/26
Michael J. Loiacono					
Chief Financial Officer, Chief Accounting Officer and Principal Accounting Officer	11,575	42,592	-	$5.70	08/25/26

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

(2) Effective February 16, 2011, the option exercise price was reduced to $204.00.

(3) Share amounts reflected in this table have been adjusted to reflect the one for twelve reverse split that occurred on September 15, 2016, unless such share awards occurred after the date of the reverse split.

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, 2016, 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 (1)	Option Awards (2)	All Other Compensation	Total
Glynn Wilson(3)	-	-	-	-	-
John Bonfiglio(3)	$ 7,000	-	-	-	$7,000
Sherry Grisewood	$ 11,000	-	-	-	$11,000
David Laskow-Pooley	$ 11,000	-	-	-	$11,000
Mark Reddish	$ 11,000	-	-	-	$11,000
Joshua Silverman	$ 4,000	-	$60,200(4)	-	$64,200
Frederick Wasserman	$ 11,000	-	$94,500(4)	-	$105,500

(1) There are no stock awards outstanding for any non-employee director.

(2) Dr. Wilson, Dr. Bonfiglio, Ms. Grisewood, Mr. Laskow-Pooley, Mr. Reddish, Mr. Silverman, Mr. Wasserman have aggregate options to acquire 168,167, 95,834, 12,500, 12,500, 12,875, 12,500 and 12,500, respectively.

(3) There was no amount paid to Dr. Wilson for his services as a director given his service as our Chief Executive Officer for the compensation paid to him for such services. See Summary Compensation Table. The reflected amount paid to Dr. Bonfiglio was for services as a director prior to the time he became employed as our President and Chief Operating Officer. See Summary Compensation Table.

(4) Represents awards of options upon joining our Board of Directors in the share amount of 12,500 for each of Mr. Wasserman and Mr. Silverman. See Note 12 of the Notes to the Consolidated Financial Statements contained in this Annual Report for a discussion of all assumptions made by us in the valuation of the equity awards.

(5) Share amounts reflected in the notes to this table have been adjusted to reflect the one for twelve reverse split that occurred on September 15, 2016, unless such share awards occurred after the date of the reverse split.

On November 6, 2015 the Board of Directors met and ratified and approved the Non-Employee Director Compensation Plan which provided for the following for non-employee directors:

· An initial grant upon joining the Board of 12,500 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.

Employee Directors did not receive any compensation for board services.

Employment, Consulting and Services Agreements

Dr. Glynn Wilson

On November 12, 2015, we entered into a new employment agreement with Dr. Glynn Wilson, our 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 our Chief Executive Officer, President and Chairman. The initial term of the agreement ends November 11, 2017, but it will automatically be extended for 12-months unless terminated by us 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 us 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 us for our full time employees generally, on terms comparable to those provided to such employees from time to time by us.

In connection with entering into the new agreement, Dr. Wilson received equity awards under our 2014 Omnibus Stock Ownership Plan consisting of (i) an award of 26,250 shares of unregistered common stock, which immediately vested, and (ii) an award of stock options to purchase 166,667 shares of our common stock, prior to November 12, 2025, for $7.26 per share (the closing price of the common stock on November 12, 2015). One-half of the stock options immediately vested, and the remaining half will vest ratably over the following 24 months.

If the agreement is terminated by us without cause (as defined in the agreement), or if the agreement is terminated by Dr. Wilson for good reason (as defined in the agreement), we are 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 us 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, we are 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, we 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 our equity plans which are not fully vested at the time his employment is terminated either by us 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 our employees or compete directly or indirectly with us during the term of the agreement and for one year after its expiration anywhere in the United States. The agreement contains customary confidentiality provisions.

On July 18, 2016, we amended the employment agreement of Dr. Wilson such that Dr. Wilson relinquished the office of President.

Dr. John Bonfiglio

On July 18, 2016, we entered into an Employment Agreement with Dr. John Bonfiglio. Pursuant to that Agreement, Dr. Bonfiglio was to (a) serve as our President and Chief Operating Officer; (b) dedicate his full business time, attention and energies to performing his duties to us, as prescribed by the CEO; (c) report to our CEO; and (d) carry out the decisions and otherwise abide by and enforce our lawful rules and policies. The Agreement provided that Dr. Bonfiglio would perform such services in exchange for an annual salary of $260,000 per year. The agreement provided for equity awards under our 2014 Omnibus Stock Ownership Plan consisting of stock options to purchase 62,500 shares of our common stock at an exercise price of $5.70 which options will vest one third (20,834) immediately and the remaining options shall vest in 23 equal monthly installments of 1,737 options on the last day of each of the 23 months following the grant date, and the remaining 1,737 options shall vest on the last day of the 24th month, and 1,737 shares of unregistered, restricted common stock, all of which shall vest upon the earlier to occur of (i) the listing of our common stock on a national securities exchange in the United States or (ii) the first anniversary of the July 18, 2016, so long as Dr. Bonfiglio is employed with us at such time or on such date, either as an employee or consultant. The term of the Agreement is two years, and will be automatically extended for successive additional twelve (12) month periods, unless terminated by us or Dr. Bonfiglio by written notice. The options awarded to Dr. Bonfiglio at the time he became a consultant have fully vested and, would continue to be exercisable notwithstanding the termination of his consulting services.

Michael J. Loiacono

On August 25, 2016, we entered into an Employment Agreement with Michael J. Loiacono. Pursuant to that Agreement, Mr. Loiacono was to (a) serve as our Chief Financial Officer and Chief Accounting Officer, Secretary and Treasurer; (b) dedicate his full business time, attention and energies to performing his duties to us, as prescribed by the CEO; (c) manage our financial affairs and perform the duties typically assigned to the chief financial officer and chief accounting officer of a similarly situated company in our industry; and (d) perform such other reasonable duties as may hereafter be assigned to him by the CEO, consistent with his abilities and position as the Chief Financial Officer and Chief Accounting Officer and providing such further services to us as may reasonably be requested of him. The Agreement provided that Mr. Loiacono would perform such services in exchange for an annual base salary of $200,000 per year. The agreement provided for equity awards under our 2014 Omnibus Stock Ownership Plan consisting stock options to purchase 54,167 shares of our common stock at an exercise price of $5.70, which 6,251 options shall vest immediately and the remaining options shall vest in 36 equal monthly installments of 1,331 options on the last day of each of the 36 months following the grant date. The term of the Agreement is two years, and will be automatically extended for successive additional twelve (12) month periods after the end of the initial term, unless terminated by us or Mr. Loiacono by written notice.

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 Ownership(1)**	**Percent of Class**	
Directors and Officers:			
Dr. Glynn Wilson, Chairman and Chief Executive Officer (2)	225,955	2.6	%
Mark Reddish, Director (3)	31,764	*	
Sherry Grisewood, Director (4)	14,861	*	
Dr. John Bonfiglio, Director (5)	92,026	*	
David Laskow-Pooley, Director (6)	12,500	*	
Frederick Wasserman, Director (7)	6,771	*	
Joshua Silverman, Director (8)	1,563	*	
Michael J. Loiacono, Chief Financial Officer (9)	15,568	*	
All executive officers and directors as a group (8 persons)	401,008	4.7	%
5% Stockholders:			
Eastern Capital Limited (10) 10 Market St. #773 Camana Bay, Grand Cayman KY1-1206 Cayman Islands	4,000,000	39.8	%
Iroquois Capital Management L.L.C. (11)			
205 East 42nd St., 20th Floor	878,860	9.9	%
New York, NY 10017			
Brio Capital Master Fund (12) 100 Merrick Road, Suite 401 W. Rockville Center, NY 11570	1,155,515	12.6	%
Empery Asset Management LP (13)	939,999	10.9	%

1 Rockefeller Plaza, Suite 1205 New York, New York 10020 Kimberly Page (14)			
205 East 42nd St., 20th Floor New York, NY 10017	1,425,427	15.4	%

*Less than one percent (1%)

65

(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 February 28, 2017 there were 8,421,185 shares of common stock issued and outstanding.

(2) This figure includes 85,567 shares directly owned by Dr. Glynn Wilson, 140,388 shares subject to currently exercisable stock options and excludes 27,779 shares subject to options that have not yet vested.

(3) This figure includes 18,889 shares directly owned by Mark Reddish and 12,875 shares subject to currently exercisable stock options.

(4) This figure includes 2,361 shares directly owned by Sherry Grisewood and 12,500 shares subject to currently exercisable stock options.

(5) This figure includes 26,053 shares directly or indirectly owned by Dr. John Bonfiglio, 65,973 shares subject to currently exercisable stock options and excludes 29,861 shares subject to options that have not yet vested.

(6) This figure includes 12,500 shares subject to currently exercisable stock options.

(7) This figure includes 6,771 shares subject to currently exercisable stock options and excludes 5,729 shares subject to options that have not yet vested.

(8) This figure includes 1,563 shares subject to currently exercisable stock options and excludes 10,467 shares subject to options that have not yet vested.

(9) This figure includes 15,568 shares subject to currently exercisable stock options and excludes 38,599 shares subject to options that have not yet vested.

(10) 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 August 12, 2016. Eastern Capital beneficially owns 2,333,333 shares of common stock and 1,666,667 shares of common stock issuable upon exercise of the Series A-1 Warrants, Series D-1 Warrants, Series E-1 Warrants and Series F-1 Warrants. 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% of the common stock after giving effect to such exercise.

(11) All information is based upon the Schedule 13G jointly filed with the Securities and Exchange Commission by Iroquois Capital Management L.L.C. ("Iroquois"), Richard Abbe and Kimberly Page on February 14, 2017. Includes 358,025 shares of common stock and warrants to purchase 520,835 shares of common stock (312,501 shares pursuant to Series A Warrants, Series D Warrants and Series E Warrants, and 208,334 shares pursuant to Series C Warrants and

Series F Warrants) held by Iroquois Master Fund Ltd (the "Fund"). The Series A Warrants, Series D Warrants and Series E Warrants are subject to a limit of exercise to the extent (and only to the extent) that Iroquois or any of its affiliates would beneficially own in excess of 4.9% of the common stock after giving effect to such exercise. The Series C and Series F Warrants are subject to a limit of exercise to the extent (and only to the extent) that Iroquois or any of its affiliates would beneficially own in excess of 9.9% of the common stock after giving effect to such exercise. Mr. Abbe shares authority and responsibility for the investments made on behalf of the Fund with Ms. Page, each of whom is a director of the Fund. Iroquois is the investment manager for the Fund and Mr. Abbe is the President of Iroquois.

(12) All information is based upon the Schedule 13G filed with the Securities and Exchange Commission by Brio Capital Master Fund Ltd. on February 6, 2017. Includes 347,179 shares of common stock and warrants to purchase 808,336 shares of common stock (416,668 shares pursuant to Series D Warrants and Series E Warrants, and 391,668 shares pursuant to Series C Warrants and Series F Warrants). The Series C Warrants and Series F Warrants 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% of the common stock after giving effect to such exercise. The Series D Warrants and Series E Warrants 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.

(13) All information is based upon (i) the Schedule 13G jointly filed with the Securities and Exchange Commission by Empery Asset Management LP, Empery Tax Efficient II, LP, Ryan M. Lane and Martin D. Hoe on January 19, 2016, (ii) the Company's records relating to the issuance of shares of common stock and Series F Warrants to Empery Asset Management and its affiliates in August 2016, and (iii) the Company's records relating to the transfer in December 2016 by Empery and its affiliates of warrants issued to them in August 2014. Includes 360,000 shares of common stock and warrants to purchase 579,999 shares of common stock (386,666 shares pursuant to the Series D Warrants and Series E Warrants, and 193,333 shares pursuant to Series F Warrants). The Series F Warrants are subject to a limit of exercise to the extent (and only to the extent) that Empery Asset Management or any of its affiliates would beneficially own in excess of 9.9% of the common stock after giving effect to such exercise. The Series D Warrants and Series E Warrants are subject to a limit of exercise to the extent (and only to the extent) that Empery Asset Management or any of its affiliates would beneficially own in excess of 4.9% of the common stock after giving effect to such exercise. Empery Asset Management LP, which serves as the investment manager to Empery Tax Efficient II, LP and other funds (the "Empery Funds"), may be deemed to be the beneficial owner of all shares of common stock held by, and underlying the warrants held by, the Empery Funds. Each of the reporting individuals, as managing members of the general partner of Empery Asset Management LP 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 held by, the Empery Funds. Each of the reporting individuals has disclaimed beneficial ownership of any such shares of common stock.

(14) All information is based upon the Schedule 13G jointly filed with the Securities and Exchange Commission by Iroquois Capital Management L.L.C. (“Iroquois”), Richard Abbe and Kimberly Page on February 14, 2017. Includes 358,025 shares of common stock and warrants to purchase 520,835 shares of common stock (312,501 shares pursuant to Series A Warrants, Series D Warrants and Series E Warrants, and 208,334 shares pursuant to Series C Warrants and Series F Warrants) held by Iroquois Master Fund Ltd (the “Fund”). Also includes 234,000 shares of common stock and warrants to purchase 312,567 shares of common stock (187,500 shares pursuant to Series A Warrants, Series D Warrants and Series E Warrants, and 125,067 shares pursuant to Series C Warrants and Series F Warrants) held by American Capital Management (“American Capital”). The Series A Warrants, Series D Warrants and Series E Warrants held by the Fund and those held by American Capital are subject to a limit of exercise to the extent (and only to the extent) that Iroquois or any of its affiliates, or American Capital or any of its affiliates, respectively, would beneficially own in excess of 4.9% of the common stock after giving effect to such exercise. The Series C and Series F Warrants are subject to a limit of exercise to the extent (and only to the extent) that Iroquois or any of its affiliates, or American Capital or any of its affiliates, respectively, would beneficially own in excess of 9.9% of the common stock after giving effect to such exercise. Ms. Page shares authority and responsibility for the investments made on behalf of the Fund with Mr. Abbe, each of whom is a director of the Fund. Iroquois is the investment manager for the Fund and Mr. Abbe is the President of Iroquois. Ms. Page has sole authority and responsibility for the investments made on behalf of American Capital by virtue of her relationship as manager of American Capital.

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 stockholder approval.

Changes in Control

Other than the changes in stock ownership by our major stockholders 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 our equity securities may be issued as of December 31, 2016:

	(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 stockholders[1]	3,679	$ 215.27	4,654
Equity compensation plans not approved by stockholders[2]	442,500	$ 6.38	140,834
Totals	446,179	$ 8.11	145,488

[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, we adopted the 2009 Stock Incentive Plan (the "2009 Plan"). The 2009 Plan allows for the issuance of up to 8,333 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 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, 3,679 options have been issued under the 2009 Plan, of which 2,013 are outstanding.

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 our employees and non-employee directors. 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 our stockholders, 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 Nasdaq Stock Market. Under the 2014 as originally approved, stock could be issued under the 2014 Plan as a bonus to any employee, other than our executive officers, and 166,667 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 416,667 shares to 583,334 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, 442,500 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.

Review and Approval of Related Person Transactions

In order to ensure that material transactions and relationships involving a potential conflict of interest for any of our executive officers or directors are in our best interests, 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 us to enter into any such transaction or relationship. Pursuant to the Code of Ethics, none of our officers or employees may, on our behalf, 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, nonoe of our officers or employees may, on our behalf, authorize or approve any transaction or relationship, or enter into any agreement, if they are aware that one of our executive officers or directors, or any member of any such person's family, may have a personal interest in such transaction or relationship, without such Audit Committee approval.

Our Audit Committee reviews all conflict of interest transactions involving our executive officers and directors, 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 us;

- 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 our best interests; 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.

Since January 1, 2016, we entered into transactions with certain of our officers and directors as follows:

The Dr. John 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. John Bonfiglio. Pursuant to that Agreement, Dr. John 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. John 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 20,834 options to purchase shares of our common stock for $1.74 per share. The stock options vested as follows: 2,778 options vested at the end of each of the first three months and 1,389 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. John 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. John Bonfiglio was a director at the time of the most recent amendment, the amendment was approved by our audit committee. On July 18, 2016, we entered into an employment agreement with Dr. John Bonfiglio. Pursuant to that agreement, Dr. John Bonfiglio agreed to serve as our President and Chief Operating Officer.

Joshua Silverman

On November 28, 2016, Joshua Silverman, age 46, of Scarsdale, New York, was appointed to our Board of Directors. Mr. Silverman is currently and has been the Co–founder and Managing Member of Parkfield Funding LLC, an investment and consulting firm, since August 1, 2016. Mr. Silverman was a former Principal and Managing Partner of Iroquois Capital Management, LLC ("Iroquois"), where he served as Co–Chief Investment Officer of Iroquois from 2003 until August 1, 2016. From 2000 to 2003, Mr. Silverman served as Co–Chief Investment Officer of Vertical Ventures, LLC, a merchant bank. Prior to forming Iroquois, Mr. Silverman was a Director of Joele Frank, a boutique consulting firm specializing in mergers and acquisitions. Previously, Mr. Silverman served as Assistant Press Secretary to the President of the United States. Mr. Silverman received his B.A. from Lehigh University in 1992. In the past five years, Mr. Silverman has served on the boards of directors of Neurotrope, Inc., MGT Capital Investments Inc., National Holdings Corporation, Alanco Technologies Inc., Protagenic Therapeutics, Inc. and WPCS International Incorporated.

We agreed to add Mr. Silverman to the Board pursuant to the terms of the Warrant Amendment Agreement, dated August 10, 2016, between us and Iroquois Master Fund Ltd., American Capital Management LLC, The Merav Abbe Irrevocable Trust, The Samantha Abbe Irrevocable Trust, The Talia Abbe Irrevocable Trust and The Bennett Abbe Irrevocable Trust (collectively, the "Warrant Amendment Entities"). The Warrant Amendment Agreement with the Warrant Amendment Entities was one of four such agreements entered into on August 10, 2016, pursuant to which holders of an aggregate of 3,096,665 outstanding Series A Warrants, Series A-1 Warrants, Series C Warrants, Series C-1 Warrants, Series D Warrants, Series D-1 Warrants, Series E Warrants and Series E-1 Warrants (the "Outstanding Series Warrants") agreed to amend the terms of the Outstanding Series Warrants to remove provisions from the Outstanding Series Warrants that had previously caused them to be classified as a derivative liability as opposed to equity on our balance sheets. Such agreements were described in, and included as exhibits to, our Current Report on Form 8-K dated August 10, 2016.

Pursuant to the Warrant Amendment Agreement with the Warrant Amendment Entities, the Warrant Amendment Entities were issued an aggregate of 166,667 additional shares of our common stock and new five-year warrants to purchase an aggregate of 196,667 shares of our common stock at an exercise price of $7.20 per share in consideration of their exercise of warrants to purchase an aggregate of 196,667 shares of our common stock at $6.00 per share and the amendment of their remaining warrants to remove the provisions that had previously caused them to be classified as a derivative liability as opposed to equity on our balance sheets.

The Warrant Amendment Entities were also purchasers of our common stock and warrants in January 2015, pursuant to a Securities Purchase Agreement, dated January 12, 2015, when they purchased, for an aggregate of $500,000, an aggregate of 208,333 shares of common stock and Series A, Series B, Series C, Series D and Series E Warrants entitling them to purchase an aggregate of 208,333 shares of common stock under each such Series over various time periods and at various purchase prices. The Securities Purchase Agreement and the warrants were described in, and included as exhibits to, our Current Report on Form 8-K, dated January 12, 2015. The terms of such warrants were modified pursuant to a Restructuring Agreement, dated May 28, 2015, and in connection with entering into the

Restructuring Agreement, we issued an aggregate of 208,333 additional Series B Warrants and an aggregate of 208,333 additional Series C Warrants to the Warrant Amendment Entities for no additional cash consideration. The Restructuring Agreement was described in, and included as an exhibit to, our Current Report on Form 8-K dated May 28, 2015.

Pursuant to the Director Compensation Plan previously approved by the Board of Directors, in connection with his appointment to the Board, Mr. Silverman was granted an option to purchase 12,500 shares of our common stock under the 2014 Omnibus Stock Ownership Plan, at a price equal to the closing price of the common stock on the date of his appointment, with such options to vest in in equal monthly installments over the following 24 months.

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, 2016 and December 31, 2015. Aggregate fees for professional services rendered to us by our auditor are set forth below:

	Year Ended December 31, 2015	Year Ended December 31, 2016
Audit Fees	$ 95,000	$ 194,800
Audit Related Fees	-	-
Tax Fees	60,000	68,300
All Other Fees	-	-
	$ 155,000	$ 263,100

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.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The documents filed as part of this report are as follows:

1. The financial statements and accompanying report of independent registered public accounting firm are set forth immediately following the signature page of this report on pages F-1 through F-24.

2. All financial statement schedules are omitted because they are inapplicable, not required or the information is included elsewhere in the financial statements or the notes thereto.

3. The exhibits required to be filed by this report or able to be incorporated by reference are listed in the "Exhibit Index" following the financial statements.

(b) Other Exhibits

Exhibits required by Item 601 of Regulation S-K are submitted (or incorporated by reference) and listed in a separate section herein immediately following the "Exhibit Index" and are incorporated herein by reference.

(c) Not Applicable.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

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.

Dated: March 14, 2017

TapImmune Inc.

By: /s/ Glynn Wilson
Dr. Glynn Wilson
Chief Executive Officer (Principal Executive Officer)

By: /s/ Michael J. Loiacono
Michael J. Loiacono
Chief Financial Officer (Principal Accounting Officer)

POWER OF ATTORNEY

Each of the undersigned officers and directors of TapImmune, Inc., hereby constitutes and appoints Glynn Wilson and Michael J. Loiacono, their true and lawful attorney-in-fact and agent, for them and in their name, place and stead, in any and all capacities, to sign their name to any and all amendments to this Report on Form 10-K, and other related documents, and to cause the same to be filed with the Securities and Exchange Commission, granting unto said attorneys, full power and authority to do and perform any act and thing necessary and proper to be done in the premises, as fully to all intents and purposes as the undersigned could do if personally present, and the undersigned for himself hereby ratifies and confirms all that said attorney shall lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on March 14, 2017 on behalf of the registrant and in the capacities indicated.

By: /s/ Glynn Wilson
Glynn Wilson,
Director

By: /s/ Sherry Grisewood
Sherry Grisewood,
Director

By: /s/ David Laskow-Pooley
David Laskow-Pooley,
Director

By: /s/ Mark Reddish
Mark Reddish,
Director

By: /s/ John Bonfiglio
John Bonfiglio,
Director

By: /s/ Frederick Wasserman
Frederick Wasserman,
Director

By: /s/ Joshua Silverman
Joshua Silverman,
Director

By: /s/ Michael J. Loiacono
Michael J. Loiacono, Chief
Financial Officer

TAPIMMUNE INC.

CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016

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, 2016 and 2015, and the related consolidated statements of operations, 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, 2016 and 2015, 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

March 14, 2017

TAPIMMUNE INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2016	December 31, 2015
ASSETS		
Current Assets		
Cash	$7,851,243	$6,576,564
Prepaid expenses and deposits	70,149	68,803
Total Assets	$7,921,392	$6,645,367
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities		
Accounts payable and accrued liabilities	$1,224,940	$967,358
Research agreement obligations	492,365	492,365
Warrant liability	14,500	26,493,000
Promissory notes	5,000	30,000
Promissory note, related party	-	23,000
Total Liabilities	1,736,805	28,005,723
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, 2016 and December 31, 2015	-	-
Series B, $0.001 par value, 1,500,000 shares designated, -0- shares issued and outstanding as of December 31, 2016 and December 31, 2015	-	-
Common stock, $0.001 par value, 41,666,667 shares authorized, 8,421,185 and 5,882,955 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	8,421	5,884
Additional paid-in capital	151,991,974	112,142,187
Accumulated deficit	(145,815,808)	(133,508,427)
Total stockholders' equity (deficit)	6,184,587	(21,360,356)
Total liabilities and stockholders' equity (deficit)	$7,921,392	$6,645,367

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

TAPIMMUNE INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31, 2016	Year Ended December 31, 2015
Operating expenses:		
Research and development	$ 3,800,035	$ 1,711,177
General and administrative	4,692,234	4,447,781
Loss from Operations	(8,492,269)	(6,158,958)
Other Income (Expense)		
Changes in fair value of warrant liabilities	5,939,500	(27,872,585)
Foreign exchange gain	-	775
Grant income	231,200	-
Interest and financing charges	-	(10,925)
Loss on debt settlement agreement	(135,640)	(24,697)
Other income	1,828	-
Net Loss	$ (2,455,381)	$ (34,066,390)
Basic net loss per share	$ (0.36)	$ (9.30)
Diluted net loss per share	$ (0.72)	$ (9.30)
Weighted Average Number of Common Shares Outstanding, Basic	6,889,898	3,662,256
Weighted Average Number of Common Shares Outstanding, Diluted	7,420,995	3,662,256

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

TAPIMMUNE INC.

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock Number of shares	Amount	Additional Paid In Capital	Accumulated Deficit	Total
Balance, January 1, 2015	1,693,238	$ 1,695	$85,284,400	$(86,309,731)	$(1,023,636)
Accounts payable settled in shares	9,871	10	21,903	-	21,913
Private placement (net of finders' fee)	1,030,288	1,028	2,324,987	-	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	3,090,000	3,094	9,216,904	-	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	4,163	5	26,468	-	26,473
Stock- based compensation	51,676	52	1,514,214	-	1,514,266
Net loss	-	-	-	(34,066,390)	(34,066,390)
Adjustment for rounded shares due to reverse stock split	3,719				
Balance, December 31, 2015	5,882,955	$ 5,884	$112,142,187	$(133,508,427)	$(21,360,356)
Issuance of common stock in private placement	653,187	653	3,134,543	-	3,135,196
Finders' fee and legal costs relating to private placements	-	-	(804,070)	-	(804,070)
Fair value of shares issued as inducement on August 10, 2016	750,000	750	4,499,250	(4,500,000)	-
Fair value of series F and F-1 warrants issued as inducement in August 2016	-	-	5,352,000	(5,352,000)	-
Reclassification of fair value of derivative liabilities to equity on amendment of warrant agreements	-	-	15,465,000	-	15,465,000
Exercise of stock warrants	1,000,000	1,000	5,999,000	-	6,000,000
Finders' fee on exercise of warrants	-	-	(516,651)	-	(516,651)
Reclassification of fair value of warrant liabilities at exercise date	-	-	5,074,000	-	5,074,000
Exercise of stock options	10,417	10	18,115	-	18,125
Shares issued in debt settlement agreements	10,191	10	70,305	-	70,315
Stock- based compensation	114,435	114	1,558,295	-	1,558,409

Net loss	-	-	-	(2,455,381)	(2,455,381)
Balance, December 31, 2016	8,421,185	$ 8,421	$151,991,974	$(145,815,808)	$6,184,587

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

TAPIMMUNE INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2016	Year Ended December 31, 2015
Cash flow from operating activities		
Net loss	$(2,455,381)	$(34,066,390)
Adjustments to reconcile net loss to net cash from operating activities:		
Changes in fair value of warrant liabilities	(5,939,500)	27,872,585
Loss on debt settlement agreements	70,315	24,697
Non-cash interest and finance charges	-	10,925
Stock-based compensation	1,558,409	1,705,067
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(1,346)	13,701
Accounts payable and accrued liabilities	257,582	96,018
Net cash used in operating activities	(6,509,921)	(4,343,397)
Cash flow from financing activities		
Private placements	3,135,196	2,464,000
Finders' fee and legal costs on private placements	(804,070)	(137,985)
Repayment of promissory note	(25,000)	-
Repayment of promissory note – related party	(23,000)	-
Proceeds from exercise of stock options	18,125	-
Proceeds from exercise of warrants	6,000,000	9,219,998
Finders' fee on exercise of warrants	(516,651)	(767,996)
Net cash provided by financing activities	7,784,600	10,778,017
Net increase in cash	1,274,679	6,434,620
Cash, beginning of year	6,576,564	141,944
Cash, end of year	$7,851,243	$6,576,564

Supplemental disclosure of cash flow information		
Cash paid for interest	$-	$-
Cash paid for taxes	$-	$-

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

TAPIMMUNE INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2016	Year Ended December 31, 2015
Supplemental schedule of non-cash investing and financing activities:		
Reclassification of accrued liability upon issuance of common shares relating to Dr. Glynn Wilson's compensation	$191,000	$-
Accounts payable settled in common stock	-	22,000
Fair value of issuance of series F and F-1 warrants as inducement in August 2016	5,352,000	-
Fair value of shares issued as inducement on August 10, 2016	4,500,000	-
Reclassification of fair value of derivative liabilities to equity on amendment of warrant agreements	15,465,000	-
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	$5,074,000	$16,835,000

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

TAPIMMUNE INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016

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 2017.

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 2017.

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.

Liquidity, financial condition and managements plans

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, 2016, the Company had cash balances of approximately $7,851,000. Historically, the Company has incurred significant losses 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 current clinical trials, ongoing research and development, maintenance and protection of patents 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 and is continuing initiatives to raise capital through private placements, related party loans and other institutional sources to meet future working capital requirements.

Historically the Company has raised capital through issuances of various financial instruments and during 2016, the Company 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 beyond the next twelve months.

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

Reverse stock split

On September 13, 2016, the Company's Board of Directors approved a 1-for-12 reverse stock split of the Company's authorized and issued and outstanding common stock. The reverse stock split became effective on September 16, 2016. Upon the effectiveness of the reverse stock split, (i) every twelve shares of outstanding common stock was combined into one share of common stock, (ii) the number of shares of common stock into which each outstanding warrant or option to purchase common stock is exercisable was proportionally decreased and (iii) the exercise price of each outstanding warrant or option to purchase common stock was proportionately increased. All historical share and per share amounts reflected in this annual report have been adjusted to reflect the reverse stock split.

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 and dormant subsidiary GeneMax Pharmaceuticals Inc. 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 warrant liabilities and accrued liabilities.

Fair Value Measurements

The Company follows Accounting Standards Codification ("ASC") 820, "Fair Value Measurements and Disclosures," ("ASC 820") for the Company's financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and are re-measured and reported at fair value at least annually using a fair value hierarchy that is broken down into three levels. Level inputs are defined as follows:

· 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.

Patents and Patent Application Costs

Although the Company believes that its patents and underlying technology have continuing value, the amount of future benefits to be derived from the patents is uncertain. Patent costs are, therefore, expensed as incurred.

Stock-Based Compensation

The Company follows the provisions ASC 718, “Compensation – Stock Compensation”, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, non-employee directors and consultants, including employee stock options. Stock compensation expense based on the grant date fair value estimated in accordance with the provisions of ASC 718 is recognized as an expense over the requisite service period and are recorded in general and administrative expenses. For stock options and warrants granted in consideration for services rendered by non-employees, the Company recognizes compensation expense in accordance with the requirements of ASC Topic 505, “Equity”. Non-employee option and warrant grants that do not vest immediately upon grant are recorded as an expense over the vesting period. At the end of each financial reporting period prior to vesting, the value of these options and warrants, as calculated using the Black-Scholes option-pricing model, is being re-measured using the fair value of the Company’s common stock and the non-cash compensation recognized during the period will be adjusted accordingly. Since the fair market value of options and warrants granted to non-employees is subject to change in the future, the amount of the future compensation expense will include fair value re-measurements until the stock options and warrants are fully vested.

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 research and development rights to certain technologies. The rights and licenses acquired are considered rights to unproven technology which may not have alternate future uses and therefore, are expensed as incurred as research and development costs.

Clinical trial expenses include direct costs associated with contract research organizations (“CROs”), as well as patient-related costs at sites at which our trials are being conducted. Direct costs associated with our CROs are generally payable on a time and materials basis, or when certain enrollment and monitoring milestones are achieved.

The Company incurred costs of approximately $3,800,000 and $1,711,000 on research and development for the year ended December 31, 2016 and 2015, respectively.

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 the statement of operations in the period that includes the date of allowances against deferred tax assets.

Tax benefits are recognized only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon settlement. A liability for “unrecognized tax benefits” is recorded for any tax benefits claimed in the Company’s tax returns that do not meet these recognition and measurement standards. As of December 31, 2016 and 2015, no liability for unrecognized tax benefits was required to be reported. The guidance also discusses the classification of related interest and penalties on income taxes. The Company’s policy is to record interest and penalties on uncertain tax positions as a component of income tax expense. No interest or penalties were recorded during the years ended December 31, 2016 and 2015.

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.

Grant Income

The Company recognizes grant income in accordance with the terms stipulated under the grant awarded to the Company's collaborators at the Mayo Foundation from the U. S. Department of Defense. In various situations, the Company receives certain payments from the U.S. Department of Defense for reimbursement of clinical supplies. These payments are non-refundable, and are not dependent on the Company's ongoing future performance. The Company has adopted a policy of recognizing these payments as grant income when received.

Earnings (Loss) per Common Share

Basic earnings (loss) per share include only the weighted average common shares outstanding, without consideration of potentially dilutive securities. Diluted earnings per share include the weighted average common shares outstanding and any potentially dilutive common stock equivalent shares in the calculation.

Cash and Credit Risk

The Company maintains cash in accounts which are in excess of the Federal Deposit Insurance Corporation ("FDIC") insured limits of $250,000. As of December 31, 2016 and 2015, approximately $7.6 million and $6.3 million, respectively, in cash was uninsured based upon the FDIC insurance coverage limits.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies that we adopt as of the specified effective date. Unless otherwise discussed, we do not believe that the impact of recently issued standards that are not yet effective will have a material impact on our financial position or results of operations upon adoption.

Statement of Cash Flows

In August 2016, the FASB issued Accounting Standards Update (“ASU”) No. 2016-15, Statement of Cash Flows (Topic 230). This amendment provides guidance on the presentation and classification of specific cash flow items to improve consistency within the statement of cash flows. ASU 2016-15 is effective for fiscal years, and interim periods within those fiscal years beginning after December 15, 2017, with early adoption permitted. The Company is evaluating the effect that ASU 2016-15 will have on its financial statements and related disclosures.

Going Concern

In August 2014, the FASB issued ASU No. 2014-15, ”Presentation of Financial Statements-Going Concern”, which defines management's responsibility to assess an entity's ability to continue as a going concern, and requires related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. ASU No. 2014-15 is effective for the Company for the fiscal year ending on December 31, 2016, with early adoption permitted. The Company adopted ASU 2014-15 as of December 31, 2016 in its consolidated financial statements and related disclosures, which did not have a material impact on its results of operations, cash flows or financial position.

Deferred Taxes

In November 2015, FASB issued ASU No. 2015-17, ”Balance Sheet Classification of Deferred Taxes”. ASU No. 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU No. 2015-17 is effective for financial statements issued for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. The Company adopted ASU No. 2015-17 on January 1, 2017 and its adoption did not have a material impact on the Company’s financial position and results of operations.

Compensation-Stock Compensation

In March 2016, the FASB issued ASU No. 2016-09, Compensation-Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting. Under ASU No. 2016-09, companies will no longer record excess tax benefits and certain tax deficiencies in additional paid-in capital ("APIC"). Instead, they will record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement and the APIC pools will be eliminated. In addition, ASU No. 2016-09 eliminates the requirement that excess tax benefits be realized before companies can recognize them. ASU No. 2016-09 also requires companies to present excess tax benefits as an operating activity on the statement of cash flows rather than as a financing activity. Furthermore, ASU No. 2016-09 will increase the amount an employer can withhold to cover income taxes on awards and still qualify for the exception to liability classification for shares used to satisfy the employer's statutory income tax withholding obligation. An employer with a statutory income tax withholding obligation will now be allowed to withhold shares with a fair value up to the amount of taxes owed using the maximum statutory tax rate in the employee's applicable jurisdiction(s). ASU No. 2016-09 requires a company to classify the cash paid to a tax authority when shares are withheld to satisfy its statutory income tax withholding obligation as a financing activity on the statement of cash flows. Under current U.S. GAAP, it was not specified how these cash flows should be classified. In addition, companies will now have to elect whether to account for forfeitures on share-based payments by (1) recognizing forfeitures of awards as they occur or (2) estimating the number of awards expected to be forfeited and adjusting the estimate when it is likely to change, as is currently required. The amendments of this ASU are effective for reporting periods beginning after January 1, 2017, with early adoption permitted but all of the guidance must be adopted in the same period. The Company adopted this on January 1, 2017. The Company has evaluated the impact of ASU No. 2016-09 and has determined that the adoption of the impact of forfeitures, net of income taxes, will not have a material impact on the Company's future financial statements.

Note 3: NET LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDER

Net Loss per Share Applicable to Common Stockholders

Basic loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the reporting period. Diluted loss per common share is computed similar to basic loss per common share except that it reflects the potential dilution that could occur if dilutive securities or other obligations to issue common stock were exercised or converted into common stock.

The following table sets forth the computation of loss per share for the years ended December 31, 2016 and 2015, respectively:

	For the years ended December 31,	
	2016	2015
Net loss	$(2,455,381)	$(34,066,390)
Less: Non cash income from changes in fair value of derivative liabilities	(2,856,000)	-
Net loss - diluted	$(5,311,381)	$(34,066,390)
Weighted average common shares outstanding - basic	6,889,898	3,662,256
Common stock warrants	531,097	-
Weighted average common shares outstanding - diluted	7,420,995	3,662,256
Net loss per share data:		
Basic	$(0.36)	$(9.30)
Diluted	$(0.72)	$(9.30)

The following securities, rounded to the thousand, were not included in the diluted net loss per share calculation because their effect was anti-dilutive for the periods presented:

	For the years ended December 31,	
	2016	2015
Common stock options	434,000	299,000
Common stock warrants - equity treatment	5,054,000	212,000
Common stock warrants - liability treatment	4,000	4,130,000
Potentially dilutive securities	5,492,000	4,641,000

Note 4: accounts payable and accrued liabilities

Accounts payable and accrued liabilities consist of the following as of December 31, 2016 and 2015, respectively:

	For the years ended December 31,	
	2016	2015
Accounts payable	$680,181	$691,094

Compensation and benefits	217,622	191,000
Professional fees	53,428	15,000
Consulting agreements	94,576	-
Technology license fees	105,000	-
Other	74,133	70,264
Total accounts payable and accrued liabilities	$1,224,940	$967,358

Note 5: 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, 2016 and 2015, the Company has accrued $492,000 as amounts owed under the amended agreement.

Note 6: WARRANT LIABILITY

A weighted average 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 2016 and 2015 is as follows:

Stock Purchase Warrants	Weighted Average Inputs for the Period			
Date of valuation	For the Year Ending December 31, 2016		For the Year Ending December 31, 2015	
Exercise price	$ 1.20		$ 0.74	
Contractual term (years)	1.15		4.2	
Volatility (annual)	100	%	155	%
Risk-free rate	1.00	%	2.00	%
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.

The following table presents changes in Level 3 warrant liabilities measured at fair value for the year ended December 31, 2016 and 2015, respectively:

	Warrant Liability
Balance - January 1, 2015	$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
Reclassification of derivative liabilities to equity at exercise date	(5,074,000)
Reclassification of fair value of derivative liabilities to equity on amendment of warrant agreements	(15,465,000)
Change in fair value of warrant liability	(5,939,500)
Balance – December 31, 2016	$14,500

Note 7: FAIR VALUE MEASUREMENTS

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:

	Fair value measured at December 31, 2016			
	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Fair value at December 31, 2016
Derivative liability - warrants	$-	$ -	$ 14,500	$ 14,500

	Fair value measured at December 31, 2015			
	Quoted prices in active markets	Significant other observable inputs	Significant unobservable inputs	Fair value at

	(Level 1)	(Level 2)	(Level 3)	December 31, 2015
Derivative liability - warrants	$-	$ -	$26,493,000	$26,493,000

There were no transfers between Level 1, 2 or 3 during the year ended December 31, 2016 and 2015, respectively.

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.

Warrant Amendment Transaction

On August 10, 2016, the Company and holders of an aggregate of 3,096,665 outstanding Series A Warrants, Series A-1 Warrants, Series C Warrants, Series C-1 Warrants, Series D Warrants, Series D-1 Warrants, Series E Warrants and Series E-1 Warrants entered into warrant amendment agreements (the “Amended Warrants”) in which they agreed to amend the terms of the outstanding series warrants to remove provisions that had previously precluded equity classification treatment on the Company’s balance sheets.

The fair value of the Amended Warrants was re-measured immediately prior to the date of amendment with changes in fair value recorded as a gain of $5.1 million in the statement of operations and $15.5 million was reclassified to equity.

Note 8: Promissory notes

At December 31, 2016, the Company had outstanding promissory notes in the amount of $5,000 as compared to two outstanding promissory notes totaling $30,000 at December 31, 2015. The one promissory note outstanding and due at December 31, 2016 bears 10% annual interest.

Note 9: Promissory note, related party

At December 31, 2015, the Company had an outstanding promissory note in the amount of $23,000 owed to an officer of the Company. The promissory note bore no interest charges and had no fixed repayment terms. During the year ended December 31, 2016, the note was paid in full.

Note 10: stockholders' equity

Preferred Stock

The Company has authorized up to 5,000,000 shares of preferred stock, $0.0001 par value per share, for issuance. The preferred stock will have such rights, privileges and restrictions, including voting rights, dividend conversion rights, redemption privileges and liquidation preferences, as shall be determined by the Company's board of directors upon its issuance. To date, the Company has not issued any preferred shares.

Series A Preferred Stock - The Company has designated up to 1,250,000 shares of Series A Preferred Stock, $0.0001 par value per share, for issuance. To date, the Company has not issued any Series A preferred shares.

Series B Preferred Stock - The Company has designated up to 1,500,000 shares of Series B Preferred Stock, $0.0001 par value per share, for issuance. To date, the Company has not issued any Series B preferred shares.

Common Stock

The Company has authorized up to 41,666,667 shares of common stock, $0.0001 par value per share, for issuance. Significant 2016 and 2015 common stock transactions were as follows:

2016 Common Stock Transactions

Private placements

On August 10, 2016 and August 25, 2016, the Company completed private placements of units with certain accredited investors. The units consisted of (i) one share of the Company's common stock, par value $0.001 per share and (ii) one five-year warrant to purchase one share of Company common stock for $6.00. The Company issued and sold an aggregate of 653,187 units at a purchase price per unit of $4.80 for an aggregate of approximately $3.1 million. The Company incurred approximately $0.8 million in agency fees and legal costs. The estimated fair value of the warrants was approximately $3.5 million. The fair value was estimated using inputs of : strike price of $6.00, expected term of five years, estimated volatility of 146%, risk-free rate of 1.1% and expected dividend rate of 0%.

Warrant Amendment Transaction

On August 10, 2016, the Company and holders of outstanding Series A Warrants, Series A-1 Warrants, Series C Warrants, Series C-1 Warrants, Series D Warrants, Series D-1 Warrants, Series E Warrants and Series E-1 Warrants entered into warrant amendment agreements in which they agreed to amend the terms of the outstanding series warrants to remove provisions that had previously precluded equity classification treatment on the Company's balance sheets.

In consideration for such amendment and the exercise of the Series C Warrants and Series C-1 Warrants, the Company issued an aggregate of 750,000 additional shares of common stock to such warrant holders and new five-year warrants to purchase 1,000,000 shares of Company common stock at an exercise price of $7.20 per share.

Warrant Exercises

On August 11, 2016, holders of an aggregate of 583,333 outstanding Series C Warrants and 416,667 Series C-1 Warrants, each providing for the purchase of one share of our common stock for $6.00 per share, exercised their warrants for an aggregate exercise price of $6,000,000.

Exercise of Stock Options

In December 2016, Dr. John Bonfiglio exercised 10,417 shares of common stock pursuant to stock options at an exercise price equal to $1.74 per share.

Debt Settlement

In May 2016, the Company issued 10,191 common shares as part of debt conversion agreements from 2014. The fair value of the common stock of approximately $70,000 was recognized as loss on debt settlement agreements in other income (expense).

2016 Management Compensation

In July 2016, the Company entered into an employment agreement with Dr. John Bonfiglio relating to his appointment as the Company's President and Chief Operating Officer. As part of the agreement, Dr. John Bonfiglio was awarded 20,833 common shares, which will vest upon the earlier of (i) the listing of the Company's common stock on a national securities exchange in the United States or (ii) the first anniversary of the employment agreement, so long as Dr. John Bonfiglio is employed with the Company. The fair value of the common stock of approximately $103,000 was recognized as stock-based compensation in general and administrative expense.

Consulting arrangements

During the year ended December 31, 2016, the Company issued 75,000 common shares as part of consulting agreements. The fair value of the common stock of approximately $480,000 was recognized as stock-based compensation in general and administrative expense.

2015 Common Stock Transactions

Private placements

In January, 2015, the Company entered into a Securities Purchase Agreement with certain investors for the sale of 610,000 units at a purchase price of $2.40 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 $18.00 per share, with a five-year term. Series B warrants are exercisable at $4.80 per share, with a six-month term. Series C warrants are exercisable at $12.00 per share, with a five-year term. Series D warrants are exercisable at $9.00 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 $15.00 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 30,500 common shares with substantially the same terms as the January 2015 Warrants and pay a 7% finder's 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 416,667 units at a purchase price of $2.40 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 10,417 common shares with substantially the same terms as the March 2015 Warrants and pay a 3.5% finder's fee on gross proceeds from the sale of securities.

2015 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 26,250 shares of unregistered common stock, fully vested. The Company recorded an obligation to deliver the shares of $191,000 based on the fair value of the common stock at December 31, 2015. The Company issued the shares in March 2016 and reclassified the accrued liability to stockholders' equity (deficit). In the nine months ended September 30, 2016, to adjust for the withholding tax liability, which was payable in cash, Dr. Wilson returned the 26,250 fully vested common shares and was issued 19,018 fully vested common shares.

Note 11: WARRANTS

Share Purchase Warrants

A summary of the Company's share purchase warrants as of December 31, 2016 and 2015, respectively, and changes during the period is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Intrinsic Value
Balance - January 1, 2015	222,000	$ 21.96	4.15	$-
Issued	7,228,000	6.48	4.30	
Exercised	(3,090,000)	3.00	-	
Extinguished or expird	(17,000)	28.68	-	
Balance - December 31, 2015	4,343,000	8.67	4.24	5,547,000
Issued	1,718,000	6.65	4.62	
Exercised	(1,000,000)	6.00	-	
Expired	(2,000)	287.20	-	
Balance - December 31, 2016	5,059,000	$ 8.49	3.68	$1,713,000

2016 Warrant Transactions

August 2016 Warrant Exercises

On August 11, 2016, holders of an aggregate of 583,333 outstanding Series C Warrants and 416,667 Series C-1 Warrants, each providing for the purchase of one share of our common stock for $6.00 per share, exercised their warrants for an aggregate exercise price of $6,000,000.

August 2016 Warrant Amendments

As discussed in Note 10, Stockholders' Equity, simultaneous with the exercise of the warrants, the Company and holders of outstanding Series A Warrants, Series A-1 Warrants, Series C Warrants, Series C-1 Warrants, Series D Warrants, Series D-1 Warrants, Series E Warrants and Series E-1 Warrants entered into warrant amendment agreements, in which they agreed to amend the terms of the existing warrant agreements to remove provisions that had previously caused them to be classified as a derivative liability as opposed to equity on our balance sheet. In consideration for such amendment and the exercise of the Series C Warrants and Series C-1 Warrants, we issued an aggregate of 750,000 additional shares of common stock to such warrant holders and new five-year warrants to purchase 1,000,000 shares of our common stock at an exercise price of $7.20 per share (the "Series F and F-1Warrants"). The value of the shares was treated as dividend on the statement of stockholders' equity of $4.5 million. The estimated fair value of the warrants was approximately $5.4 million. The fair value was estimated using inputs of : strike price of $7.20, expected term of five years, estimated volatility of 146%, risk-free rate of 1.1% and expected dividend rate of 0%.

In addition, the Company issued five-year warrants to the placement agent in the offering providing for the purchase of up to 65,317 shares of Company common stock for $4.80 per share. The estimated fair value of the warrants was approximately $0.4 million. The fair value was estimated using inputs of : strike price of $4.80, expected term of five years, estimated volatility of 146%, risk-free rate of 1.1% and expected dividend rate of 0%.

2015 Warrant Transactions

January 2015 Financing

In January, 2015, we entered into a Securities Purchase Agreement with certain investors for the sale of 610,000 units at a purchase price of $2.40 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 were exercisable at $18.00 per share, with a five-year term. Series B warrants were exercisable at $4.80 per share, with a six-month term. Series C warrants were exercisable at $12.00 per share, with a five-year term. Series D warrants were exercisable at $9.00 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 were exercisable at $15.00 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 30,500 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 416,667 units at a purchase price of $2.40 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 10,417 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 $18.00 per share to $1.20 per share,
- The exercise price of Series B and Series B-1 warrants was changed from $4.80 per share to $2.40 per share,
- 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 $12.00 per share to $6.00 per share, 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 1,026,667 Series B and B-1 warrants and 1,026,667 Series C and C-1 Warrants.

The following table reflects the status of the outstanding warrants from the January 2015, March 2015, and August 2016 private placement financings (including placement agent warrants) following the Amendment Agreement and private placement:

Series	Outstanding Warrants	Exercise Price	Expiration
A	214,433	$ 1.20	01/13/2020
C	424,433	$ 6.00	01/13/2020
D	610,000	$ 9.00	Between 07/16/2020 and 08/13/2020 and 08/19/2020 and 09/09/2020
E	616,100	$ 15.00	Between 10/01/2020 and 11/12/2020 and 11/30/2020 and 12/09/2020
A-1	418,750	$ 1.20	03/09/2020
C-1	2,083	$ 6.00	01/13/2020
D-1	416,667	$ 9.00	Between 08/19/2020 and 09/09/2020
E-1	418,750	$ 15.00	06/16/2020
F	583,333	$ 7.20	08/11/2021
F-1	416,667	$ 7.20	08/11/2021
PIPE Warrants	653,187	$ 6.00	08/11/2021
Broker Warrants	65,327	$ 4.80	08/11/2021

Note 12: stock-based compensation

Options to Purchase Shares of Common Stock

2009 Stock Omnibus 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 8,333 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 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, 3,679 options have been issued under the 2009 Plan, of which 2,013 are outstanding.

2014 Stock Omnibus 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 stockholders, 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 166,667 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 416,667 shares to 583,334 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, 442,500 options have been issued under the 2014 Plan.

Stock Options

A summary of the Company’s stock option activity is as follows for stock options:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Intrinsic Value
Outstanding as of December 31, 2014	5,453	$ 215.26	3.4	$-
Options granted	295,000	6.65	9.8	177,000
Forfeited/expired	(1,774)	-	-	-
Outstanding as of December 31, 2015	298,679	9.22	9.7	177,000
Options granted	147,500	5.84	9.3	-
Exercised	(10,417)	1.74	-	-
Forfeited/expired	(1,667)	228.00	-	-
Outstanding as of December 31, 2016	434,095	$ 7.41	8.9	39,000
Options vested and exercisable	281,209	$ 8.03	8.7	38,000

The Black-Scholes option pricing model is used to estimate the fair value of stock options granted under the Company’s share-based compensation plans. The weighted average average assumptions used in calculating the fair values of stock options that were granted during the years ended December 31, 2016, 2015, respectively, were as follows:

	For the years ended December 31,	
	2016	2015
Exercise price	$ 5.84	$ 6.65
Expected term (years)	9.7	9.1
Expected stock price volatility	237.7 %	230.0 %
Risk-free rate of interest	1.6 %	2.1 %
Expected dividend rate	0 %	0 %

The Company recorded $1,558,409 and $1,705,067 of stock-based compensation expense for the years ended December 31, 2016 and 2015, respectively.

Total stock-based compensation cost related to unvested awards not yet recognized and the weighted average periods over which the awards are expected to be recognized as of December 31, 2016 are as follows:

Unrecognized stock-based compensation cost:	$954,000

Expected weighted average period compensation costs to be recognized (years): 0.84

Note 13: grant income

During the year ended December 31, 2016, the Company received approximately $231,000 of grant awarded to Mayo Foundation from the U.S. Department of Defense for the Phase II Clinical Trial of TPIV 200. The grant paid for the clinical supplies purchased by the Company.

Note 14: ContingencIES AND COMMITMENTs

Employment Agreements

On November 12, 2015, the Company entered into an employment agreement with Dr. Glynn Wilson, the Company's Chief Executive Officer. In connection with Dr. Wilson's appointment, he entered into an employment agreement with the Company. The employment agreement provides that Dr. Wilson's base salary will be $280,000 per year and he is eligible for an annual performance bonus of up to 50% of his base salary. The term of the employment agreement is for two years and will be automatically extended for an additional 12 months unless terminated by Dr. Wilson or the Company.

On July 18, 2016, the Company appointed Dr. John Bonfiglio as the Company's President and Chief Operating Officer. In connection with Dr. Bonfiglio's appointment, he entered into an employment agreement with the Company. The employment agreement provides that Dr. Bonfiglio's base salary will be $260,000 per year and he is eligible for an annual performance bonus of up to 50% of his base salary. The term of the employment agreement is for two years and will be automatically extended for an additional 12 months unless terminated by Dr. Bonfiglio or the Company.

On August 25, 2016, the Company appointed Michael J. Loiacono as the Company's Chief Financial Officer, Chief Accounting Officer, Secretary and Treasurer. In connection with Mr. Loiacono's appointment, he entered into an employment agreement with the Company. The employment agreement provides that Mr. Loiacono's base salary will be $200,000 per year and he is eligible for an annual performance bonus of up to 50% of his base salary. The term of the employment agreement is for two years and will be automatically extended for an additional 12 months unless terminated by Mr. Loiacono or the Company.

Leased facilities

We have multiple month-to-month leases that aggregate approximately $3,000 per month. Our principal business office lease agreement expires in July 2017 and the rent is approximately $3,500 per month.

The minimum rental payments required for 2017 under the operating office leases as of December 31, 2016 was approximately $38,700.

Note 15: LEGAL PROCEEDINGS

From time to time, the Company may be party to ordinary, routine litigation incidental to their business. We know of no material, active or pending legal proceedings against the Company, nor are we involved as a plaintiff in any material proceeding or pending litigation. There are no proceedings in which any of our directors, officers or affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest adverse to our interest.

NOTE 16: INCOME TAXES

The Company has no income tax expense due to operating losses incurred for the years ended December 31, 2016 and 2015. Approximately $380,000 in non-qualified stock options were cancelled during 2016 due to terminations that resulted in a reversal of the deferred tax asset of approximately $140,000. The cancellations did not result in a book

income for December 31, 2016.

The effects of temporary differences that give rise to significant portions of the deferred tax assets as of December 31, 2016 and 2015 are as follows:

	For the years ended December 31,	
	2016	2015
Deferred tax assets:		
Net operating loss carryforward	$10,934,000	$8,359,000
Stock-based compensation	2,066,000	1,897,000
License agreements	490,000	268,000
Research and development	117,000	117,000
Technology licensing fee	185,000	185,000
Valuation allowance	(13,792,000)	(10,826,000)
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, 2016 and 2015. The valuation allowance increased by $3.0 million as of December 31, 2016. 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 $31,000,000 of federal and $11,200,000 of state Net Operating Loss ("NOL"s) 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 2036. The state net operating loss carryforwards, if not utilized, will expire in 2036.

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, 2016 and 2015, the expected tax expense (benefit) based on the U. S. federal statutory rate is reconciled with the actual tax provision (benefit) as follows:

	For the years ended December 31,	
	2016	2015
U. S. federal statutory rate	$(835,000)	$(11,582,000)
State taxes, net of federal benefit	(286,000)	(199,000)
Permanent differences		
- Change in fair value of derivative liabilities	(2,019,000)	9,477,000
- Write off of net operating loss	-	3,591,000
-Other permanent differences	46,000	12,000
Change in valuation allowance	2,966,000	(1,645,000)
Other	128,000	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, 2016 and 2015, 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, 2016 and 2015. 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.

A reconciliation of the Company's effective tax rate to the statutory U.S. federal rate is as follows:

For the years ended

	December 31,	
	2016	2015
U. S. federal statutory rate	(34.0 %)	(34.0 %)
State taxes, net of federal benefit	(11.6 %)	(0.6 %)
Permanent differences		
- Change in fair value of derivative liabilities	(82.2 %)	27.8 %
- Write off of net operating loss	0.0 %	10.5 %
-Other permanent differences	1.9 %	0.0 %
Change in valuation allowance	120.8 %	(4.8 %)
Other	5.2 %	1.0 %
Income tax provision (benefit)	0.0 %	0.0 %

EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
3.1	Articles of Incorporation as Amended	10-Q	001-37939	3.1	11/4/16	
3.2	Certificate of Change	8-K	000-27239	3.1	9/15/16	
3.3	Amended and Restated Bylaws	8-K	000-27239	3.1	7/15/16	
4.1	Securities Purchase Agreement, dated May 17, 2010	8-K	000-27239	10.1	5/18/10	
4.2	Registration Rights Agreement, dated May 24, 2010	8-K	000-27239	10.4	5/18/10	
4.3	Security Agreement, dated May 24, 2010	8-K	000-27239	10.3	5/18/10	
4.4	Form of Senior Secured Convertible Note	8-K	000-27239	10.2	5/18/10	
4.5	Form of Series A Warrants	8-K	000-27239	10.5	5/18/10	
4.6	Form of Series B Warrants	8-K	000-27239	10.6	5/18/10	
4.7	Form of Series C Warrants	8-K	000-27239	10.7	5/18/10	
4.8	Securities Purchase Agreement, dated February 24, 2011	8-K	000-27239	10.1	3/2/11	
4.9	Form of Convertible Note	8-K	000-27239	10.2	3/2/11	
4.10	Security Agreement, dated February 24, 2011	8-K	000-27239	10.3	3/2/11	
4.11	Form of Warrant	8-K	000-27239	10.4	3/2/11	
4.12	Form of Convertible Note in connection with the sale of same on April 12, 2011	10-K	000-27239	4.12	4/18/11	
4.13	Security Agreement dated April 12, 2011	10-K	000-27239	4.13	4/18/11	
4.14	Form of Securities Purchase Agreement in connection with the sale of Units on April 14, 2011	10-K	000-27239	4.14	4/18/11	
4.15	Form of Warrant in connection with Securities Purchase Agreement dated April 14, 2011	10-K	000-27239	4.15	4/18/11	

4.16	Form of Common Stock Purchase Warrant	8-K	000-27239	4.1	8/14/14
4.17	Form of Placement Agent Warrant	8-K	000-27239	4.2	8/14/14
4.18	Form of Common Stock Purchase Warrants-Series A	8-K	000-27239	4.1	1/12/15
4.19	Form of Common Stock Purchase Warrants-Series B	8-K	000-27239	4.2	1/12/15
4.20	Form of Common Stock Purchase Warrants-Series C	8-K	000-27239	4.3	1/12/15
4.21	Form of Common Stock Purchase Warrants-Series D	8-K	000-27239	4.4	1/12/15
4.22	Form of Common Stock Purchase Warrants-Series E	8-K	000-27239	4.5	1/12/15

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
4.23	Form of Placement Agent Common Stock Purchase Warrants-Series A	8-K	000-27239	4.6	1/12/15	
4.24	Form of Placement Agent Common Stock Purchase Warrants-Series B	8-K	000-27239	4.7	1/12/15	
4.25	Form of Placement Agent Common Stock Purchase Warrants-Series C	8-K	000-27239	4.8	1/12/15	
4.26	Form of Placement Agent Common Stock Purchase Warrants-Series D	8-K	000-27239	4.9	1/12/15	
4.27	Form of Placement Agent Common Stock Purchase Warrants-Series E	8-K	000-27239	4.10	1/12/15	
4.28	Form of Common Stock Purchase Warrants-Series A-1	8-K	000-27239	4.1	3/10/15	
4.29	Form of Common Stock Purchase Warrants-Series B-1	8-K	000-27239	4.2	3/10/15	
4.30	Form of Common Stock Purchase Warrants-Series C-1	8-K	000-27239	4.3	3/10/15	
4.31	Form of Common Stock Purchase Warrants-Series D-1	8-K	000-27239	4.4	3/10/15	
4.32	Form of Common Stock Purchase Warrants-Series E-1	8-K	000-27239	4.5	3/10/15	
4.33	Form of Placement Agent Common Stock Purchase Warrants-Series A-1	8-K	000-27239	4.6	3/10/15	
4.34	Form of Placement Agent Common Stock Purchase Warrants-Series B-1	8-K	000-27239	4.7	3/10/15	
4.35	Form of Placement Agent Common Stock Purchase Warrants-Series C-1	8-K	000-27239	4.8	3/10/15	
4.36	Form of Placement Agent Common Stock Purchase Warrants-Series D-1	8-K	000-27239	4.9	3/10/15	
4.37	Form of Placement Agent Common Stock Purchase Warrants-Series E-1	8-K	000-27239	4.10	3/10/15	
4.38	Form of PIPE Warrant	8-K	000-27239	4.1	8/11/16	
4.39	Form of Amended Series A Warrant	8-K	000-27239	4.2	8/11/16	

4.40	Form of Amended Series C Warrant	8-K	000-27239	4.3	8/11/16
4.41	Form of Amended Series D Warrant	8-K	000-27239	4.4	8/11/16
4.42	Form of Amended Series E Warrant	8-K	000-27239	4.5	8/11/16
4.43	Form of Amended Series A-1 Warrant	8-K	000-27239	4.6	8/11/16

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
4.44	Form of Amended Series D-1 Warrant	8-K	000-27239	4.7	8/11/16	
4.45	Form of Amended Series E-1 Warrant	8-K	000-27239	4.8	8/11/16	
4.46	Form of Series F Warrant	8-K	000-27239	4.9	8/11/16	
4.47	Form of Series F-1 Warrant	8-K	000-27239	4.10	8/11/16	
4.48	Form of Katalyst Warrant	8-K	000-27239	4.11	8/11/16	
10.1	Executive Services Agreement with Denis Corin	10-QSB	000-27239	10.1	11/14/07	
10.2	Amended Executive Services Agreement with Denis Corin	10-QSB	000-27239	10.2	11/14/07	
10.3	License Agreement made March 6, 2000 between GeneMax Pharmaceuticals, UBC and Dr. Jefferies	10-KSB	000-27239	10.2	4/15/05	
10.4	Collaborative Research Agreement made September 1, 2000 between GeneMax Pharmaceuticals, GeneMax Pharmaceuticals Inc. and UBC	10-KSB	000-27239	10.3	4/15/05	
10.5	Production Services Agreement made March 18, 2003 between the Company and Molecular Medicine	10-KSB	000-27239	10.5	4/15/05	
10.6	Biological Materials Transfer Agreement made October 21, 2003 between the Company and National Institutes of Health	10-KSB	000-27239	10.6	4/15/05	
10.7	Option and Settlement Agreement made January 23, 2006 between GeneMax Pharmaceuticals, GeneMax Pharmaceuticals Inc., UBC and Dr. Jefferies	8-K	000-27239	10.1	2/3/06	
10.8	2009 Stock Incentive Plan*	DEF14-C	000-27239	B	1/29/10	
10.9	Technology Option Agreement, dated June 1, 2010, between TapImmune Inc. and Mayo Foundation for Education and Research	8-K	000-27239	10.1	6/4/10	
10.10	Form of Securities Purchase Agreement, dated as of August 11, 2014, by and among the Company and the Purchasers	8-K	000-27239	10.1	8/11/14	

10.11	Placement Agency Agreement, dated as of July 29, 2014, by and between the Company and H. C. Wainwright & Co., LLC	8-K	000-27239	10.2	8/14/14
10.12	Form of Securities Purchase Agreement, dated as of January 12, 2015, by and among the Company and the Purchasers	8-K	000-27239	10.1	1/12/15
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	8-K	000-27239	10.2	1/12/15
10.14	Finders Agreement, dated as of January 12, 2015, by and between the Company and Olympus Securities LLC	8-K	000-27239	10.3	1/12/15
10.15	Securities Purchase Agreement, dated as of March 9, 2015, by and among the Company and Eastern Capital Limited	8-K	000-27239	10.1	3/9/15
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	8-K	000-27239	10.2	3/10/15

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
10.17	Form of Restructuring Agreement dated May 28, 2015	8-K	000-27239	10.1	6/3/15	
10.18	Amended and Restated Restructuring Agreement, dated as of June 2, 2015	8-K	000-27239	10.1	6/5/15	
10.19	License and Assignment Agreement, dated July 21, 2015, with The Mayo Foundation for Medical Education and Research**	10-Q	000-27239	10.1	8/14/15	
10.20	License and Assignment Agreement with Mayo Foundation for Medical Education and Research dated May 19, 2016**	10-Q	000-27239	10.1	8/15/15	
10.21	2014 Omnibus Stock Ownership Plan*	10-Q	000-27239	10.1	11/16/15	
10.22	Amendment to 2014 Omnibus Stock Ownership Plan (February 10, 2015) *	10-Q	000-27239	10.2	11/16/15	
10.23	Amendment to 2014 Omnibus Stock Ownership Plan (November 6, 2015) *	10-Q	000-27239	10.3	11/16/15	
10.24	Form of Stock Option Award Agreement – Key Employee*	10-Q	000-27239	10.4	11/16/15	
10.25	Form of Stock Option Award Agreement – Non-employee Director*	10-Q	000-27239	10.5	11/16/15	
10.26	Form of Stock Option Award Agreement – Consultant*	10-Q	000-27239	10.6	11/16/15	
10.27	Form of Restricted Stock Award Agreement – Consultant*	10-Q	000-27239	10.7	11/16/15	
10.28	Consulting Agreement, dated February 10, 2015, between TapImmune Inc. and Dr. John Bonfiglio*	8-K	000-27239	10.1	7/30/15	
10.29	Amendment to Consulting Agreement between TapImmune Inc. and Dr. John Bonfiglio dated as of June 12, 2015*	8-K	000-27239	10.2	2/16/16	
10.30	Second Amendment to the Consulting Agreement by and between TapImmune Inc. and Dr. John Bonfiglio dated as of February 10, 2016*	8-K	000-27239	10.3	2/16/16	
10.31		10-Q	000-27239	10.8	11/16/15	

	Employment Agreement between TapImmune, Inc. and Dr. Glynn Wilson, dated November 12, 2015*					
10.32	Amendment to Employment Agreement between TapImmune Inc. and Glynn Wilson, dated as of July 18, 2016*	8-K	000-27239	10.1	7/19/16	
10.33	Employment Agreement by and between by and between TapImmune Inc. and Dr. John Bonfiglio dated as of July 18, 2016*	8-K	000-27239	10.1	7/19/16	
10.34	Employment Agreement by and between by and between TapImmune Inc. and Michael J. Loiacono dated as of August 25, 2016*	8-K	000-27239	10.1	8/25/16	
14	Code of Ethics	10-Q	000-27239	14	11/16/15	
23.1	Consent of Marcum LLP, an independent public accounting firm.					X
24.1	Powers of Attorney (included on signature page).					X
31.1	Certification of Chief Executive Officer pursuant to Securities Exchange Act of 1934 Rule 13a-14(a) or 15d-14(a).					X

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
31.2	Certification of Chief Financial Officer and Chief Accounting Officer pursuant to Securities Exchange Act of 1934 Rule 13a-14(a) or 15d-14(a).					X
32.1	Certification of Chief Executive Officer pursuant to 18 U. S. C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2	Certification of Chief Financial Officer and Chief Accounting Officer pursuant to 18 U. S. C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document	X				
101.SCH	XBRL Taxonomy Extension Schema Document	X				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X				

*Executive management contract or compensatory plan or arrangement.

** Confidential treatment has been granted as to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended, or Rule 24b-2 of the Securities Exchange Act of 1934, as amended.