Registration No. 333-

#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

#### FORM S-3

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933** 

**TAPIMMUNE INC.** 

(Name of Issuer as Specified in Its Charter)

<u>Nevada</u>

(State or other jurisdiction of incorporation)

<u>2834</u>

(Primary Standard Industrial Classification Code Number)

50 N. Laura Street, Suite 2500

Jacksonville, FL <u>904-516-5436</u>

(Address including zip code, and telephone number, including area code, of registrant's principal executive offices)

Sierra Corporate Services 100 West Liberty Street, 10th Floor Reno, Nevada 89501 (775) 788-2000

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to: Mark A. Catchur Shumaker, Loop & Kendrick, LLP 101 E. Kennedy Blvd., Suite 2800 Tampa, FL 33602 Telephone: 813-229-7600 Fax: 813-229-1660

Approximate date of commencement of proposed sale to the public: from time to time after this registration statement becomes effective as the selling shareholders shall determine.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: 🗆

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  $\Box$ Non-accelerated filer  $\Box$ (Do not check if a smaller reporting company) Accelerated filer  $\Box$ Smaller reporting company x

# CALCULATION OF REGISTRATION FEE

Amount to

Be

Registered

Title of Each Clas	s of Securities to Be
Registered	

Proposed	Proposed
Maximum	Maximum
Offering	Aggregate
Price	Offering
Per	Price (1)

Amount of Registration Fee (1)

<u>45-4497941</u>

(IRS Employer Identification No.)

		Se	curity		
			(1)		
Common Stock	2,371,701	\$	4.75	\$ 11,265,580	\$ 1,305.68
Total:	2,371,701		4.75	 11,265,580	\$ 1,305.68

•.

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457 under the Securities Act of 1933, as amended.

This Registration Statement contains a combined prospectus under Rule 429 promulgated under the Securities Act of 1933 which also relates to (i) the Form S-3 registration statement (File No. 333-196115), initially filed May 20, 2014 and originally declared effective by the SEC on July 23, 2014, as last amended by Post-Effective Amendment No. 2 to the Registration Statement on Form S-1/A (File No. 333-205757), initially filed on June 2, 2016, and declared effective by the SEC on June 10, 2016, and (ii) the Form S-1 registration statement (File No. 333-205757), initially filed July 20, 2015 and originally declared effective by the SEC on August 7, 2015, as last amended by Post-Effective Amendment No. 2 to Form S-1/A, initially filed on June 2, 2016, and declared effective by the SEC on June 10, 2016. Upon effectiveness, this Registration Statement will also act as a post-effective amendment to both of such earlier registration statements.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion—Dated December 22, 2016

### PROSPECTUS



# 7,708,935 Shares of Common Stock

We are registering for resale 2,736,521 shares of our common stock which are currently held by the selling stockholders named herein.

We are registering 4,972,414 shares of our common stock issuable upon the exercise of the following warrants held by the selling shareholders named herein:

<ul> <li>(the "PIPE Warrants"), and</li> <li>65,327 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$4.80</li> </ul>	•	157,233	shares of common stock issuable upon exercise of warrants issued on August 13, 2014,
<ul> <li>418,333 shares of common stock issuable upon exercise of Series C Warrants,</li> <li>610,000 shares of common stock issuable upon exercise of Series D Warrants,</li> <li>416,667 shares of common stock issuable upon exercise of Series E Warrants,</li> <li>610,000 shares of common stock issuable upon exercise of Series E Warrants,</li> <li>416,667 shares of common stock issuable upon exercise of Series E-1 Warrants,</li> <li>583,333 shares of common stock issuable upon exercise of Series F Warrants,</li> <li>416,667 shares of common stock issuable upon exercise of Series F Warrants,</li> <li>653,187 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$6.00 (the "PIPE Warrants"), and</li> <li>65,327 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$4.80</li> </ul>	•	208,333	shares of common stock issuable upon exercise of Series A Warrants,
<ul> <li>610,000 shares of common stock issuable upon exercise of Series D Warrants,</li> <li>416,667 shares of common stock issuable upon exercise of Series D-1 Warrants,</li> <li>610,000 shares of common stock issuable upon exercise of Series E Warrants,</li> <li>416,667 shares of common stock issuable upon exercise of Series E-1 Warrants,</li> <li>583,333 shares of common stock issuable upon exercise of Series F Warrants,</li> <li>416,667 shares of common stock issuable upon exercise of Series F-1 Warrants,</li> <li>653,187 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$6.00 (the "PIPE Warrants"), and</li> <li>65,327 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$4.80</li> </ul>	•	416,667	shares of common stock issuable upon exercise of Series A-1 Warrants,
<ul> <li>416,667 shares of common stock issuable upon exercise of Series D-1 Warrants,</li> <li>610,000 shares of common stock issuable upon exercise of Series E Warrants,</li> <li>416,667 shares of common stock issuable upon exercise of Series E-1 Warrants,</li> <li>583,333 shares of common stock issuable upon exercise of Series F Warrants,</li> <li>416,667 shares of common stock issuable upon exercise of Series F.1 Warrants,</li> <li>653,187 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$6.00 (the "PIPE Warrants"), and</li> <li>65,327 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$4.80</li> </ul>	·	418,333	shares of common stock issuable upon exercise of Series C Warrants,
<ul> <li>610,000 shares of common stock issuable upon exercise of Series E Warrants,</li> <li>416,667 shares of common stock issuable upon exercise of Series E-1 Warrants,</li> <li>583,333 shares of common stock issuable upon exercise of Series F Warrants,</li> <li>416,667 shares of common stock issuable upon exercise of Series F-1 Warrants,</li> <li>653,187 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$6.00 (the "PIPE Warrants"), and</li> <li>65,327 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$4.80</li> </ul>	•	610,000	shares of common stock issuable upon exercise of Series D Warrants,
<ul> <li>416,667 shares of common stock issuable upon exercise of Series E-1 Warrants,</li> <li>583,333 shares of common stock issuable upon exercise of Series F Warrants,</li> <li>416,667 shares of common stock issuable upon exercise of Series F-1 Warrants,</li> <li>653,187 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$6.00 (the "PIPE Warrants"), and</li> <li>65,327 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$4.80</li> </ul>	·	416,667	shares of common stock issuable upon exercise of Series D-1 Warrants,
<ul> <li>583,333 shares of common stock issuable upon exercise of Series F Warrants,</li> <li>416,667 shares of common stock issuable upon exercise of Series F-1 Warrants,</li> <li>653,187 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$6.00 (the "PIPE Warrants"), and</li> <li>65,327 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$4.80</li> </ul>	·	610,000	shares of common stock issuable upon exercise of Series E Warrants,
<ul> <li>416,667 shares of common stock issuable upon exercise of Series F-1 Warrants,</li> <li>653,187 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$6.00 (the "PIPE Warrants"), and</li> <li>65,327 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$4.80</li> </ul>	·	416,667	shares of common stock issuable upon exercise of Series E-1 Warrants,
<ul> <li>653,187 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$6.00 (the "PIPE Warrants"), and</li> <li>65,327 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$4.80</li> </ul>	·	583,333	shares of common stock issuable upon exercise of Series F Warrants,
<ul> <li>(the "PIPE Warrants"), and</li> <li>65,327 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$4.80</li> </ul>	•	416,667	shares of common stock issuable upon exercise of Series F-1 Warrants,
• 65,327 shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$4.80	·	653,187	shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$6.00
			(the "PIPE Warrants"), and
	·	65,327	shares of common stock issuable upon exercise of five-year warrants to purchase one share of our common stock for \$4.80
(the "Broker PIPE Warrants"),			(the "Broker PIPE Warrants"),

in order for the holders of such warrants to exercise the warrants, in their discretion, as well as for the resale of such shares of common stock by the selling stockholders.

Our outstanding warrants issued in August 2014 have an exercise price equal to \$14.04 per share, subject to adjustments.

Our outstanding Series A and Series A-1 Warrants have an exercise price equal to \$1.20 per share, subject to adjustments.

Our outstanding Series C have an exercise price equal to \$6.00 per share, subject to adjustments.

Our outstanding Series D and Series D-1 Warrants have an exercise price equal to \$9.00 per share, subject to adjustments.

Our outstanding Series E and Series E-1 Warrants have an exercise price equal to \$15.00 per share, subject to adjustments.

Our outstanding Series F and Series F-1 Warrants have an exercise price equal to \$7.20 per share, subject to adjustments.

Our outstanding PIPE Warrants and Broker PIPE Warrants have an initial exercise price equal to \$6.00 and \$4.80, respectively, subject to adjustments.

The terms of the Series A, Series D and Series E Warrants provide that in no event shall shares of common stock be issued to any holder of those Warrants to the extent such issuances of shares of common stock would result in such holder having ownership in excess of 4.9% of our outstanding shares of common stock. The terms of the Warrants issued in August 2014, Series C and Series F Warrants provide that in no event shall shares of common stock be issued to any holder of those Warrants to the extent such issuances of shares of common stock would result in such holder having ownership in excess of 9.9% of our outstanding shares of 5.9% of our outstanding shares of common stock. The terms of the Series A-1, Series D-1, Series E-1 and Series F-1 Warrants provide that in no event shall shares of common stock be issued to any holder of those Warrants to the extent such issuances of shares of shares of common stock would result in such holder having ownership in excess of 49.9% of our outstanding shares of common stock.

The prices at which the selling stockholders may sell the shares of common stock underlying the securities held by them will be determined by the prevailing market price for the shares or in negotiated transactions. We provide more information on how the selling stockholders may resell their respective shares of our common stock in the Section titled "Plan of Distribution" beginning on page 24. We are not selling any securities under this prospectus and we will not receive proceeds from the sale of the shares by the selling stockholders, except pursuant to the exercise of the Warrants.

We are obligated to pay the expenses of registering these shares, but all selling and other expenses incurred by the selling stockholders will be paid by the selling stockholder.

Our common stock is quoted on the Nasdaq Capital Market under the symbol "TPIV." On December 15, 2016, the last reported sale price of our common stock on the Nasdaq Capital Market was \$5.07 per share, and we had 8,395,768 shares of common stock outstanding.

This prospectus provides a general description of the securities being offered. You should carefully read this prospectus and the registration statement of which it forms a part carefully before you invest in any securities.

Investing in our securities involves risks. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page 7.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is \_\_\_\_\_\_, 2016.

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# ABOUT THIS PROSPECTUS

In this prospectus, 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.

You should rely only on the information we have provided or incorporated by reference into this prospectus, any applicable prospectus supplement and any related free writing prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus supplement or any related free writing prospectus supplement or any related free writing prospectus. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

The Selling Stockholders are offering the common stock only in jurisdictions where such issuances are permitted. The distribution of this prospectus and the issuance of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the issuance of the common stock and the distribution of this prospectus outside the United States. This prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, the common stock offered by this prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, under which the Selling Stockholders may offer from time to time up to an aggregate of 7,708,935 shares of our common stock in one or more offerings. If required, each time a Selling Stockholder offers common stock, in addition to this prospectus, we will provide you with a prospectus supplement that will contain specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to that offering. We may also use a prospectus supplement and any related free writing prospectus to add, update or change any of the information contained in this prospectus or in documents we have incorporated by reference. This prospectus, together with any applicable prospectus supplements, any related free writing prospectus and the documents incorporated by reference into this prospectus, includes all material information relating to this offering. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus and any prospectus supplement together with additional information described below under "Where You Can Find More Information" and "Incorporation of Certain Information by Reference".

# 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 prospectus have been adjusted to reflect the reverse stock splits.

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# FORWARD-LOOKING STATEMENTS

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



# PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all the information that you should consider before investing in the common stock. You should carefully read the entire prospectus. In particular, attention should be directed to our "Risk Factors," "Information with Respect to the Company," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes thereto contained herein before making an investment decision.

### **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 TPIV 100/110 HER2/neu+ Breast Cancer Vaccine	<b>Description</b> Peptide Vaccine	Application Treatment of HER2/neu+ Breast Cancer	Status 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.

### 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. 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. 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. We anticipate this Phase II study of TPIV 200 in the treatment of triple-negative breast cancer will begin to enroll patients in the fourth quarter of 2016 or 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 multiepitope 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 are planning to initiate a Phase II study in this indication by the end of 2016 in at least one clinical site. The remainder will follow in 2017.

We have opened nine clinical sites, which will grow to 12, 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 plans to participate in an ovarian cancer study sponsored by Memorial Sloan Kettering Cancer Center in New York City in collaboration with AstraZeneca Pharmaceuticals. This study, a Phase II study of TPIV 200 in ovarian cancer patients who are not responsive to platinum, a commonly used chemotherapy for ovarian cancer, 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. We recently received approval for our first patent on Polystart. Additional patent filings are anticipated.

# **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.

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

#### Mayo HER2/neu License

On April 13, 2012, we entered into a Patent & Know-How Agreement with the Mayo Foundation 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 19, 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.

#### 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.

# **Corporate Information**

Our principal executive offices are located at 50 North Laura Street, Jacksonville, Florida 32202 and our telephone number is 904-516-5436.

Common stock outstanding:	8,395,768 shares as of December 15, 2016
Common stock offered by selling stockholders:	7,708,935 shares
Common stock outstanding after the offering:	13,368,182 shares (1)
Use of Proceeds:	We will not receive any proceeds from the sale of the common stock by the selling stockholders. We may receive proceeds if the following warrants are exercised:
	<ul> <li>\$2,207,551 if the outstanding warrants issued in August 2014 are exercised,</li> <li>\$250,000 if the outstanding Series A Warrants are exercised,</li> <li>\$500,000 if the outstanding Series A-1 Warrants are exercised,</li> <li>\$2,509,998 if the outstanding Series C Warrants are exercised,</li> <li>\$5,490,000 if the outstanding Series D Warrants are exercised,</li> <li>\$3,750,003 if the outstanding Series D-1 Warrants are exercised,</li> <li>\$9,150,000 if the outstanding Series E Warrants are exercised,</li> <li>\$6,250,005 if the outstanding Series E-1 Warrants are exercised,</li> <li>\$6,250,005 if the outstanding Series F Warrants are exercised,</li> <li>\$4,199,998 if the outstanding Series F-1 Warrants are exercised,</li> <li>\$3,000,002 if the outstanding Series F-1 Warrants are exercised,</li> <li>\$3,919,122 if the outstanding PIPE Warrants are exercised, and</li> <li>\$313,570 if the outstanding Broker PIPE Warrants are exercised,</li> <li>(to the extent the registration statement of which this prospectus is a part is then effective and, if applicable, the "cashless exercise" provision is not utilized by the holder). Any proceeds will be used for general corporate and working capital or for other purposes that the Board of Directors, in their good faith, deems to be in the best interest of the Company. No assurances can be given that any of such warrants will be exercised. See "Use of Proceeds."</li> </ul>
Listing of common stock:	Our common stock is listed on the Nasdaq Capital Market under the symbol "TPIV."
Dividend policy:	We currently intend to retain any future earnings to fund the development and growth of our business. Therefore, we do not currently anticipate paying cash dividends on our common stock.
Risk factors:	An investment in our company is highly speculative and involves a significant degree of risk. See "Risk Factors" and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

(1) Assumes the exercise of all of the outstanding warrants issued in August 2014 and all of the outstanding Series A Warrants, Series A-1 Warrants, Series C Warrants, Series D Warrants, Series D-1 Warrants, Series E Warrants, Series E-1 Warrants, Series F Warrants, Series F-1 Warrants, PIPE Warrants and Broker PIPE Warrants, for which the underlying shares of common stock are registered herein, and that we do not issue any other shares of common stock.

#### **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 Prospectus 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 Prospectus 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 September 30, 2016, we had cash of approximately \$9,587,000. We anticipate that our cash resources will 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 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, 2015 contains an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may be necessary in the event we are unable to continue as a going concern. The Company believes its current capital resources are sufficient to support its operations through the end of 2017. Management intends to continue its research efforts and to finance operations of the Company 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 the Company will be successful in obtaining additional financing on favorable terms, or at all. These matters raise substantial doubt about the Company's 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 September 30, 2016, we had an accumulated deficit of \$144,238,988 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 posteffective 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 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 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.

# 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 9, 2016, we had seven 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 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 and our President and Chief Operating Officer Dr. John Bonfiglio, as well as the services of several key consultants, including Dr. Robert Florkiewicz. The loss or unavailability of the services of either of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

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

### **Risks Related to our Industry**

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

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed immunotherapies could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies, 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 do not have product liability insurance because we are not yet selling our products. We intend to maintain product liability insurance consistent with industry standards upon commencement of the marketing and distribution. 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.

#### **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.

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 brokerdealers 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 15, 2016, we had 8,395,768 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 15, 2016, we had outstanding warrants and options to purchase an aggregate of 5,503,788 shares of our common stock with exercise prices ranging between \$1.20 and \$240.00 per share will result in dilution if and when exercised. See "Description of Securities" on page 26. Fear of such ownership dilution could reduce the desirability of our shares and reduce the price at which you are able to resell your shares.

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



Certain of our outstanding warrants contain or 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 September 30, 2016, the fair value of the derivative liability – warrants was \$29,000. Changes in the valuations of these rights, the valuation methodology or the assumptions on which the valuations are based could cause us to take charges to our earnings, which would adversely impact our results of operations. Moreover, the methodologies, assumptions and related interpretations of accounting or regulatory authorities associated with these embedded derivatives are complex and in some cases uncertain, which could cause our accounting for these derivatives, and as a result, our financial results, to fluctuate.

#### 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. See "Description of Securities" on page 26. 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.

#### **USE OF PROCEEDS**

We will not receive any proceeds from the sale of shares by the selling stockholders. We may receive proceeds of up to \$41,540,249 if all of the outstanding warrants issued in August 2014 and all outstanding Series A Warrants, Series A-1 Warrants, Series C Warrants, Series D Warrants, Series D-1 Warrants, Series E Warrants, Series E-1 Warrants, Series F Warrants, Series F-1 Warrants, PIPE Warrants and Broker PIPE Warrants, for which the underlying shares of common stock are registered herein, are exercised (to the extent the registration statement of which this prospectus is a part is then effective and, if applicable, the "cashless exercise" provision is not utilized by the holder). Any net proceeds we receive will be used for general corporate and working capital or other purposes that our Board of Directors deems to be in our best interest. As of the date of this prospectus, we cannot specify with certainty the particular uses for the net proceeds we may receive. Accordingly, we will retain broad discretion over the use of these proceeds, if any.

#### DETERMINATION OF OFFERING PRICE

The selling stockholders will offer common stock at the prevailing market prices or privately negotiated prices. The offering price of our common stock does not necessarily bear any relationship to our book value, assets, past operating results, financial condition or any other established criteria of value. Our common stock may not trade at market prices in excess of the offering price as prices for common stock in any public market will be determined in the marketplace and may be influenced by many factors, including the depth and liquidity.

#### SELLING STOCKHOLDERS

The shares of common stock being offered by the selling stockholders include those issuable to the selling stockholders upon the exercise of warrants as described in this prospectus. Upon the effectiveness of the registration statement of which this prospectus forms a part, the selling stockholders may offer the shares underlying those warrants for resale from time to time. Except as otherwise set out in this prospectus, the selling stockholders have not had any material relationship with us within the past three years.

The table below lists the selling stockholders and other information regarding the ownership of shares of common stock by each of the selling stockholders. The second column lists the number of shares of common stock owned by the selling stockholders as of December 15, 2016, assuming exercise of the warrants held by each such selling stockholder on that date and not taking account of any limitations on conversion and exercise set forth therein.

The third column lists the shares of common stock being offered by this Prospectus by the selling stockholders and does not take in account any limitations on exercise of the warrants set forth therein.



The fourth column assumes the sale of all of the shares offered by the selling stockholders pursuant to this Prospectus, but not the sale of any other shares held by the selling stockholders.

The terms of the Series A, Series D and Series E warrants provide that in no event shall shares of common stock be issued to any holder of those warrants to the extent such issuances of shares of common stock would result in such holder having ownership in excess of 4.9% of our outstanding shares of common stock. The terms of the warrants issued in August 2014, Series C and Series F warrants provide that in no event shall shares of common stock be issued to any holder of those warrants to the extent such issuances of shares of common stock would result in such holder having ownership in excess of 9.9% of our outstanding shares of common stock. The terms of the Series A-1, Series D-1, Series E-1 and Series F-1 warrants provide that in no event shall shares of common stock be issued to any holder of those warrants to the extent such issuances of shares of shares of common stock would result in such holder having ownership in excess of 9.9% of our outstanding shares of common stock be issued to any holder of those warrants to the extent such issuances of shares of common stock would result in such holder having ownership in excess of 9.9% of our outstanding shares of common stock be issued to any holder of those warrants to the extent such issuances of shares of common stock would result in such holder having ownership in excess of 49.9% of our outstanding shares of common stock. The number of shares in the second column and the third column do not reflect these limitations. The selling stockholders may sell all, some or none of their shares in this offering. See "Plan of Distribution".

Empery Asset Master, LTD (3)         209,560         178,665         110,895         1.29%           Empery Tax Efficient, LP (4)         69,239         42,722         26,517         *           Empery Tax Efficient, LP (5)         581,201         338,614         222,287         2.54%           Iroquois Master Fund Ltd. (6)         702,500         520,833         181,667         2.04%           American Capital Management LLC (7)         421,500         112,500         104,166         36,334         *           The Samantha Abbe Irrevocable Trust (8)         140,500         104,166         36,334         *           The Taila Abbe Irrevocable Trust (10)         46,832         34,720         12,112         *           The Bennet Abe Irrevocable Trust (11)         46,832         34,720         12,112         *           Brio Capital Linited (13)         4,000,000         3,750,000         250,000         2.48%           OTA, LLC (14)         157,233         0         0%         64           Kola Agbaje         111         111         0         0%           Barclay Armitage         3,334         3,334         0         0%           Aller Chase Foundation-Special Investment Account         4,168         4,168         0	Name of Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Prior to Offering	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus (1)	Number of Shares of Common Stock Beneficially Owned After Offering (2)	Percentage of Shares of Common Stock Beneficially Owned After the Offering (1) (2)
Empery Tax Efficient, LP (4)         69,239         42,722         26,517         *           Empery Tax Efficient II, LP (5)         581,201         358,614         222,587         2.54%           Iroquois Master Fund Lt. (6)         702,500         520,833         181,667         2.04%           American Capital Management LLC (7)         421,500         312,500         109,000         1.25%           The Mark Abbe Irrevocable Trust (8)         140,500         104,166         36,334         *           The Samantha Abbe Irrevocable Trust (10)         46,832         34,720         12,112         *           The Bennett Abbe Irrevocable Trust (11)         46,832         34,720         12,112         *           Brio Capital Master Fund, Ltd. (12)         1,177,576         808,337         369,239         4,01%           Cral A Armitage         1,117,576         808,337         369,239         4,01%           OTA, LLC (14)         157,233         0         0%         0%           Allen Chase Foundation-Special Investment Account         4,168         4,168         0         0%           Allen Chase Foundation-Special Investment Account         4,168         4,168         0         0%           Allen Chase Foundation-Special Investment Account         1	Empery Asset Master, LTD (3)	289.560		110.895	
Empery Tax Efficient II, LP (5)         581,201         358,614         222,587         2.54%           Iroquois Master Fund Ltd. (6)         702,500         520,833         181,667         2.04%           American Capital Mangement LLC (7)         421,500         1102,500         122,807         128,907           The Merav Abbe Irrevocable Trust (8)         140,500         104,166         36,334         *           The Samantha Abbe Irrevocable Trust (9)         46,832         34,720         12,112         *           The Bament Abbe Irrevocable Trust (10)         46,832         34,720         12,112         *           Brio Capital Limited (13)         4,000,00         3,750,000         220,000         2.48%           OTA, LLC (14)         157,233         157,233         0         0%           Kola Agbaje         1111         111         0         0%           Allen Chase Foundation-Special Investment Account         4,168         4,168         0         0%           Allen Chase Foundation-Special Investment Account         12,500         12,500         0         0%           Andrew Brenner         12,500         12,500         0         0%         0%           OStard Cardone         1,223         1,223         0					*
Iroquois Master Fund Ltd. (6)         702,500         520,833         181,667         2.04%           American Capital Management LLC (7)         421,500         312,500         109,000         1.25%           The Marav Abbe Irrevocable Trust (8)         140,500         104,166         363,334         *           The Samantha Abbe Irrevocable Trust (10)         46,832         34,720         12,112         *           The Bennett Abbe Irrevocable Trust (11)         46,832         34,720         12,112         *           Brio Capital Master Fund, Ltd. (12)         1,177,576         808,337         369,239         4.01%           Eastern Capital Limited (13)         4,000,000         3,750,000         250,000         2.48%           OTA, LLC (14)         157,233         157,233         0         0%           Barclay Armitage         3,334         3,334         0         0%           Altexander Arrow         10,418         10,418         0         0%           Wayne K Baldwin         12,500         12,500         0         0%           Andrew Brenner         12,500         12,500         0         0%           Scott Cardone         12,230         12,230         0         0%           Othayat Family Gr					2.54%
American Capital Management LLC (7)         421,500         312,500         109,000         1.25%           The Merav Abbe Irrevocable Trust (8)         140,500         104,166         36,334         *           The Samantha Abbe Irrevocable Trust (10)         46,832         34,720         12,112         *           The Bennett Abbe Irrevocable Trust (11)         46,832         34,720         12,112         *           Brio Capital Master Fund, Ltd. (12)         1,177,576         808,337         369,239         4.01%           Eastern Capital Limited (13)         4,000,000         3,750,000         250,000         2.48%           OTA, LLC (14)         157,233         157,233         0         0%           Barclay Armitage         3,334         3,334         0         0%           Allen Chase Foundation-Special Investment Account         4,168         4,168         0         0%           Allen Chase Foundation-Special Investment Account         10,418         10,418         0         0%           Andrew Brenner         12,500         12,500         0         0%         0%           Cott Cardone         1,223         1,223         0         0%         0%         0%         0%         0%         0%         0% <td< td=""><td></td><td></td><td></td><td></td><td></td></td<>					
The Merav Abbe Irrevocable Trust (8)         140,500         104,166         36,334         *           The Samantha Abbe Irrevocable Trust (9)         46,832         34,724         12,110         *           The Talia Abbe Irrevocable Trust (10)         46,832         34,720         12,112         *           The Bennett Abbe Irrevocable Trust (11)         46,832         34,720         12,112         *           Brio Capital Master Fund, Ltd. (12)         1,177,576         808,337         369,239         4.01%           Eastern Capital Limited (13)         4,000,000         3,750,000         250,000         2.48%           OTA, LLC (14)         157,233         157,233         0         0%           Barclay Armitage         3,334         3,334         0         0%           Allen Chase Foundation-Special Investment Account         4,168         4,168         0         0%           Alexander Arrow         10,418         10,418         0         0%         0%         0%         0%           Scott Cardone         12,250         12,250         0         0%         0%         0%         0%         0%         0%         0%         0%         0%         0%         0%         0%         0%         0%			,		1.25%
The Samantha Abbe Irrevocable Trust (9)       46,834       34,724       12,110       *         The Talia Abbe Irrevocable Trust (10)       46,832       34,720       12,112       *         The Bennett Abbe Irrevocable Trust (11)       46,832       34,720       12,112       *         Brio Capital Master Fund, Ltd. (12)       1,177,576       808,337       369,239       4,01%         Eastern Capital Limited (13)       4,000,000       3,750,000       250,000       2.48%         OTA, LLC (14)       157,233       157,233       0       0%         Barclay Armitage       3,334       3,334       0       0%         Allen Chase Foundation-Special Investment Account       4,168       4,168       0       0%         Andrew Brenner       12,500       12,500       0       0%         Scott Cardone       1,223       1,223       0       0%         Chitayat Family Gift Trust       20,834       20,834       0       0%         Lee Harrison Corbin       20,834       20,834       0       0%         John A. & Wendy M. Cotter       10,418       10,418       0       0%         Christopher Cozzolino       7,759       7,759       0       0%         David M. Ri					
The Talia Abbe Irrevocable Trust (10)       46,832       34,720       12,112       *         The Bennett Abbe Irrevocable Trust (11)       46,832       34,720       12,112       *         Brio Capital Master Fund, Ltd. (12)       1,177,576       808,337       369,239       4.01%         Eastern Capital Limited (13)       4,000,000       3,750,000       2250,000       2.48%         OTA, LLC (14)       157,233       157,233       0       0%         Barclay Armitage       3,334       3,334       0       0%         Barclay Armitage       3,334       3,334       0       0%         Allen Chase Foundation-Special Investment Account       4,168       4,168       0       0%         Alexander Arrow       10,418       10,418       0       0%         Wayne K Baldwin       12,500       12,500       0       0%         Scott Cardone       1,223       1,223       0       0%         Chitayat Family Gift Trust       20,834       20,834       0       0%         Lee Harrison Corbin       20,834       20,834       0       0%         John A. & Wendy M. Cotter       10,418       10,418       0       0%         David M. Rickey Trust dtd 5/8/02					*
The Bennett Abbe Irrevocable Trust (11) $46,832$ $34,720$ $12,112$ *Brio Capital Master Fund, Ltd. (12) $1,177,576$ $808,337$ $369,239$ $4.01\%$ Eastern Capital Limited (13) $4,000,000$ $3,750,000$ $250,000$ $2.48\%$ OTA, LLC (14) $157,233$ $157,233$ $0$ $0\%$ Barclay Armitage $3.334$ $3.334$ $0$ $0\%$ Barclay Armitage $3.334$ $3.334$ $0$ $0\%$ Allen Chase Foundation-Special Investment Account $4,168$ $4,168$ $0$ $0\%$ Alexander Arrow $10,418$ $10,418$ $0$ $0\%$ Mayne K Baldwin $12,500$ $12,500$ $0$ $0\%$ Andrew Brenner $12,500$ $12,500$ $0$ $0\%$ Scott Cardone $1,223$ $1,223$ $0$ $0\%$ O. Stuart Chase $4,168$ $4,168$ $0$ $0\%$ Chitayat Family Gift Trust $20,834$ $20,834$ $0$ $0\%$ Lee Harrison Corbin $20,834$ $20,834$ $0$ $0\%$ John A. & Wendy M. Cotter $10,418$ $10,418$ $0$ $0\%$ Christopher Cozzolino $7,759$ $7,759$ $0$ $0\%$ David M. Rickey Trust dtd $5/8/02$ $10,418$ $10,418$ $0$ $0\%$ Ernest Dronenburg $16,668$ $16,668$ $0$ $0\%$ Ernest Dronenburg $16,71$ $167$ $0$ $0\%$ Ernest N. Moody Revocable Trust $208,334$ $208,334$ $0$ $0\%$					*
Brio Capital Master Fund, Ltd. (12)       1,177,576       808,337       369,239       4.01%         Eastern Capital Limited (13)       4,000,000       3,750,000       250,000       2.48%         OTA, LLC (14)       157,233       157,233       0       0%         Kola Agbaje       111       111       0       0%         Barclay Armitage       3,334       0       0%         Allen Chase Foundation-Special Investment Account       4,168       4,168       0       0%         Allen Chase Foundation-Special Investment Account       4,168       4,168       0       0%         Allen Chase Foundation-Special Investment Account       10,418       10,418       0       0%         Andrew Brenner       12,500       12,500       0       0%         Scott Cardone       1,223       1,223       0       0%         O. Stuart Chase       4,168       4,168       0       0%         Chitayat Family Gift Trust       20,834       20,834       0       0%         John A. & Wendy M. Cotter       10,418       10,418       0       0%         Christopher Cozzolino       7,759       7,759       0       0%         David M. Rickey Trust dtd 5/8/02       10,418					*
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Christopher Cozolino7,7597,75900%David M. Rickey Trust dtd 5/8/0210,41810,41800%Ernest Dronenburg16,66816,66800%EFD Capital Inc.2,3172,31700%Paul Ehrenstein16716700%Equity Investments L.P.104,168104,16800%Ernest W. Moody Revocable Trust208,334208,33400%	Lee Harrison Corbin	20,834	20,834	0	0%
David M. Rickey Trust dtd 5/8/02       10,418       10,418       0       0%         Ernest Dronenburg       16,668       16,668       0       0%         EFD Capital Inc.       2,317       2,317       0       0%         Paul Ehrenstein       167       167       0       0%         Equity Investments L.P.       104,168       104,168       0       0%         Ernest W. Moody Revocable Trust       208,334       208,334       0       0%	John A. & Wendy M. Cotter	10,418	10,418	0	0%
Ernest Dronenburg16,66816,66800%EFD Capital Inc.2,3172,31700%Paul Ehrenstein16716700%Equity Investments L.P.104,168104,16800%Ernest W. Moody Revocable Trust208,334208,33400%	Christopher Cozzolino	7,759	7,759	0	0%
EFD Capital Inc.2,3172,31700%Paul Ehrenstein16716700%Equity Investments L.P.104,168104,16800%Ernest W. Moody Revocable Trust208,334208,33400%	David M. Rickey Trust dtd 5/8/02	10,418	10,418	0	0%
Paul Ehrenstein         167         167         0         0%           Equity Investments L.P.         104,168         104,168         0         0%           Ernest W. Moody Revocable Trust         208,334         208,334         0         0%	Ernest Dronenburg	16,668	16,668	0	0%
Equity Investments L.P.         104,168         104,168         0         0%           Ernest W. Moody Revocable Trust         208,334         208,334         0         0%	EFD Capital Inc.	2,317	2,317	0	0%
Ernest W. Moody Revocable Trust         208,334         208,334         0         0%	Paul Ehrenstein		167	0	0%
	Equity Investments L.P.	104,168	104,168	0	0%
Philip W. Faucette, II         10,418         10,418         0         0%		208,334	208,334	0	
	Philip W. Faucette, II	10,418	10,418	0	0%

CommonStock to beCommonStockStockSoldStockBeneficiallyBeneficiallyPursuant toBeneficiallyOwnedOwnedthisOwnedAfter thePrior toProspectusAfterOfferingName of Selling StockholderOffering(1)Offering (2)(1) (2)	
FirstFire Global Opportunities Fund LLC52,08452,0840	0%
Albert & Hiedi Gentile         8,334         8,334         0	0%
Gibralt Capital Corporation 125,000 125,000 0	0%
Bruce D. & Laura K. Goethe 16,668 0	0%
Kimberly Hanley 159 0	0%
Todd Harrigan 1,223 1,223 0	0%
Timothy Herrmann 1,223 1,223 0	0%
Daniel W. and Allaire Hummel, JTWROS 4,168 4,168 0	0%
Morgan Janssen 3,438 0	0%
Peter K. Janssen 18,210 0	0%
Mackie Klingbeil 10,418 0	0%
Peter M. Knapp 6,250 6,250 0	0%
Ryan Konik 256 256 0	0%
David Landskowsky 5,658 0	0%
Brian K. Langham 10,418 0	0%
Clay Lebhar 10,418 0	0%
Roman Livson 365 365 0	0%
Veronica Marano & Thomas M. Volckening 20,906 20,906 0	0%
Ernest J. & Michele M. Mattei 10,418 0	0%
Samantha McGrandy 104 104 0	0%
Thomas McGurk 4,310 4,310 0	0%
Stephen R. Mut 41,668 41,668 0	0%
Northlea Partners LLLP 6,250 6,250 0	0%
Nybor Group Inc. 4,168 4,168 0	0%
OS Media SEZC Ltd. 25,000 0	0%
Osprey I LLC 20,834 20,834 0	0%
Kenneth S. Pizzo, Jr. 208,334 0	0%
Joel Pruzansky 10,418 0	0%
Stephen Renaud 9,410 9,410 0	0%
Dyke Rogers 63,834 63,834 0	0%
Eric Rubenstein 5,658 5,658 0	0%
Art Sadin 10,418 0	0%
Joseph Schump 41,668 41,668 0	0%
Aaron Segal 1,223 1,223 0	0%
Stephen Shumpert         41,668         41,668         0	0%
Michael Silverman 27,548 27,548 0	0%
Clayton Struve         33,334         33,334         0	0%
The Steve and Kaye Yost Family Trust dtd 2.7.929,5769,5760	0%
John Wagner 20,834 20,834 0	0%
WestPark Capital Inc. 111 111 0	0%
Jacob D. Wiznitzer 10,418 10,418 0	0%

Name of Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Prior to Offering	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus (1)	Number of Shares of Common Stock Beneficially Owned After Offering (2)	Percentage of Shares of Common Stock Beneficially Owned After the Offering (1) (2)
Bobby Kato Jr.	5,210	5,210	0	0%
Michael Zimmerman	3,334	3,334	0	0%

# Less than 1%.

(1) Includes shares of common stock underlying warrants held by the Selling Stockholder that are covered by this Prospectus, including warrants that, due to contractual restrictions, may not be exercisable if such exercise would result in beneficial ownership greater than 4.9%, 9.9% and 49.9% of our outstanding common stock, as applicable. As these ownership amounts are not calculated according to Rule 13d-3 under the Securities Exchange Act of 1934, as amended, they differ from the amounts shown in the section of this Prospectus entitled "Beneficial Ownership of Principal Stockholders, Officers and Directors".

(2) Based on 13,368,182 shares of common stock, which includes 8,395,768 shares of common stock issued and outstanding on December 15, 2016 and 4,972,414 shares of common stock being offered in this Prospectus that may be issued upon exercise of the warrants. In determining this amount, we assumed that (i) all 4,972,414 shares of common stock being offered in this Prospectus that may be issued upon exercise of the warrants will be sold and (ii) we issue no other shares of common stock. If these assumptions are incorrect, the number of shares and percentages included in this column will differ from what we have provided.

(3) Empery Asset Management LP, the authorized agent of Empery Asset Master Ltd ("EAM"), has discretionary authority to vote and dispose of the shares held by EAM and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by EAM. EAM, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.

The shares listed under "Number of Shares of Common Stock Owned Prior to Offering" and "Shares of Common Stock to be Sold Pursuant to this Prospectus" include 335,898 shares issuable upon the exercise of the warrants set forth below that are held by the stockholder. This amount does not (i) give effect to limitations on ownership set out in any of the warrants that may be exercised into such shares or (ii) include any shares that may be beneficially owned by an affiliate. The warrants referred to in the immediately preceding paragraph are comprised of (i) 59,555 shares of common stock issuable upon exercise of the Series D Warrants, (ii) 59,555 shares of common stock issuable upon exercise of the Series E Warrants and (iii) 59,555 shares of common stock issuable upon stock issuable upon exercise of the Series F Warrants.

(4) Empery Asset Management LP, the authorized agent of Empery Tax Efficient, LP ("ETE"), has discretionary authority to vote and dispose of the shares held by ETE and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE. ETE, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.

The shares listed under "Number of Shares of Common Stock Owned Prior to Offering" and "Shares of Common Stock to be Sold Pursuant to this Prospectus" include 42,722 shares issuable upon the exercise of the warrants set forth below that are held by the stockholder. This amount does not (i) give effect to limitations on ownership set out in any of the warrants that may be exercised into such shares or (ii) include any shares that may be beneficially owned by an affiliate.

The warrants referred to in the immediately preceding paragraph are comprised of (i) 14,241 shares of common stock issuable upon exercise D Warrants, (ii) 14,241 shares of common stock issuable upon exercise of the Series E Warrants and (iii) 14,241 shares of common stock issuable upon exercise of the Series F Warrants.

(5) Empery Asset Management LP, the authorized agent of Empery Tax Efficient, LP ("ETE II"), has discretionary authority to vote and dispose of the shares held by ETE II and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE II. ETE II, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.

The shares listed under "Number of Shares of Common Stock Owned Prior to Offering" and "Shares of Common Stock to be Sold Pursuant to this Prospectus" include 358,614 shares issuable upon the exercise of the warrants set forth below that are held by the stockholder. This amount does not (i) give effect to limitations on ownership set out in any of the warrants that may be exercised into such shares or (ii) include any shares that may be beneficially owned by an affiliate.

The warrants referred to in the immediately preceding paragraph are comprised of (i) 119,538 shares of common stock issuable upon exercise D Warrants, (ii) 119,538 shares of common stock issuable upon exercise of the Series E Warrants and (iii) 119,538 shares of common stock issuable upon exercise of the Series F Warrants.

(6) Iroquois Capital Management L.L.C. ("Iroquois Capital") is the investment manager of Iroquois Master Fund Ltd. ("Iroquois Master Fund") and consequently has voting control and investment discretion over securities held by Iroquois Master Fund. Each of Joshua Silverman and Richard Abbe may be deemed to have voting control and investment discretion over securities held by Iroquois Master Fund. As a result of the foregoing, each of Iroquois Capital, Mr. Silverman and Mr. Abbe may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended) of the securities being registered hereunder.

The shares listed under "Number of Shares of Common Stock Owned Prior to Offering" and "Shares of Common Stock to be Sold Pursuant to this Prospectus" include 520,833 shares issuable upon the exercise of the warrants set forth below that are held by the stockholder. This amount does not (i) give effect to limitations on ownership set out in any of the warrants that may be exercised into such shares or (ii) include any shares that may be beneficially owned by an affiliate.

The warrants referred to in the immediately preceding paragraph are comprised of (i) 104,167 shares of common stock issuable upon exercise of the Series A Warrants, (ii) 110,000 shares of common stock issuable upon exercise of the Series C Warrants, (iii) 104,167 shares of common stock issuable upon exercise of the Series D Warrants, (iv) 104,167 shares of common stock issuable upon exercise of the Series E Warrants and (v) 98,334 shares of common stock issuable upon exercise of the Series F Warrants.

(7) Kimberly Page has the authority and responsibility for the investments made on behalf of American Capital Management LLC ("ACM") and accordingly, has voting and dispositive power over the securities held by ACM.

The shares listed under "Number of Shares of Common Stock Owned Prior to Offering" and "Shares of Common Stock to be Sold Pursuant to this Prospectus" include 312,500 shares issuable upon the exercise of the warrants set forth below that are held by the stockholder. This amount does not (i) give effect to limitations on ownership set out in any of the warrants that may be exercised into such shares or (ii) include any shares that may be beneficially owned by an affiliate.

The warrants referred to in the immediately preceding paragraph are comprised of (i) 62,500 shares of common stock issuable upon exercise of the Series A Warrants, (ii) 66,000 shares of common stock issuable upon exercise of the Series C Warrants, (iii) 62,500 shares of common stock issuable upon exercise of the Series D Warrants, (iii) 62,500 shares of common stock issuable upon exercise of the Series E Warrants and (iv) 59,000 shares of common stock issuable upon exercise of the Series F Warrants.

(8) By virtue of his position as trustee, Leo Abbe has voting and dispositive power over the securities held by The Merav Abbe Irrevocable Trust.

The shares listed under "Number of Shares of Common Stock Owned Prior to Offering" and "Shares of Common Stock to be Sold Pursuant to this Prospectus" include 104,166 shares issuable upon the exercise of the warrants set forth below that are held by the stockholder. This amount does not (i) give effect to limitations on ownership set out in any of the warrants that may be exercised into such shares or (ii) include any shares that may be beneficially owned by an affiliate.

The warrants referred to in the immediately preceding paragraph are comprised of (i) 20,833 shares of common stock issuable upon exercise of the Series A Warrants, (ii) 22,000 shares of common stock issuable upon exercise of the Series C Warrants, (iii) 20,833 shares of common stock issuable upon exercise of the Series D Warrants, (iv) 20,833 shares of common stock issuable upon exercise of the Series E Warrants and (v) 19,667 shares of common stock issuable upon exercise of the Series F Warrants.

(9) By virtue of his position as trustee, Richard Abbe has voting and dispositive power over the securities held by The Samantha Abbe Irrevocable Trust.

The shares listed under "Number of Shares of Common Stock Owned Prior to Offering" and "Shares of Common Stock to be Sold Pursuant to this Prospectus" include 34,724 shares issuable upon the exercise of the warrants set forth below that are held by the stockholder. This amount does not (i) give effect to limitations on ownership set out in any of the warrants that may be exercised into such shares or (ii) include any shares that may be beneficially owned by an affiliate.

The warrants referred to in the immediately preceding paragraph are comprised of (i) 6,945 shares of common stock issuable upon exercise of the Series A Warrants, (ii) 7,333 shares of common stock issuable upon exercise of the Series C Warrants, (iii) 6,945 shares of common stock issuable upon exercise of the Series D Warrants, (iv) 6,945 shares of common stock issuable upon exercise of the Series E Warrants and (v) 6,556 shares of common stock issuable upon exercise of the Series F Warrants.

(10) By virtue of his position as trustee, Richard Abbe has voting and dispositive power over the securities held by The Talia Abbe Irrevocable Trust.

The shares listed under "Number of Shares of Common Stock Owned Prior to Offering" and "Shares of Common Stock to be Sold Pursuant to this Prospectus" include 34,720 shares issuable upon the exercise of the warrants set forth below that are held by the stockholder. This amount does not (i) give effect to limitations on ownership set out in any of the warrants that may be exercised into such shares or (ii) include any shares that may be beneficially owned by an affiliate.

The warrants referred to in the immediately preceding paragraph are comprised of (i) 6,944 shares of common stock issuable upon exercise of the Series A Warrants, (ii) 7,333 shares of common stock issuable upon exercise of the Series C Warrants, (iii) 6,944 shares of common stock issuable upon exercise of the Series D Warrants, (iv) 6,944 shares of common stock issuable upon exercise of the Series E Warrants and (v) 6,555 shares of common stock issuable upon exercise of the Series F Warrants.

(11) By virtue of his position as trustee, Richard Abbe has voting and dispositive power over the securities held by The Bennett Abbe Irrevocable Trust.

The shares listed under "Number of Shares of Common Stock Owned Prior to Offering" and "Shares of Common Stock to be Sold Pursuant to this Prospectus" include 34,720 shares issuable upon the exercise of the warrants set forth below that are held by the stockholder. This amount does not (i) give effect to limitations on ownership set out in any of the warrants that may be exercised into such shares or (ii) include any shares that may be beneficially owned by an affiliate.

The warrants referred to in the immediately preceding paragraph are comprised of (i) 6,944 shares of common stock issuable upon exercise of the Series A Warrants, (ii) 7,333 shares of common stock issuable upon exercise of the Series C Warrants, (iii) 6,944 shares of common stock issuable upon exercise of the Series D Warrants, (iv) 6,944 shares of common stock issuable upon exercise of the Series E Warrants and (v) 6,555 shares of common stock issuable upon exercise of the Series F Warrants.

(12) Shaye Hirsch has voting and dispositive power over the securities owned by the selling stockholder.

The shares listed under "Number of Shares of Common Stock Owned Prior to Offering" and "Shares of Common Stock to be Sold Pursuant to this Prospectus" include 808,337 shares issuable upon the exercise of warrants held by the stockholder. This amount does not (i) give effect to limitations on ownership set out in any of the warrants that may be exercised into such shares or (ii) include any shares that may be beneficially owned by an affiliate.

The warrants referred to in the immediately preceding paragraph are comprised of (i) 198,334 shares of common stock issuable upon exercise of the Series C Warrants, (ii) 208,334 shares of common stock issuable upon exercise of the Series D Warrants, (iii) 208,334 shares of common stock issuable upon exercise of the Series E Warrants and (iv) 193,334 shares of common stock issuable upon exercise of the Series F Warrants.

(13) Eastern Capital Limited is a direct wholly-owned subsidiary of Portfolio Services Ltd. Kenneth B. Dart is the beneficial owner of all of the outstanding shares of Portfolio Services Ltd. Eastern Capital Limited, Portfolio Services Ltd. and Mr. Dart have shared voting and dispositive powers with respect to the shares of common stock referenced above."

"Number of Shares of Common Stock Owned Prior to Offering" and "Shares of Common Stock to be Sold Pursuant to this Prospectus" include 1,666,667 shares issuable upon the exercise of the warrants set forth below that are held by the stockholder. This amount does not (i) give effect to limitations on ownership set out in any of the warrants that may be exercised into such shares or (ii) include any shares that may be beneficially owned by an affiliate.

"Shares of Common Stock to be Sold Pursuant to this Prospectus" includes (i) 416,667 shares of common stock issuable upon exercise of the Series A-1 Warrants, (ii) 416,667 shares of common stock issuable upon exercise of the Series D-1 Warrants (iii) 416,667 shares of common stock issuable upon exercise of the Series E-1 Warrants and (iv) 416,667 shares of common stock issuable upon exercise of the Series F-1 Warrants.

(14) OTA LLC ("OTA") is a broker-dealer registered with the Securities and Exchange Commission and a member of the Financial Industry Regulatory Authority. Ira M. Leventhal, as a senior managing director of OTA, has voting and investment control over the reported securities. The shares listed under "Number of Shares of Common Stock Owned Prior to Offering" and "Shares of Common Stock to be Sold Pursuant to this Prospectus" include 157,233 shares of common stock issuable upon exercise of the warrants sold in August 2014. This amount does not (i) give effect to limitations on ownership set out in any of the warrants that may be exercised into such shares or (ii) include any shares that may be beneficially owned by an affiliate.

# PLAN OF DISTRIBUTION

The common stock held by the selling stockholders may be sold or distributed from time to time by the selling stockholders directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed on any stock exchange, market or trading facility on which the shares are traded or in private transactions. The sale of the selling stockholders' common stock offered by this prospectus may be effected in one or more of the following methods:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- transactions involving cross or block trades;
- · purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- $\cdot$  an exchange distribution in accordance with the rules of the applicable exchange;

- in privately negotiated transactions;
- short sales after the registration statement, of which this prospectus forms a part, becomes effective;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- "at the market" into an existing market for the common stock;
- through the writing of options on the shares;
- · a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

In order to comply with the securities laws of certain states, if applicable, the shares of each of the selling stockholders may be sold only through registered or licensed brokers or dealers. In addition, in certain states, such shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

The selling stockholders may also sell shares of common stock under Rule 144 promulgated under the Securities Act, if available, or any other exemption available under the Securities Act rather than under this prospectus. In addition, the selling stockholders may transfer the shares of common stock by other means not described in this prospectus.

The selling stockholders may also sell the shares directly to market makers acting as principals and/or broker-dealers acting as agents for themselves or their customers. Such broker-dealers may receive compensation in the form of discounts, concessions or commissions from the selling stockholders and/or the purchasers of shares for whom such broker-dealers may act as agents or to whom they sell as principal or both, which compensation as to a particular broker-dealer might be in excess of customary commissions. Market makers and block purchasers purchasing the shares will do so for their own account and at their own risk. It is possible that a selling stockholder will attempt to sell shares of common stock in block transactions to market makers or other purchasers at a price per share which may be below the then market price. The selling stockholders cannot assure that all or any of the shares offered in this prospectus will be issued to, or sold by, such selling stockholder.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares held by the selling stockholders as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholders and/or purchasers of the common stock for whom the broker-dealers may act as agent. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.

Each of the selling stockholders acquired the securities offered hereby in the ordinary course of business and has advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their shares of common stock, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of shares of common stock by any selling stockholder. If we are notified by any selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock, if required, we will file a supplement to this prospectus.

We may suspend the sale of shares by the selling stockholders pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

If any of the selling stockholders use this prospectus for any sale of the shares of common stock, such selling stockholder will be subject to the prospectus delivery requirements of the Securities Act.

#### **Regulation M**

The anti-manipulation rules of Regulation M under the Exchange Act of 1934, as amended (the "Exchange Act") may apply to sales of our common stock and activities of the selling stockholder.

We have advised the selling stockholders that while it is engaged in a distribution of the shares included in this prospectus it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this prospectus.

### **DESCRIPTION OF SECURITIES**

#### General

As of the date hereof, we are authorized by our articles of incorporation to issue an aggregate of 41,666,667 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share. As of December 15, 2016, we had 8,395,768 shares of common stock, and no shares of preferred stock, issued and outstanding, as well as warrants and stock options outstanding to purchase an aggregate of 5,503,788 shares of our common stock at prices ranging between \$1.20 and \$240.00 per share, as follows:

Outstanding Warrants		Exercise Price	Expiration
Series A	214,433	\$1.20	01/13/2020
Series C	424,433	\$6.00	01/13/2020
Series D			Between 07/16/2020 and 08/13/2020 and
	610,000	\$9.00	08/19/2020 and 09/09/2020
Series E			Between 10/01/2020 and 11/12/2020 and
	616,100	\$15.00	11/30/2020 and 12/09/2020
Series F	583,333	\$7.20	08/11/2021
Series A-1	418,750	\$1.20	03/09/2020
Series C-1	2,083	\$6.00	01/13/2020
Series D-1	416,667	\$9.00	Between 08/19/2020 and 09/09/2020
Series E-1	418,750	\$15.00	06/16/2020
Series F-1	416,667	\$7.20	08/11/2021
PIPE Investor Warrants	653,187	\$6.00	08/11/2021
PIPE Broker Warrants	65,327	\$4.80	08/11/2021
Various	6,036	\$1.20	Various
Various	16,667	\$10.00-\$14.00	Various
Warrants issued in August 2014	157,233	\$14.04	08/14/19
Various	16,195	\$14.01-\$16.00	Various
Various	22,083	\$30.00	Various
Various	1,333	\$120.00-\$240.00	Various
Outstanding Stock Options	Exercise Price	Expiration	
Various 33,333	\$1.50-\$3.00	various	
Various 144,167	\$4.00-\$7.00	various	
Various 265,000	\$7.00-\$8.00	various	
Various 2,013	\$120.00-\$220.00	various	

The following summary of the terms of our common stock and preferred stock, respectively, may not be complete and is subject to, and qualified in its entirety by reference to, the terms and provisions of our amended and restated certificate of incorporation and our amended and restated bylaws. You should refer to, and read this summary together with, our amended and restated certificate of incorporation and amended and restated bylaws to review all of the terms of our common stock and preferred stock, respectively, that may be important to you.

#### **Preferred Stock**

We are authorized, subject to limitations prescribed by Nevada law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our Company and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. We have no current plan to issue any shares of preferred stock.

# **Common Stock**

#### Voting Rights

Holders of our common stock are entitled to one vote for each share held of record on each matter submitted to a vote of stockholders. Except as otherwise required by Nevada law, and subject to the rights of the holders of outstanding preferred stock, if any, all stockholder action is taken by the vote of a majority of the outstanding shares of common stock voting as a single class present at a meeting of stockholders at which a quorum consisting of one-third of the outstanding shares of common stock is present in person or proxy. Directors are elected by plurality vote, and stockholders do not have the ability to cumulate votes for the election of directors.

#### **Dividend Rights**

Subject to the prior rights of any class or series of preferred stock which may from time to time be outstanding, if any, holders of our common stock are entitled to receive ratably, dividends when, as, and if declared by our board of directors out of funds legally available for that purpose and, upon our liquidation, dissolution, or winding up, are entitled to share ratably in all assets remaining after payment of liabilities and payment of accrued dividends and liquidation preferences on any outstanding preferred stock.

#### No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights and is not subject to conversion, redemption or sinking fund provisions.

#### **Anti-Takeover Provisions**

Provisions of the Nevada Corporation Law and our articles of incorporation and bylaws could make it more difficult to acquire our company by means of a tender offer, a proxy contest or otherwise, or to remove incumbent officers and directors. These provisions, summarized below, would be expected to discourage certain types of takeover practices and takeover bids our Board may consider inadequate and to encourage persons seeking to acquire control of our Company to first negotiate with us. We believe that the benefits of increased protection of our ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our Company will outweigh the disadvantages of discouraging takeover or acquisition proposals because, among other things, negotiation of these proposals could result in an improvement of their terms.

#### Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval, except as may be required under the listing rules of any stock exchange on which our common stock is then listed. We may use additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

#### **Blank Check Preferred Stock**

Our articles of incorporation permit our Board to issue preferred stock with voting, conversion and exchange rights that could negatively affect the voting power or other rights of our common stockholders. The issuance of our preferred stock could delay or prevent a change of control of our Company.

#### Board Vacancies may be Filled by Remaining Directors

Our bylaws provide that vacancies on the Board may be filled by the remaining directors then in office.

#### Amendments to our Articles of Incorporation and Bylaws

Under the Nevada Corporation Law, our articles of incorporation may not be amended by stockholder action alone. Amendments to our articles of incorporation require a board resolution approved by the majority of the outstanding capital stock entitled to vote. Our bylaws may only be amended by a majority vote of the stockholders at any annual meeting or special meeting called for that purpose. Subject to the right of stockholders as described in the immediately preceding sentence, the Board has the power to make, adopt, alter, amend and repeal, from time to time, our bylaws.



# Requirements for Notice of Stockholder Director Nominations and Stockholder Business at Meetings.

Under our bylaws, nominations of persons to stand for election as a director may be made by the Board of Directors or by any stockholder entitled to vote for the election of directors who complies with the applicable notice requirements set out therein. If a stockholder wishes to nominate someone to stand for election as a director, or bring any business before an annual or special meeting, the stockholder must comply with certain procedures set out in our bylaws. These provisions specify the timing for delivery of the stockholder's notice of such business and the information that such notice must contain. The information that may be required in a stockholder notice includes general information regarding the stockholder, a description of the proposed business, and, with respect to nominations for the Board of Directors, certain specified information regarding the nominee(s). In addition to the information required in a stockholder notice described above, our bylaws require under certain circumstances a representation that the stockholder is a holder of our voting stock and intends to appear in person or by proxy at the meeting to make the nomination or bring up the matter specified in the notice. For the timing of the stockholder notice, our bylaws require that the notice must be received by our secretary:

- in the case of any annual meeting, 120 days prior to the anniversary date of the immediately preceding annual meeting of stockholders; provided, however, that in the event that the annual meeting is called for a date that is not within 30 days before or 60 days after such anniversary date, notice by the stockholder in order to be timely must be so received no later than the close of business on the tenth day following the day on which notice of the date of the annual meeting was mailed or public disclosure of the date of the annual meeting was made, whichever first occurs; and
- in the case of a special meeting of stockholders called for the purpose of electing directors, not later than the close of business on the tenth day following the day on which notice of the date of the special meeting was mailed or public disclosure of the date of the special meeting was made, whichever first occurs.

## Nevada Law

Nevada law contains a provision governing "acquisition of controlling interest." This law provides generally that any person or entity that acquires 20% or more of the outstanding voting shares of a publicly-held Nevada corporation in the secondary public or private market may be denied voting rights with respect to the acquired shares, unless a majority of the disinterested stockholders of the corporation elects to restore such voting rights in whole or in part. The control share acquisition act provides that a person or entity acquires "control shares" whenever it acquires shares that, but for the operation of the control share acquisition act, would bring its voting power within any of the following three ranges: 20 to 33-1/3%; 33-1/3 to 50%; or more than 50%.

A "control share acquisition" is generally defined as the direct or indirect acquisition of either ownership or voting power associated with issued and outstanding control shares. The stockholders or Board of Directors of a corporation may elect to exempt the stock of the corporation from the provisions of the control share acquisition act through adoption of a provision to that effect in the articles of incorporation or bylaws of the corporation. Our articles of incorporation and bylaws do not exempt our common stock from the control share acquisition act.

The control share acquisition act is applicable only to shares of "Issuing Corporations" as defined by the Nevada law. An Issuing Corporation is a Nevada corporation which (i) has 200 or more stockholders, with at least 100 of such stockholders being both stockholders of record and residents of Nevada, and (ii) does business in Nevada directly or through an affiliated corporation.

At this time, we do not believe we have 100 stockholders of record resident in Nevada and we do not conduct business in Nevada directly. Therefore, the provisions of the control share acquisition act are believed not to apply to acquisitions of our shares and will not until such time as these requirements have been met. At such time as they may apply, the provisions of the control share acquisition act may discourage companies or persons interested in acquiring a significant interest in or control of our Company, regardless of whether such acquisition may be in the interest of our stockholders.

The Nevada "Combination with Interested Stockholders Statute" may also have an effect of delaying or making it more difficult to effect a change in control of our Company. This statute prevents an "interested stockholder" and a resident domestic Nevada corporation from entering into a "combination," unless certain conditions are met. The statute defines "combination" to include any merger or consolidation with an "interested stockholder," or any sale, lease, exchange, mortgage, pledge, transfer or other disposition, in one transaction or a series of transactions with an "interested stockholder" having (i) an aggregate market value equal to 5% or more of the aggregate market value of the assets of the corporation, (ii) an aggregate market value equal to 5% or more of the corporation, or (iii) representing 10% or more of the earning power or net income of the corporation.

An "interested stockholder" means the beneficial owner of 10% or more of the voting shares of a resident domestic corporation, or an affiliate or associate thereof. A corporation affected by the statute may not engage in a "combination" within three years after the interested stockholder acquires its shares unless the combination or purchase is approved by the Board of Directors before the interested stockholder acquired such shares. If approval is not obtained, then after the expiration of the three-year period, the business combination may be consummated with the approval of the Board of Directors or a majority of the voting power held by disinterested stockholders, or if the consideration to be paid by the interested stockholder is at least equal to the highest of (i) the highest price per share paid by the interested stockholder, whichever is higher, (ii) the market value per common share on the date of announcement of the combination or the date the interested stockholder acquired the shares, whichever is higher, or (iii) if higher for the holders of preferred stock, the highest liquidation value of the preferred stock.

Nevada Law also includes express provisions preserving the right of a corporation to adopt or sign "plans, arrangements or instruments that grant or deny rights, privileges, power or authority to a holder or holders of a specified number of shares or percentage of share ownership or voting power." A common example is where the board issues the right for certain stockholders to purchase shares of the corporation at a substantially discounted price if one stockholder reaches a specified percentage of share ownership. The purchase of discounted shares dilutes the share ownership of such potential acquirer.

# **Registration Rights**

Holders of approximately 2,736,521 shares of our outstanding common stock, and of warrants to purchase approximately 4,972,414 shares of our common stock, are entitled to certain rights with respect to registration of such outstanding shares, and the shares of common stock underlying such warrants, under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of various purchase agreements and registration rights agreements entered into with us in connection with our sale of such stock and warrants to such investors. This registration statement covers all of such securities. We are required to pay all expenses incurred in connection with such registration.

The registration rights described above will terminate as to any stockholder at such time as all of such stockholder's securities (together with any affiliate of the stockholder with whom such stockholder must aggregate its sales) could be sold without compliance with the registration requirements of the Securities Act pursuant to Rule 144.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Island Stock Transfer, 1550 Roosevelt Blvd Suite 301, Clearwater, Florida 33760.

#### Listing

Our shares of common stock are listed for trading on the Nasdaq Capital Market under the symbol TPIV. On December 15, 2016, the last reported sale price per share for our common stock on the Nasdaq Capital Market was \$5.07.

#### 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**

<b>Product/ Candidate</b> TPIV 100/110 HER2/neu+ Breast Cancer Vaccine	<b>Description</b> Peptide Vaccine	Application Treatment of HER2/neu+ Breast Cancer	Status 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			

#### Clinical

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

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

On June 1, 2010, we signed an exclusive licensing option agreement with the Mayo Foundation for Medical Education and Research ("Mayo Foundation"), Rochester, 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. 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. 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. We anticipate this Phase II study of TPIV 200 in the treatment of triple-negative breast cancer will begin to enroll patients in the fourth quarter of 2016 or 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 are planning to initiate a Phase II study in this indication by the end of 2016 in at least one clinical site. The remainder will follow in 2017.

We have opened nine clinical sites, which will grow to 12, 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 plans to participate in an ovarian cancer study sponsored by Memorial Sloan Kettering Cancer Center in New York City in collaboration with AstraZeneca Pharmaceuticals. This study, a Phase II study of TPIV 200 in ovarian cancer patients who are not responsive to platinum, a commonly used chemotherapy for ovarian cancer, is currently enrolling ovarian cancer patients and is designed to look at the effects of combination therapy with 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. We recently received approval for our first patent on Polystart. Additional patent filings are anticipated.

# **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.

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

#### Mayo HER2/neu License

On April 13, 2012, we entered into a Patent & Know-How Agreement with the Mayo Foundation 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 19, 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.

## 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. The market for infectious disease vaccines is estimated at roughly \$30 billion worldwide, with the U.S. contributing approximately \$20 billion. Importantly, there still 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). 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 also 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 prospectus 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.

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The following table sets forth information as of December 15, 2016 on each issued patent currently held or licensed by us:

Patent No.	Expiration	Title	Ownership	Jurisdiction Where Granted/Filed	
Peptide Based Vaccine (Folate Rece	ptor Alpha, Breast an	d 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 Option	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	Owned	USA	
HLA DR Peptide Vaccines					
Patent No. 6006265	Expires 2028	HLA-DR Binding Peptides And Their Uses	Exclusive License Option	Japan	
Patent No. 2,215,111	Expires 2028	HLA-DR Binding Peptides And Their Uses	Exclusive License Option	Europe (DE, FR, GB, IE)	

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 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, applications for registration of the mark of POLYSTART and TAPIMMUNE. 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 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.

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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 - <u>www.hc-sc.gc.ca</u>.

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 recordkeeping 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, 2015 and 2014, we incurred research and development expenses of approximately \$1,711,000, and \$189,000, respectively.

## **Product Liability and Insurance**

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

### **Human Resources**

*Employees.* We currently have seven 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) and a Director of Administration. Additionally, the Company employs 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. Robert Florkiewicz, formerly an employee serving as Senior Director of Molecular Biology and Virology, is now a consultant to the Company and also serves as a strategic advisor. Dr. 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.

#### 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 January 24, 2017. The rent is \$2,250 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 2, 2017, and the monthly rent is \$275.

# 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 prospectus, 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.

## **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 well as our proxy statements, 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 prospectus.

# MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

# **Market Information**

Our common stock is listed for trading on the Nasdaq Capital Market under the symbol "TPIV".

The market for our common stock is limited, volatile and sporadic. The following table sets forth, for the periods indicated, the high and low closing sales prices for the Company's common stock since January 1, 2014, as reported on Nasdaq.com.

	High	Low
Fiscal Year 2016		
Fourth Quarter (through December 15, 2016)	\$ 6.66	\$ 4.07
Third Quarter	\$ 7.12	\$ 4.92
Second Quarter	\$ 9.49	\$ 5.52
First Quarter	\$ 8.15	\$ 5.34
Fiscal Year 2015		
Fourth Quarter	\$ 10.89	\$ 6.53
Third Quarter	\$ 12.60	\$ 4.17
Second Quarter	\$ 18.12	\$ 1.98
First Quarter	\$ 3.84	\$ 1.49
Fiscal Year 2014		
Fourth Quarter	\$ 8.70	\$ 2.34
Third Quarter	\$ 30.00	\$ 6.74
Second Quarter	\$ 48.00	\$ 15.96
First Quarter	\$ 49.08	\$ 42.00

As of December 15, 2016, we had 670 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 15, 2016, there were an aggregate of 5,503,788 common stock purchase warrants and stock options issued and outstanding, with exercise prices ranging between \$1.20 and \$240.00 per share.



# Securities Authorized For Issuance under Compensation Plans

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

	(a)			(c) Number of Securities Remaining Available for
	Number of Securities to be Issued Upon Exercise of Options	E	(b) eighted Average kercise Price of Outstanding Options	Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by stockholders <sup>(1)</sup>	3,679	\$	215.28	4,654
Equity compensation plans not approved by stockholders <sup>(2)</sup>	295,000	\$	6.60	288,333
Totals	298,679	\$	9.17	292,987

<sup>(1)</sup> Includes shares of common stock authorized for awards under the 2009 Stock Incentive Plan.

<sup>(2)</sup> Represents shares of common stock authorized for issuance under the 2014 Omnibus Stock Option Plan.

On October 14, 2009, the Company adopted the 2009 Stock Incentive Plan (the "2009 Plan"). The 2009 Plan allows for the issuance of up to 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 as of December 15, 2016.

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 vesting Requirement (as such terms are defined in the Plan), and (iii) provide the Board and Committee administering the vesting Requirement (as such terms are defined in the Plan), and event the 2014 Plan.

# 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 unaudited consolidated interim financial statements and related notes for the nine months ended September 30, 2016, (ii) our audited consolidated financial statements as at December 31, 2015 and December 31, 2014 and (iii) the section entitled "Business", included in this prospectus. 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. See the discussion under the heading "Forward-Looking Statements" above.



# **Company Overview**

## **Our Cancer Vaccines**

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

To enhance 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.

#### **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 the Company's 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.

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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 is being readied for initiation by 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.

The Company 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 Companysponsored 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**

Product	Indication	Phase 1	Phase 2
TPIV 200 In Combination with checkpoint inhibitor	Ovarian Cancer in Patients Not Responsive to Platinum	Enrolling Patients w/AstraZeneca & Sloan Kette	ring
TPIV 200	Triple-Negative Breast Cancer	Enrolling Patients	
TPIV 200	Triple-Negative Breast Cancer	Enrollment to Commence Q4 w/Mayo Clinic & U.S. DOD	
TPIV 200	Platinum-Sensitive Ovarian Cancer	Clinical Sites to Open Q4	
TPIV 110	Her2/neu Breast Cancer	IND to Open Q4 2016/1 <sup>st</sup> Q 2017	

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 acidbased 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). The Company announced the allowance of this patent in February 2016.

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<sup>™</sup> 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 (FRα), 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 nine clinical sites and 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 to treat cancers 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.

#### 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.

# Enrollment to Commence in the Fourth Quarter of 2016: 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 fourth quarter of this year. 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 an advisor to TapImmune. While TapImmune is supplying doses of TPIV 200 for the trial, 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.

# Clinical Sites to Open in the Fourth Quarter of 2016: Phase II TPIV 200 Trial in Platinum-Sensitive Ovarian Cancer

By the end of 2016, we expect to have at least one clinical site open 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. This multi-center, double-blind efficacy study is sponsored and conducted by TapImmune.

# Open IND with FDA for TPIV 110 in the Fourth Quarter of 2016 or in the First Quarter of 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 requested a pre-Investigational New Drug (IND) meeting with the FDA and submitted questions to the FDA related to opening the IND. We anticipate having an open IND by year-end 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 vetting of 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 the Company's intent to apply to list the common stock on the Nasdaq Capital Market. On November 2, 2016, we received notification that we were approved for listing on The Nasdaq Capital Market and our common stock 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 62,890,763 shares to 5,240,897 shares at September 30, 2015 and from 70,550,763 shares to 5,879,230 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, 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.

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

Pursuant to the registration rights agreements entered into in connection with the private placements, the Company is 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. The Company is required to file the registration statement within 120 days of the August 26, 2016 closing, or by December 27, 2016. The Company is also required to ensure that the registration statement is declared effective within 90 calendar days after filing with the Securities and Exchange Commission.

In accordance with the registration rights agreements, should the Company fail to meet the above criteria, the Company is subject to pay the investors liquidated damages. The liquidated damages shall be a cash sum payment calculated at a rate of ten percent (10%) per annum of the aggregate purchase price for the registrable securities or aggregate amount upon exercise of the placement agent warrants.

In accordance with applicable U.S. generally accepted accounting principles, a contingent obligation to make future payments must be recorded if the transfer of consideration under a registration payment arrangement is probable and can be reasonably estimated. The Company has determined that should it be required to pay liquidated damages to the investors of the private placements, the aggregate contingent liability it would be required to record would be approximately \$29,000 per month for each month it fails or is estimated to fail to meet the above criteria.

At the August 10, 2016 and August 26, 2016 private placement closings, and on September 30, 2016, the Company concluded that it is not probable that it will be required to remit any payments to the investors for failing to obtain an effective registration statement or failing to maintain its effectiveness.

# 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:(1)

Series	<b>Outstanding Warrants</b>	Ex	ercise Price	Expiration
A	214,433	\$	1.20	01/13/2020
С	424,433	\$	6.00	01/13/2020
				Between 07/16/2020 and 08/13/2020 and 08/19/2020
D	610,000	\$	9.00	and 09/09/2020
				Between 10/01/2020 and 11/12/2020 and 11/30/2020
E	616,100	\$	15.00	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

(1) This table includes additional shares issuable upon the exercise of the warrants set forth above that are not registered by this prospectus.

# Addition of Executive Officers

On July 18, 2016, we announced that Dr. John Bonfiglio, a consultant and a member of our Board of Directors, was appointed as our President and Chief Operating Officer and entered into an employment agreement with us. Concurrent with such appointment we amended the employment agreement of Dr. Wilson for Dr. Wilson to relinquish the office of President.

On August 25, 2016, we announced that Michael J. Loiacono, a consultant, was appointed as our Chief Financial Officer, Chief Accounting Officer, Secretary and Treasurer and entered into an employment agreement with us.

#### **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, 2015.

### **Results of Operations**

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

### Nine months ended September 30, 2016 Compared to Nine months ended September 30, 2015

We recorded a net loss of \$879,000 or (\$0.14) basic and (\$0.54) diluted per share during the nine months ended September 30, 2016 compared to a net loss of \$32,414,000 or (\$10.61) basic and diluted per share for the nine months ended September 30, 2015.

Operating costs increased to \$6,901,000 during the nine months ended September 30, 2016 compared to \$3,904,000 in the prior period. Significant changes in operating expenses are outlined as follows:

- Research and development costs during the nine months ended September 30, 2016 were \$3,343,000 compared to \$2,324,000 during the prior period. This was due to the Company exercising its 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 \$3,558,000 during the nine months ended September 30, 2016 from \$1,580,000 during the prior period. This was due to generally increased expenses relating to consulting, general and administrative and professional fees during the nine months ended September 30, 2016 as the Company's operating activities increased substantially.
- The change in fair value of derivative liabilities for the nine months ended September 30, 2016 was \$5,925,000 as compared to (\$28,486,000) for the nine months ended September 30, 2015. The variance in the current period is due to 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. We revalue the derivative liabilities at each balance sheet date to fair value. The most significant change in the assumptions was the difference in the share price used at September 30, 2016 of \$6.69 compared to \$7.40 at September 30, 2015, the exercise of warrants with derivative liabilities and the August 2016 amendments to certain of the warrants to remove the clause that caused the warrants to be classified as derivative liabilities. Due to these significant changes, the fair value of the derivative liabilities decreased by \$5,925,000 with a corresponding gain in the condensed consolidated statement of operations.
- During the nine months ended September 30, 2016, the Company 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 the Company.



During the nine-month period ended September 30, 2016 the Company incurred \$135,000 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 nine months ended September 30, 2015.

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

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

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

# **Operating Expenses**

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

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

The weighted average number of shares outstanding was 3,662,256 for the year ended December 31, 2015 compared to 1,288,768 for the prior year.

# 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 September 30, 2016 and December 31, 2015:

	September 30, 2016		December 31, 2015	
Cash reserves	\$	9,587,000	\$	6,577,000
Working capital (deficit)	\$	7,494,000	\$	(21,360,000)

### Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2016 and 2015:

	Nine Months En	Nine Months Ended September 30,		
	2016	2016 2015		
Net cash provided by (used in):				
Operating activities	\$ (4,756,000)	\$	(3,492,000)	
Financing activities	7,766,000		9,438,000	
Net increase in cash	\$ 3,010,000	\$	5,945,000	

#### Net Cash Used in Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2016 was \$4,756,000 compared to \$3,492,000 during the prior period. We had no revenues during the current or prior periods. Operating expenditures, excluding non-cash interest and stock-based charges during the current period primarily consisted of consulting and management fees, office and general expenditures, and professional fees.

# Net Cash Provided by Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2016 was \$7,766,000 compared to net cash provided by financing activities of \$9,438,000 during the prior period. The financing activities in the current period consisted of proceeds from private placements and warrant exercises in the current period as were in the prior period.

## 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.

# 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, (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, (v) one Series D warrant to purchase one share of common stock, (vi) one Series E warrant to purchase one share of common stock, (v) one Series B warrants were exercisable at \$18.00 per share, with a five-year term. Series B warrants were exercisable at \$12.00 per share, with a five-year term. Series D warrants were exercisable at \$12.00 per share, with a five-year term. Series B warrants are exercised. Series E warrants were exercised at the Series B warrants are exercised at \$15.00 per share, only if and to the extent that the Series C warrants are exercised. Series E warrants were 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, (v) one Series D-1 warrant to purchase one share of common stock, (v) one Series E-1 warrant to purchase one share of common stock, (v) one Series E-1 warrant to purchase one share of common stock, (v) 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, 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.

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

Pursuant to the registration rights agreements entered into in connection with the private placements, the Company is 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. The Company is required to file the registration statement within 120 days of the August 26, 2016 closing, or by December 27, 2016. The Company is also required to ensure that the registration statement is declared effective within 90 calendar days after filing with the Securities and Exchange Commission.

In accordance with the registration rights agreements, should the Company fail to meet the above criteria, the Company is subject to pay the investors liquidated damages. The liquidated damages shall be a cash sum payment calculated at a rate of ten percent (10%) per annum of the aggregate purchase price for the registrable securities or aggregate amount upon exercise of the placement agent warrants.

In accordance with applicable U.S. generally accepted accounting principles, a contingent obligation to make future payments must be recorded if the transfer of consideration under a registration payment arrangement is probable and can be reasonably estimated. The Company has determined that should it be required to pay liquidated damages to the investors of the private placements, the aggregate contingent liability it would be required to record would be approximately \$29,000 per month for each month it fails or is estimated to fail to meet the above criteria.

At the August 10, 2016 and August 26, 2016 private placement closings, and on September 30, 2016, the Company concluded that it is not probable that it will be required to remit any payments to the investors for failing to obtain an effective registration statement or failing to maintain its effectiveness.

# 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 intend to spend approximately \$7,500,000 over the next twelve months in carrying out our plan of operations. 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 condensed 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, 2015 and 2014, we have approximately \$24,123,000 of federal and \$4,336,000 of state NOLs that may be available to offset future taxable income, if any. The federal net operating loss carryforwards, if not utilized, will expire between 2029 and 2035. The state net operating loss carryforwards, if not utilized, will expire in 2035. Any greater than 50% change in ownership under Section 382 of the Internal Revenue Code, or the Code, places significant annual limitations on the use of such net operating loss carryforwards.

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

## Inflation

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

## MANAGEMENT

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

Name	Age	Position with the Company
Dr. Glynn Wilson	68	Chairman of the Board, Chief Executive Officer,
		Principal Executive Officer and a Director
Dr. John Bonfiglio	61	President, Chief Operating Officer and a Director
Michael J. Loiacono	50	Chief Financial Officer and Chief Accounting
		Officer
Mark Reddish	60	Independent Director
Sherry Grisewood	62	Independent Director
David Laskow-Pooley	61	Independent Director
Frederick Wasserman	61	Independent Director
Joshua Silverman	46	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.

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

## Sherry Grisewood, Director

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

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

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

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 19

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.

#### **David Laskow-Pooley, Director**

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

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

# Frederick Wasserman, Director

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

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

## 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.

# 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.

### **Term of Office**

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

# Audit Committee

Our Board of Directors has established an Audit Committee which functions pursuant to a written charter last amended by our Board of Directors in 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 Board has determined that Ms. Grisewood is not independent under the Nasdaq Capital Market listing standards, due to the fact that she was paid \$10,000 in 2013 for consulting work performed for the Company.



# **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, Sherry Grisewood and Joshua Silverman. Mr. Laskow-Pooley serves as Chair of the Committee.

### 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.

A copy of the charter of each of the foregoing committees of the Board can be viewed on our website at <u>http://www.tapimmune.com/investors/investor-briefcase/</u>.

# **Code of Ethics and Business Conduct**

We have adopted a Code of Ethics and Business Conduct that applies to all directors and officers. The code describes the legal, ethical and regulatory standards that must be followed by the directors and officers of the Company and sets forth high standards of business conduct applicable to each director and officer. A copy of the code can be viewed on our website at <u>http://www.tapimmune.com/investors/investors/investor-briefcase/</u>.

# **Independence of Directors**

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, at its meeting held in July 2016, 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.

#### TRANSACTIONS WITH RELATED PERSONS

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

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

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

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

Any member of the Audit Committee who has a conflict of interest with respect to a transaction under review may not participate in the deliberations or vote respecting approval of the transaction, provided, however, that such director may be counted in determining the presence of a quorum. Since January 1, 2013, 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 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 was to serve as President and Chief Operating Officer of the Company.

## Joshua Silverman

On November 30, 2016, the Company announced that Joshua Silverman, age 46, of Scarsdale, New York, has been appointed to the Board of Directors of the Company. Mr. Silverman's appointment was effective on November 28, 2016.

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.

The Company agreed to add Mr. Silverman to the Board pursuant to the terms of the Warrant Amendment Agreement, dated August 10, 2016, between the Company 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 the Company's balance sheets. Such agreements were described in, and included as exhibits to, the Company's 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 Company common stock and new five-year warrants to purchase an aggregate of 196,667 shares of Company 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 Company 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 the Company's balance sheets.

The Warrant Amendment Entities were also purchasers of Company 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, the Company's 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, the Company 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, the Company's 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 the common stock of the Company 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.

## EXECUTIVE COMPENSATION

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

	Summary Compensation Table								
Name and Principal		Salary	Bonus	Stock Awards	Option Awards	All Other Compensation	Total		
Position	Year	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)		
Glynn Wilson									
Chairman, CEO and Principal									
Executive Officer and Acting	2015	204,000	Nil	191,000	605,000	11,000	1,011,000		
Principal Accounting Officer	2014	180,000	Nil	Nil	Nil	Nil	180,000		

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

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

	Outstanding Equity Awards at Year End Table								
	Number of Securities Underlying Unexercised Options	Number of Securities Underlying Unexercised Options	Number of Securities Underlying Unexercised Unearned	Option Exercise		Option Expiration			
Name	(exercisable)	(unexercisable)	Options		Price	Date			
Glynn Wilson	83,334		Nil	\$	7.26	12/11/25			
Chairman, CEO and Principal Executive Officer	33	83,334	Nil	\$	204.00(2)	07/06/17			
	1,334(1)	Nil	Nil	\$	204.00(2)	10/14/19			
	134(1)	Nil	Nil	\$	204.00	02/16/21			
	1,667(1)	Nil	Nil	\$	228.00	03/16/16			

(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.

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

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

\*Represents fees paid to Dr. Bonfiglio for consulting services during the year pursuant to a consulting agreement we entered into with Dr. John Bonfiglio and subsequently amended.

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

- An initial grant upon joining the Board of 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.

#### **Employment Agreements**

#### Dr. Wilson

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

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

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

In connection with entering into the new agreement, Dr. Wilson received equity awards under the Company's 2014 Omnibus Stock Ownership Plan consisting of (i) an award of 26,250 shares of unregistered common stock, which immediately vested, and (ii) an award of stock options to purchase 166,667 shares of Company 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 the Company without cause (as defined in the agreement), or if the agreement is terminated by Dr. Wilson for good reason (as defined in the agreement), the Company is required to pay Dr. Wilson a severance payment in an amount equal to 2/3 of his annual base salary, plus any amount of his annual performance bonus that was earned as of the date of termination but not yet paid.

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

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

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 President and Chief Operating Officer of the Company; (b) dedicate his full business time, attention and energies to performing his duties to the Company, as prescribed by the CEO; (c) report to the CEO of the Company; and (d) carry out the decisions and otherwise abide by and enforce the lawful rules and policies of the Company. The Agreement provided that Dr. John Bonfiglio would perform such services in exchange for an annual salary of \$260,000 per year. The agreement provided for equity awards under the Company's 2014 Omnibus Stock Ownership Plan consisting of stock options to purchase 62,500 shares of the Company's 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 Company's 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. John Bonfiglio is employed with the Company 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 the Company or Dr. John Bonfiglio by written notice. The options awarded to Dr. John 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 Chief Financial Officer and Chief Accounting Officer, Secretary and Treasurer of the Company; (b) dedicate his full business time, attention and energies to performing his duties to the Company, as prescribed by the CEO; (c) manage the financial affairs of the Company and perform the duties typically assigned to the chief financial officer and chief accounting officer of a similarly situated company in the Company's 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 the Company as may reasonably be requested of him. The Agreement provided that Michael J. Loiacono would perform such services in exchange for an annual base salary of \$200,000 per year. The agreement provided for equity awards under the Company's 2014 Omnibus Stock Ownership Plan consisting stock options to purchase 54,167 shares of the Company's 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 the Company or Mr. Loiacono by written notice.

## BENEFICIAL OWNERSHIP OF PRINCIPAL STOCKHOLDERS, OFFICERS AND DIRECTORS

The following table sets forth, as of the date of this Prospectus 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 prospectus.

Name and Address of Beneficial Owner Directors and Officers:	Amount and Nature of Beneficial Ownership(1)	Percent of Class
Dr. Glynn Wilson, Chairman and Chief Executive Officer (2)	213,194	2.5%
Mark Reddish, Director (3)	31,764	2.370
Sherry Grisewood, Director (4)	14,861	*
Dr. John Bonfiglio, Director (5)	86,806	*
David Laskow-Pooley, Director (6)	12,500	*
Frederick Wasserman, Director (7)	6,771	*
Joshua Silverman (8)	1,563	*
Michael J. Loiacono, Chief Financial Officer (9)	15,568	*
All executive officers and directors as a group (8 persons)	383,027	4.4%
Major Stockholders:		
Eastern Capital Limited (10)	4,000,000	39.8%
Iroquois Capital Management L. L. C. (11)	702,500	7.9%
Brio Capital Master Fund (12)	1,177,576	12.8%
Empery Asset Management LP (13)	940,000	10.8%

#### \* Less than one percent (1%)

(1) Under Rule 13d-3, a beneficial owner of a security includes any person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise has or shares: (i) voting power, which includes the power to vote, or to direct the voting of shares; and (ii) investment power, which includes the power to dispose or direct the disposition of shares. Certain shares may be deemed to be beneficially owned by more than one person (if, for example, persons share the power to vote or the power to dispose of the shares). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire the shares (for example, upon exercise of an option) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person, the amount of shares outstanding is deemed to include the amount of shares beneficially owned by such person (and only such person) by reason of these acquisition rights. As a result, the percentage of outstanding shares of any person as shown in this table does not necessarily reflect the person's actual ownership or voting power with respect to the number of shares of common stock actually outstanding as of the date of this Prospectus. As of December 15, 2016 there were 8,395,768 shares of common stock issued and outstanding.

(2) This figure includes 72,806 shares directly owned by Dr. Glynn Wilson, 140,388 shares able to be acquired pursuant 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 able to be acquired pursuant to currently exercisable stock options.

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

(5) This figure includes 20,833 shares directly owned by Dr. John Bonfiglio, 65,973 shares able to be acquired pursuant 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 able to be acquired pursuant to currently exercisable stock options.

(7) This figure includes 6,771 shares able to be acquired pursuant 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 able to be acquired pursuant 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 able to be acquired pursuant 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 Limited's address is 10 Market St. #773, Camana Bay, Grand Cayman KY1-1206 Cayman Islands. 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% (the "Maximum Percentage") of the common stock after giving effect to such exercise.



(11) All information is based upon (i) the Schedule 13G jointly filed with the Securities and Exchange Commission by Iroquois Capital Management L. L. C., Joshua Silverman and Richard Abbe on February 8, 2016 and (ii) the Company's records relating to the issuance of Series F warrants to Iroquois and its affiliates in August 2016. 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 Capital Management L.L.C., or any of its affiliates would beneficially own in excess of 4.9% (the "Maximum Percentage") of the common stock after giving effect to such exercise. The Series C and Series F Warrants are subject to a limit of exercise to the extent (and only to the extent) that Iroquois Capital Management L.L.C., or any of its affiliates would beneficially own in excess of 9.9% of the common stock after giving effect to such exercise.

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

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

(12) All information is based upon the Schedule 13G filed with the Securities and Exchange Commission by Brio Capital Master Fund Ltd. on January 29, 2016 and the amendment filed on August 19, 2016. 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% (the "Maximum Percentage") 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.

Pursuant to the terms of (i) the Series C Warrants and Series F Warrants, the reporting persons cannot exercise any of such warrants if the reporting persons would beneficially own, after any such exercise, more than 9.9% of the outstanding shares of common stock, and (ii) the Series D Warrants and Series E Warrants, the reporting persons cannot exercise any of such warrants if the reporting persons would beneficially own, after any such exercise, more than 4.9% of the outstanding shares of common stock (the "Blockers"). Consequently, the reporting persons were not able to exercise all of the warrants due to the Blockers.

(13) All information is based upon (i) the Schedule 13G jointly filed with the Securities and Exchange Commission by Empery Asset Management LP, Ryan M. Lane and Martin D. Hoe on January 19, 2016 and (ii) the Company's records relating to the issuance of Series F warrants to Empery Asset Management and its affiliates in August 2016. Assumes exercise of all Series C Warrants and Series F Warrants, are subject to a limit of exercise to the extent (and only to the extent) that Empery Asset Management LP or any of its affiliates would beneficially own in excess of 9.9% (the "Maximum Percentage") of the common stock after giving effect to such exercise.

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

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.



### EXPERTS

Our consolidated financial statements as of December 31, 2015 and December 31, 2014, and for the period then ended, have been included in the prospectus in reliance upon the report of Marcum LLP, independent registered public accounting firm, and upon the authority of said firm as experts in accounting and auditing.

### LEGAL MATTERS

The firm of Shumaker, Loop & Kendrick, LLP has issued an opinion regarding the legality and validity of the securities offered under this prospectus.

## DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Our by-laws require us to indemnify any of our officers or directors, and certain other persons, under certain circumstances against all expenses and liabilities incurred or suffered by such persons because of a lawsuit or similar proceeding to which the person is made a party by reason of a his being a director or officer of TapImmune or our subsidiaries, unless that indemnification is prohibited by law. We may also purchase and maintain insurance for the benefit of any officer which may cover claims for which we could not indemnify a director or officer. We have been advised that in the opinion of the Securities and Exchange Commission, indemnification of our officers, directors and controlling persons under these provisions, or otherwise, is against public policy and is unenforceable.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended (the "Securities Act"), may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act, and is therefore unenforceable.

### WHERE YOU CAN FIND MORE INFORMATION

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. We have filed with the SEC registration statements on Forms S-1 and Form S-3 under the Securities Act with respect to the securities we are offering under this prospectus (Commission File Nos. 333-196115, 333-205757 and 333-[\_\_\_\_\_]). This prospectus does not contain all of the information set forth in the registration statements and the exhibits to the registration statements. For further information with respect to us and the securities we are offering under this prospectus, we refer you to the registration statements and the exhibits and schedules filed as a part of the registration statements. You may read and copy the registration statements, as well as our reports, proxy statements and other information, at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the Public Reference Room. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, where our SEC filings are also available. The address of the SEC's web site is http://www.sec.gov.

We maintain a website at www.tapimmune.com. The information contained in, or that can be accessed through, our website is not incorporated by reference herein and is not part of this prospectus.

Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete, and in each instance we refer you to the copy of the contract or document filed as an exhibit to the registration statement, each such statement being qualified in all respects by such reference.

#### INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The documents incorporated by reference into this prospectus contain important information that you should read about us.

The following documents are incorporated by reference into this prospectus:

Our Annual Report on Form 10-K for the fiscal years ended December 31, 2015, filed on April 14, 2016;

• Our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2016, June 30, 2016, and September 30, 2016, filed on May 16, 2016, August 15, 2016 and November 4, 2016, respectively;

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• Our Current Reports on Form 8-K filed on May 25, 2016, July 15, 2016, July 19, 2016, August 11, 2016, August 25, 2016, August 29, 2016, September 15, 2016 and November 30, 2016; and

• The description of our common stock contained in its registration statement on Form 8-A (Registration No. 001-37939), filed on November 3, 2016, including any amendments or reports filed for the purpose of updating such description.

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including those made after the date of the initial filing of the registration statement of which this prospectus forms a part and prior to effectiveness of such registration statement, until we file a post-effective amendment that indicates the termination of the offering of the common stock made by this prospectus and such future filings will become a part of this prospectus from the respective dates that such documents are filed with the SEC. Our SEC file number is 001-37939. Any statement contained herein or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes hereof or of the related prospectus supplement to the extent that a statement contained herein or in any other subsequently filed document which is also incorporated or deemed to be incorporated herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will furnish without charge to each person to whom this prospectus is delivered, upon written or oral request, a copy of any document incorporated by reference. Requests should be addressed to Corporate Secretary, 50 North Laura Street, Jacksonville, FL 32202, or may be made telephonically at (904) 516-5436.

You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with different information. You should not assume that the information contained in this prospectus or the accompanying prospectus supplement is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus and any accompanying prospectus supplement is delivered or securities are sold on a later date.

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## Index to Consolidated Financial Statements

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## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements (unaudited)

## TAPIMMUNE INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

## (UNAUDITED)

	September 30, 2016		D	December 31, 2015
ASSETS				
Current Assets				
Cash	\$	9,586,773	\$	6,576,564
Prepaid expenses and deposits		111,652		68,803
	-			
Total Assets	\$	9,698,425	\$	6,645,367
	<u> </u>	-,,	-	
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)				
Current Liabilities				
Accounts payable and accrued liabilities	\$	1,678,079	\$	967,358
Research agreement obligations		492,365		492,365
Derivative liability – warrants		29,000		26,493,000
Promissory note		5,000		30,000
Promissory note, related party		-		23,000
Total Liabilities		2,204,444	_	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		-		-
Series B, \$0.001 par value, 1,500,000 shares designated, -0- shares issued and outstanding		-		-
Common stock, \$0.001 par value, 41,666,667 shares authorized, 8,395,768 and 5,882,976 shares issued and				
outstanding at September 30, 2016 and December 31, 2015, respectively		8,396		5,884
Additional paid-in capital		151,724,573		112,142,187
Accumulated deficit	(	144,238,988)		(133,508,427)
Total Stockholders' Equity (Deficit)		7,493,981		(21,360,356)
	-			
Total Liabilities and Stockholders' Equity (Deficit)	\$	9,698,425	\$	6,645,367

See accompanying notes to these unaudited condensed consolidated financial statements.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

## (UNAUDITED)

	Three Months Ended September 30,				Nine Months Ended September 30,			
		2016		2015		2016		2015
Operating Expenses:								
Research and development	\$	1,109,332	\$	968,759	\$	3,343,248	\$	2,324,432
General and administrative		1,612,305		769,219		3,557,701		1,579,754
Loss from Operations		(2,721,637)		(1,737,978)		(6,900,949)		(3,904,186)
Other Income (Expense)								
Changes in fair value of derivative liabilities		684,000		30,266,000		5,925,000		(28,485,585)
Foreign exchange gain		-		-		-		775
Grant income		-		-		231,200		-
Loss on debt settlement agreements		(65,325)		(24,697)		(135,640)		(24,697)
Other income		-				1,828		
Net Income (Loss)	\$	(2,102,962)	\$	28,503,325	\$	(878,561)	\$	(32,413,693)
Basic Net Income (Loss) per Share	\$	(0.29)	\$	7.04	\$	(0.14)	\$	(10.61)
Diluted Net Income (Loss) per Share	\$	(0.29)	\$	4.23	\$	(0.54)	\$	(10.61)
Weighted Average Number of Common Shares Outstanding, Basic		7,281,000		4,048,750		6,370,000		3,054,297
Weighted Average Number of Common Shares Outstanding, Juste		7,281,000		6,745,416		6,935,000		3,054,297

See accompanying notes to these unaudited condensed consolidated financial statements.

# CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

## (UNAUDITED)

	Common Stock		Additional Paid In	Accumulated	
	Number of shares	Amount \$	Capital \$	Deficit \$	Total \$
Balance, December 31, 2015	5,882,976	5,884	112,142,187	(133,508,427)	(21,360,356)
Issuance of common stock in private placement	653,166	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 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 derivative liabilities at exercise date	-	-	5,074,000	-	5,074,000
Shares issued in debt settlement agreements	10,191	10	70,305	-	70,315
Stock- based compensation	99,435	99	1,309,009	-	1,309,108
Net loss				(878,561)	(878,561)
Balance, September 30, 2016	8,395,768	8,396	151,724,573	(144,238,988)	7,493,981

See accompanying notes to these unaudited condensed consolidated financial statements.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

## (UNAUDITED)

	-	Nine Months Ended September 30, 2016		Months Ended eptember 30, 2015
Cash flow from operating activities				
Net loss	\$	(878,561)	\$	(32,413,693)
Adjustments to reconcile net loss to net cash from operating activities:				
Changes in fair value of derivative liabilities		(5,925,000)		28,485,585
Loss on debt settlement agreements		70,315		24,697
Stock based compensation		1,309,109		261,805
Changes in operating assets and liabilities:				
Prepaid expenses		(42,849)		(55,782)
Accounts payable and accrued liabilities		710,720		204,956
Net cash used in operating activities		(4,756,266)		(3,492,432)
Cash flow from financing activities				
Private placements		3,135,196		2,464,000
Finders' fee and legal costs on private placements		(804,070)		(137,986)
Repayment of promissory note		(25,000)		-
Repayment of promissory note – related party		(23,000)		-
Proceeds from exercise of warrants		6,000,000		7,427,998
Finders' fee on exercise of warrants		(516,651)		(316,508)
Net cash provided by financing activities		7,766,475		9,437,504
Net increase in cash		3,010,209		5,945,072
Cash, beginning of period		6,576,564		141,944
Cash, end of period	\$		¢	
	<b>Þ</b>	9,586,773	\$	6,087,016
Supplemental disclosure of cash flow information				
Cash paid for interest	\$	-	\$	-
Cash paid for taxes	\$	-	\$	-

See accompanying notes to these unaudited condensed consolidated financial statements.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

## (UNAUDITED)

	Nine Months Ended September 30, 2016		Nine Months Ended September 30, 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		-	24,000
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	11,745,000

See accompanying notes to these unaudited condensed consolidated financial statements.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### September 30, 2016

#### (Unaudited)

### 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.

## Note 2: BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and pursuant to the instructions to Form 10-Q and Article 8 of Regulation S-X of the Securities and Exchange Commission ("SEC") and on the same basis as the Company prepares its annual audited consolidated financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of such interim results.

The results for the statement of operations are not necessarily indicative of results to be expected for the year ending December 31, 2016 or for any future interim period. The condensed consolidated balance sheet at December 31, 2015 has been derived from audited financial statements; however, it does not include all of the information and notes required by U.S. GAAP for complete financial statements. The accompanying condensed consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended December 31, 2015, and notes thereto included in the Company's annual report on Form 10-K.

## Note 3: LIQUIDITY AND FINANCIAL CONDITION

The Company's activities since inception have consisted principally of acquiring product and technology rights, raising capital, and performing research and development. Successful completion of the Company's development programs and, ultimately, the attainment of profitable operations are dependent on future events, including, among other things, its ability to access potential markets; secure financing, develop a customer base; attract, retain and motivate qualified personnel; and develop strategic alliances. From inception, the Company has been funded by a combination of equity and debt financings.

The Company expects to continue to incur substantial losses over the next several years during its development phase. To fully execute its business plan, the Company will need to complete certain research and development activities and clinical studies. Further, the Company's product candidates will require regulatory approval prior to commercialization. These activities may span many years and require substantial expenditures to complete and may ultimately be unsuccessful. Any delays in completing these activities could adversely impact the Company. The Company plans to meet its capital requirements primarily through issuances of debt and equity securities and, in the longer term, revenue from product sales.

As of September 30, 2016, the Company had cash and cash equivalents of approximately \$9,587,000. Historically, the Company had net losses and negative cash flows from operations. Management intends to continue its research efforts and to finance operations of the Company 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 the Company will be successful in obtaining additional financing on favorable terms, or at all. These matters raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.



### Note 4: SIGNIFICANT ACCOUNTING POLICIES

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the Company's annual report on Form 10-K, which was filed with the SEC on April 14, 2016 other than the one disclosed below relating to grant income:

#### **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.

#### **Recent Accounting Pronouncement**

Accounting Standards Update ("ASU"), No. 2016-09 - In March 2016, the Financial Accounting Standards Board (the "FASB") issued ASU No. 2016-09, Compensation-Stock Compensation. The areas for simplification in this update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Some of the specific changes associated with the update include all excess tax benefits and tax deficiencies (including tax benefits of dividends on share-based payment awards) being recognized as income tax expense or benefit in the income statement. The tax effects of exercised or vested awards should be treated as discrete items in the reporting period in which they occur. An entity also should recognize excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. An entity can make an entity-wide accounting policy election to either estimate the number of awards that are expected to vest (current GAAP) or account for forfeitures when they occur. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years.

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 5: NET INCOME (LOSS) PER SHARE

Basic income (loss) per common share is computed by dividing net income by the weighted average number of common shares outstanding during the reporting period. Diluted income per common share is computed similar to basic income 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.

Income (loss) per-share amounts for all periods have been retroactively adjusted to reflect the Company's 1-for-12 reverse stock split, which was effective September 16, 2016.

The following table sets forth the computation of income (loss) per share:

	For the Three Months Ended September 30,				For the Nine Months Ende September 30,			
	2016			2015		2016		2015
Net income (loss)	\$	(2,102,962)	\$	28,503,325	\$	(878,561)	\$	(32,413,693)
Less: Non cash income from changes in fair value of derivative liabilities		-		-		(2,856,000)		-
Net income (loss) - diluted		(2,102,962)		28,503,325		(3,734,561)		(32,413,693)
		· · · · · · · · · · · · · · · · · · ·						
Weighted average shares outstanding - basic		7,281,000		4,048,750		6,370,000		3,054,297
Common stock warrants		-		2,663,333		565,000		-
Common stock options		-		33,333		-		-
Weighted average shares outstanding - diluted		7,281,000		6,745,416		6,935,000		3,054,297
							_	
Net income (loss) per share data:								
Basic	\$	(0.29)	\$	7.04	\$	(0.14)	\$	(10.61)
Diluted	\$	(0.29)	\$	4.23	\$	(0.54)	\$	(10.61)



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:

	Nine Months End	ed September 30,
	2016	2015
Common stock options	432,000	39,000
Common stock warrants - equity treatment	5,054,000	211,000
Common stock warrants - liability treatment	6,000	4,750,000
Potentially dilutive securities	5,492,000	5,000,000

## Note 6: DERIVATIVE LIABILITY - WARRANTs

A summary of quantitative information with respect to valuation methodology and significant unobservable inputs used for the Company's common stock purchase warrants that are categorized within Level 3 of the fair value hierarchy for the nine months ended 2016 and 2015 is as follows:

Share Purchase Warrants	Weig	nputs for the	Period	
	Fo	r the Nine	For the l	Nine
	Months Ending		Months Ending	
	Sep	September 30,		er 30,
Date of valuation		2016	2015	
Exercise price	\$	1.20	\$	7.56
Contractual term (years)		1.3		4.5
Volatility (annual)		105%		159%
Risk-free rate		1%		1%
Dividend yield (per share)		0%		0%

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

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

The fair value accounting standards define fair value as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. Fair value measurements are rated on a three-tier hierarchy as follows:

- Level 1 inputs: Quoted prices (unadjusted) for identical assets or liabilities in active markets;
  - Level 2 inputs: Inputs, other than quoted prices included in Level 1, that are observable either directly or indirectly; and
- · Level 3 inputs: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

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

		As of September 30, 2016						
		Fair Value Measurements						
	Fair Value	Level 1	Level 2	Lev	vel 3	Total		
Derivative liability - warrants	\$ 29,000		-	- \$	29,000	\$	29,000	
Total	\$ 29,000		-	- \$	29,000	\$	29,000	

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	As of December 31, 2015							
	Fair Value Measurements							
Fair Value Level 1 Level 2		Level 3	Total					
\$ 26,493,000		\$ 26,493,000	\$ 26,493,000					
\$ 26,493,000		\$ 26,493,000	\$ 26,493,000					
	\$ 26,493,000	Fair Value MeasurenFair ValueLevel 1Level 2\$ 26,493,000	Fair Value MeasurementsFair ValueLevel 1Level 2Level 3\$ 26,493,000\$ 26,493,000					

There were no transfers between Level 1, 2 or 3 during the nine months ended September 30, 2016.

The following table presents changes in Level 3 liabilities measured at fair value for the nine months ended September 30, 2016:

	Derivative lia	bility – warrants
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		(5,925,000)
Balance – September 30, 2016	\$	29,000

#### 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.

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. The value of the shares and fair value of the warrants was treated as dividend on the statement of stockholders' equity of \$4.5 million.

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 \$556,000 in the statement of operations and \$15.5 million was reclassified to equity.

#### Note 7: STOCK-BASED COMPENSATION

The following table summarizes the components of stock-based compensation expense in the condensed consolidated statements of operations for the three and nine months ended September 30, 2016 and 2015, respectively:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016		2015		2016		2015	
Research and development	\$	-	\$	-	\$	-	\$	-
General and administrative		573,137		13,244		1,309,109		261,805
Total stock-based compensation	\$	573,137	\$	13,244	\$	1,309,109	\$	261,805

## Stock Options

A summary of the Company's stock option activity is as follows:

	Stock Options	Weighted AverageWeighted AverageExercise Price per ShareContractual L		Aggre Intrinsic	0
Outstanding as of December 31, 2015	298,679	\$ 9.25	9.75	\$ 1	77,000
Granted Exercised Forfeited/Cancelled	135,000 - (1,667)	6.00 - 228.00			
Outstanding as of September 30, 2016	432,013	\$ 7.25	9.25	\$ 2	71,000
Exercisable as of September 30, 2016	262,395	\$ 8.00	9.00	\$ 1	74,000

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 September 30, 2016 are as follows:

Unrecognized stock-based compensation cost:	\$ 1,081,000
Expected weighted average period compensation costs to be recognized (years):	1.75

#### Note 8: PROMISSORY NOTE

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

During the nine months ended September 30, 2016, the Company paid a \$25,000 promissory note and \$6,524 of accrued interest in final settlement.

#### 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. In September 2016, the note was paid in full.

### Note 10: CAPITAL STOCK

#### **Reverse Stock Split**

Effective September 16, 2016, the Company effected a one for twelve reverse stock-split of our issued and outstanding common stock and has retroactively adjusted our common shares outstanding, options and warrants amounts outstanding. The Company has presented its share data for and as of all periods presented on this basis. The par value was not adjusted as a result of the one for twelve reverse stock split. All prior period share transactions included in the Company's stock transactions and balances have been retroactively restated.

#### 2016 Common Stock Transactions

#### Private placements

On August 10, 2016 and August 26, 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.

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

Pursuant to the registration rights agreements entered into in connection with the private placements, the Company is 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. The Company is required to file the registration statement within 120 days of the August 26, 2016 closing, or by December 27, 2016. The Company is also required to ensure that the registration statement is declared effective within 90 calendar days after filing with the Securities and Exchange Commission.

In accordance with the registration rights agreements, should the Company fail to meet the above criteria, the Company is subject to pay the investors liquidated damages. The liquidated damages shall be a cash sum payment calculated at a rate of ten percent (10%) per annum of the aggregate purchase price for the registrable securities or aggregate amount upon exercise of the placement agent warrants.

In accordance with applicable U.S. generally accepted accounting principles, a contingent obligation to make future payments must be recorded if the transfer of consideration under a registration payment arrangement is probable and can be reasonably estimated. The Company has determined that should it be required to pay liquidated damages to the investors of the private placements, the aggregate contingent liability it would be required to record would be approximately \$29,000 per month for each month it fails or is estimated to fail to meet the above criteria.

At the August 10, 2016 and August 26, 2016 private placement closings, and on September 30, 2016, the Company concluded that it is not probable that it will be required to remit any payments to the investors for failing to obtain an effective registration statement or failing to maintain its effectiveness.

### 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.

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. The value of the shares and fair value of the warrants was treated as dividend on the statement of stockholders' equity of \$4.5 million.

#### Share Purchase Warrants

A summary of the Company's share purchase warrants as of September 30, 2016 and changes during the period is presented below:

	Number of Warrants	Weighted Average Exercise Price
Balance, December 31, 2015	4,343,000	\$ 8.67
Exercised	(1,000,000)	6.00
Issued	1,718,000	6.65
Expired	(2,000)	300
Balance, September 30, 2016	5,059,000	\$ 8.51

#### **Consulting Arrangements**

During the nine months ended September 30, 2016, the Company issued 60,000 common shares as part of consulting agreements. The fair value of the common stock of approximately \$414,000 was recognized as stock-based compensation in general and administrative expense.



### **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).

In September 2016, the Company paid \$27,000 for a promissory note from 2008 and related \$38,000 of accrued interest. The \$65,000 payment was recognized as loss on debt settlement agreements in other income (expense).

### Note 11: GRANT INCOME

During the nine months ended September 30, 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 12: COMMITMENTs

#### **Employment Agreements**

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, Dr. Wilson was awarded 19,018 fully vested common shares in March 2016. The fair value of the common stock of approximately \$146,000 was recognized as stock-based compensation in general and administrative expense.

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. 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. 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.

In August 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.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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

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

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

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

/s/ Marcum LLP New York, NY April 14, 2016, except for Note 1A, as to which the date is December 22, 2016

## TAPIMMUNE INC. CONSOLIDATED BALANCE SHEETS

	D	December 31, 2015		ecember 31, 2014
ASSETS				
Current Assets				
Cash	\$	6,576,564	\$	141,944
Prepaid expenses and deposits		68,803		82,504
	\$	6,645,367	\$	224,448
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)				
Current Liabilities				
Accounts payable and accrued liabilities	\$	967,358	\$	693,362
Research agreement obligations		492,365		492,365
Derivative liability – warrants		26,493,000		9,415
Promissory notes		30,000		29,942
Promissory note, related party		23,000		23,000
		28,005,723	_	1,248,084
COMMITMENTS AND CONTINGENCIES	_		_	
Stockholders' Equity (Deficit)				
Convertible preferred stock, \$0.001 par value — 5,000,000 shares authorized:				
Series A, \$0.001 par value, 1,250,000 shares designated, -0- shares issued and outstanding as of December 31, 2015 and				
December 31, 2014		_		
Series B, \$0.001 par value, 1,500,000 shares designated, -0- shares issued and outstanding as of December 31, 2015 and				
December 31, 2014		_		_
Common stock, \$0.001 par value, 41,666,667 shares authorized 5,882,976 shares issued and outstanding (2014 –				
1,693,235)		5,884		1,695
Additional paid-in capital		112,142,187		85,284,400
Accumulated deficit	(	(133,508,427)		(86,309,731)
Accumulated other comprehensive loss				_
		(21,360,356)		(1,023,636)
	\$	6,645,367	\$	224,448

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

## TAPIMMUNE INC. CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31, 2015		Year Ended ecember 31, 2014
Operating expenses:			
General and administrative	\$ 4,447,781	\$	3,181,927
Research and development	1,711,177		189,000
Loss from Operations	 (6,158,958)		(3,370,927)
Other Income (Expense)			
Foreign exchange (loss) gain	775		(52,976)
Changes in fair value of derivative liabilities	(27,872,585)		581
Accretion of discount on convertible notes			(492,296)
Interest and financing charges	(10,925)		(83,247)
Loss on extinguishment of debt			(26,884,231)
Loss on settlement agreement	(24,697)		
	 	_	
Net Loss for the Period	(34,066,390)		(30,883,096)
Other comprehensive income			
Foreign exchange translation adjustment			58,334
TOTAL COMPREHENSIVE LOSS	\$ (34,066,390)	\$	(30,824,762)
Basic and Diluted Net Loss per Share	\$ (9.30)	\$	(24.00)
Weighted Average Number of Common Shares Outstanding	 3,662,256	_	1,288,768

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

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

			Additional Paid In	Accumulated	Accumulated Other Comprehensive	
	Number of shares	Amount \$	Capital \$	Deficit \$	Loss \$	Total \$
	Shares	ψ	Ψ	Ψ	Ψ	ψ
Balance, December 31, 2013	122,143	123	46,716,843	(55,426,635)	(58,334)	(8,768,003)
Convertible notes, promissory notes, loan payable-related party, due to related parties and accrued interest converted into Series A and B preferred stock and immediately						
converted into commons stock	1,170,726	1,171	30,949,907			30,951,078
Conversion of accounts payable to common						
stock	153,031	153	4,349,275	—	—	4,349,428
Private placement (net of finders' fee)	179,754	180	1,877,320	_		1,877,500
Foreign exchange translation adjustment					58,334	58,334
Stock- based compensation	67,584	68	1,391,055		_	1,391,123
Net loss				(30,883,096)		(30,883,096)
Balance, December 31, 2014	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	3,740					
Balance, December 31, 2015	5,882,976	5,884	112,142,187	(133,508,427)		(21,360,356)

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

## TAPIMMUNE INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

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

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

## TAPIMMUNE INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

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

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

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

## NOTE 1: NATURE OF OPERATIONS

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

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

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

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

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

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

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

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

## NOTE 1A: 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.

## 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 derivative liabilities - warrants and accrued liabilities.

### **Fair Value Measurements**

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

· Level 1-Quoted prices (unadjusted) in active markets for identical assets and liabilities.

• Level 2-Inputs other than Level 1 that are observable, either directly or indirectly, such as unadjusted quoted prices for similar assets and liabilities, unadjusted quoted prices in the markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

• Level 3-Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Financial Instruments and Concentration of Credit Risk.

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

#### **Prior Period Reclassifications**

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

#### **Stock-Based Compensation**

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

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

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

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

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

## **Research and Development Costs**

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

### **Income Taxes**

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

#### **Derivative Liability**

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

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

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

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

### Loss per Common Share

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



## **Recently Issued Accounting Pronouncements**

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

## NOTE 3: NET LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDER

#### Net Loss per Share Applicable to Common Stockholders

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

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

	Decemb	oer 31,
	2015	2014
Common stock options	298,679	5,453
Common stock warrants - equity treatment	212,386	213,011
Common stock warrants - liability treatment	4,129,822	8,607
Excluded potentially dilutive securities	4,640,887	227,071

### NOTE 4: RESEARCH AGREEMENTS

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

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

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

### NOTE 5: DERIVATIVE LIABILITY

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

Stock Purchase Warrants		Weighted Average Inputs for the Perio			
	En	For the Year Ending December 31,		ear Iber 31,	
Date of valuation		2015	2014		
Strike price	\$	0.74	\$	10.70	
Volatility (annual)		155%		166%	
Risk-free rate		1.8%		1.00%	
Contractual term (years)		4.2		2.25	
Dividend yield (per share)		0%		0%	

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

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

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

		As of December 31, 2	015		
	Fair Value Measurements				
	Fair Value	Level 1 Level 2	Level 3	Total	
Derivative liability - warrants	\$ 26,493,000		\$ 26,493,000	\$ 26,493,000	
Total	\$ 26,493,000		\$ 26,493,000	\$ 26,493,000	
		As of December 31, 2	014		
		Fair Value Measurem	ents		
	Carrying				
	Value	Level 1 Level 2	Level 3	Total	
Derivative liability - warrants	\$ 9,000		\$ 9,000	\$ 9,000	
Total	\$ 9,000		\$ 9,000	\$ 9,000	

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

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

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

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

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

#### NOTE 6: PROMISSORY NOTES

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

## NOTE 7: PROMISSORY NOTE, RELATED PARTY

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

## NOTE 8: CAPITAL STOCK

### Stock Split and increase in authorized shares

On February 18, 2014, the Company completed a reverse stock split thereby issuing 1 new share for each 100 outstanding shares of the Company's common stock and amended the Company's Articles of Incorporation to increase the authorized shares of common stock from 12,500,000 shares of common stock to 41,666,667 shares.

## **Share Capital**

### Series A Convertible Preferred Stock

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

#### Series B Convertible Preferred Stock

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

- rank pari passu to the common stock with respect to rights on liquidation, winding up and dissolution;
- have no dividend rights except as may be declared by the Board in its sole and absolute discretion;

• shall have the right to cast one thousand (1,000) votes for each share held of record on all matters submitted to a vote of holders of the Corporation's common stock; and

shall automatically convert into seven (7) shares of common upon the occurrence of a 1:100 reverse stock split.

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

### **2015 Share Transactions**

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, (iii) one Series C warrant to purchase one share of common stock, (v) one Series D warrant to purchase one share of common stock, (iv) one Series E warrant to purchase one share of common stock, (v) one Series E warrant to purchase one share of common stock, (v) one Series E warrant to purchase one share of common stock, (v) one Series E warrant to purchase one share of common stock, (v) one Series B warrants are exercisable at \$18.00 per share, with a five-year term. Series B warrants are exercisable at \$12.00 per share, with a five-year term. Series D warrants are exercisable at \$12.00 per share, with a five-year term. Series D warrants are exercisable at \$12.00 per share, with a five-year term. Series B warrants are exercisable at \$12.00 per share, with a five-year term. Series B warrants are exercisable at \$12.00 per share, with a five-year term. Series B warrants are exercisable at \$12.00 per share, with a five-year term. Series B warrants are exercisable at \$12.00 per share, with a five-year term. Series B warrants are exercised. Series E warrants are exercised at the Series C warrants are exercised, with a five-year term from the date that the Series B warrants are exercised. Series E warrants are exercised 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.

## **Initial Fair Value of Warrants Issued**

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

## May 2015 Restructuring Agreement

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

- The exercise price of Series A warrants was changed from \$18.00 per warrant to \$1.20 per warrant,
- The exercise price of Series B warrants was changed from \$4.80 per warrant to \$2.40 per warrant,
- · Each warrant of Series B existing prior to the restructuring agreement was replaced with two warrants of such series,
- The exercise price of Series C warrants was changed from \$12.00 per warrant to \$6.00 per warrant, and
- Each warrant of Series C existing prior to the restructuring agreement was replaced with two warrants of such series.

As a result of the restructuring agreement, the Company issued an additional 1,026,667 Series B warrants and 1,026,667 Series C Warrants. The fair value of the warrants issued pursuant to the May 2015 restructuring agreement was \$6,133,000. The weighted average inputs include contractual term of 2.46 years, volatility of 141% and risk free rate of 1.5%.

#### Management Compensation

In November 2015, the Company entered into an employment agreement with Dr. Glynn Wilson, the Company's Chief Executive Officer, President and Chairman of the Company. As part of the agreement, the Company granted Dr. Wilson 26,250 shares of unregistered common stock, fully vested. The Company recorded an obligation to deliver the shares of \$26,250 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. The recorded obligation was reduced to approximately \$146,000 based on the fair value of the common stock at May 1, 2016.

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.

## **Share Purchase Warrants**

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

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life
Balance, December 31, 2014	221,618	21.96	3 4.15
Issued	7,227,582	6.48	4.30
Exercised	(3,090,000)	3.00	—
Extinguished or expired	(16,992)	28.68	_
Balance, December 31, 2015	4,342,208	\$ 8.88	4.24

During the year ended December 31, 2015, a warrant holder exercised 401,667 of Series A warrants at \$1.20 per warrant for a total of \$482,000.

During the year ended December 31, 2015, warrant holders exercised 2,053,332 of Series B warrants at \$2.40 per warrant for a total of \$4,928,000.

During the year ended December 31, 2015, warrant holders exercised 635,000 of Series C warrants at \$6.00 per warrant for a total of \$3,810,000.

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

#### **Stock Compensation Plan**

On March 19, 2014, the Company adopted the 2014 Omnibus Stock Option Plan ("2014 Plan"). The 2014 Plan was amended in February 2015 to provide for grants to consultants, and again in November 2015 to (i) increase the number of shares reserved for issuance under the Plan by 416,667 shares to 583,334 shares. Options granted under the Plan shall be at prices and for terms as determined by the Board of Directors.

## Share purchase options

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

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life	Intrinsic Value
Outstanding at January 1, 2014	5,453	216.00	5.04	\$ —
Issued		—	—	
Cancelled/Forfeited		—	—	
Outstanding at January 1, 2015	5,453	216.00	4.04	
Issued	295,000	6.60	4.39	
Cancelled/Forfeited	(1,774)	204.00	_	_
Outstanding at December 31, 2015	298,679	\$ 9.24	9.69	\$ 177,000
Exercisable at December 31, 2015	165,583	\$ 11.04	9.59	\$ 132,000

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

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

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

## NOTE 9: INCOME TAXES

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

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

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

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

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

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

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

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

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



# NOTE 10: CONTINGENCIES AND COMMITMENTS

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

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

1. Make upfront license fee payments of \$100,000 and \$350,000 as partial consideration by March 21, 2016 and June 21, 2016, respectively;

2. Pay annual license maintenance fees of \$50,000 beginning on July 21, 2017 and every year thereafter until the Company starts paying 6% royalty on sales of the licensed product.

3. Pay milestone fees for each licensed product developed by the Company on achievement of certain events.

#### **Contingencies:**

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



## PROSPECTUS

# TAPIMMUNE INC.

## 7,708,935 Shares of Common Stock

\_\_\_\_\_, 2016

Until \_\_\_\_\_\_\_, 2017 (the 90th day after the date of this Prospectus), all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a Prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a Prospectus when acting as underwriters and with respect to unsold allotments or subscriptions.

No dealer, salesperson or other individual has been authorized to give any information or to make any representations not contained in this Prospectus in connection with the offering covered by this Prospectus. If given or made, such information or representations must not be relied upon as having been authorized by us. This Prospectus does not constitute an offer to sell, or a solicitation of an offer to buy the offered securities in any jurisdiction where, or to any person to whom, it is unlawful to make any such offer or solicitation. Neither the delivery of this Prospectus nor any offer or sale made hereunder shall, under any circumstances, create an implication that there has not been any change in the facts set forth in this Prospectus or in our affairs since the date hereof.

### PART II

#### INFORMATION NOT REQUIRED IN THE PROSPECTUS

# ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The table below itemizes the expenses payable by the registrant in connection with the registration and issuance of the securities being registered hereunder, other than underwriting discounts and commissions. All amounts except the Securities and Exchange Commission registration fee are estimated.

Securities and Exchange Commission Registration Fee	
Legal Fees and Expenses	\$ 1,305.68
Accountants' Fees and Expenses	+
Transfer agent and registrar's fees and expenses	+
Miscellaneous Expenses	+
Total	†

+ Estimated expenses are not presently known. The foregoing sets forth the general categories of expenses (other than underwriting discounts and commissions) that the Company anticipates it will incur in connection with the offering of securities under the registration statement.

## ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Our officers and directors are indemnified under Nevada law. Our Amended and Restated Articles of Incorporation and our By-laws are silent as to director and officer indemnification.

Nevada Revised Statute. The registrant is a Nevada corporation.

Section 78.138 of the Nevada Revised Statutes provides that a director or officer will not be personally liable to the corporation and its stockholders unless it is proven that (i) the director's or officer's acts or omissions constituted a breach of his fiduciary duties, and (ii) such breach involved intentional misconduct, fraud or a knowing violation of the law. The provisions of the Nevada Revised Statutes with respect to limiting personal liability for directors and officers are self-executing and, to the extent the provisions of our Amended and Restated Articles of Incorporation and By-laws would be deemed to be inconsistent therewith, the provisions of the Nevada Revised Statutes will control.

Section 78.7502 of the Nevada Revised Statutes permits a corporation to indemnify a present or former director, officer, employee or agent of the corporation, or of another entity or enterprise for which such person is or was serving in such capacity at the request of the corporation, who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, except an action by or in the right of the corporation, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred in connection therewith, arising by reason of such person's service in such capacity if such person (i) is not liable pursuant to Section 78.138 of the Nevada Revised Statutes, or (ii) acted in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to a criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. In the case of actions brought by or in the right of the corporation, after exhaustion of all appeals therefrom, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court in which the action or suit was brought or other court of competent jurisdiction determines upon application that in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses as the court deems proper.

Section 78.751 of the Nevada Revised Statutes permits any discretionary indemnification under Section 78.7502 of the Nevada Revised Statutes, unless ordered by a court or advanced to a director or officer by the corporation in accordance with the Nevada Revised Statutes, to be made by a corporation only as authorized in each specific case upon a determination that indemnification of the director, officer, employee or agent is proper in the circumstances. Such determination must be made (1) by the stockholders, (2) by the board of directors by majority vote of a quorum consisting of directors who were not parties to the action, suit or proceeding, (3) if a majority vote of a quorum consisting of directors who were not parties to the action, suit or proceeding so orders, by independent legal counsel in a written opinion, or (4) if a quorum consisting of directors who were not parties to the action, suit or proceeding cannot be obtained, by independent legal counsel in a written opinion.

# ITEM 16. EXHIBITS.

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

		Incorporated by Reference				
Exhibit number	Exhibit description	Form	File no.	Exhibit	Filing date	Filed herewith
3.1	Articles of Incorporation as Amended	10 <b>-</b> 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-К	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-К	000-27239	4.14	4/18/11	
4.15	Form of Warrant in connection with Securities Purchase Agreement dated April 14, 2011	10-К	000-27239	4.15	4/18/11	
4.16	Form of Warrants issued in November 2009 private placements					
4.17	Form of Common Stock Purchase Warrant	8-K	000-27239	4.1	8/14/14	
4.18	Form of Placement Agent Warrant	8-K	000-27239	4.2	8/14/14	
4.19	Form of Common Stock Purchase Warrants-Series A	8-K	000-27239	4.1	1/12/15	
4.20	Form of Common Stock Purchase Warrants-Series B	8-K	000-27239	4.2	1/12/15	

4.21	Form of Common Stock Purchase Warrants-Series C	8-K	000-27239	4.3	1/12/15
4.22	Form of Common Stock Purchase Warrants-Series D	8-K	000-27239	4.4	1/12/15
4.23	Form of Common Stock Purchase Warrants-Series E	8-K	000-27239	4.5	1/12/15

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

4.44 Form of Amended Series A-1 Warrant	8-K	000-27239	4.6	8/11/16
4.45 Form of Amended Series D-1 Warrant	8-K	000-27239	4.7	8/11/16
4.46 Form of Amended Series E-1 Warrant	8-K	000-27239	4.8	8/11/16
4.47 Form of Series F Warrant	8-K	000-27239	4.9	8/11/16
4.48 Form of Series F-1 Warrant	8-K	000-27239	4.10	8/11/16
4.49 Form of Katalyst Warrant	8-K	000-27239	4.11	8/11/16

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	_	Incorporated by Reference				
Exhibit number	Exhibit description	Form	File no.	Exhibit	Filing date	Filed herewith
5.1	Opinion of Shumaker, Loop & Kendrick, LLP					X
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	В	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
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	Consulting Agreement, dated February 10, 2015, between TapImmune Inc. and Dr. John Bonfiglio*	8-K	000-27239	10.1	7/30/15
10.20	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
10.21	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	Employment Agreement between TapImmune, Inc. and Dr. Glynn Wilson, dated November 12, 2015*	10-Q	000-27239	10.8	11/16/15
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

			Incorporated by Referen	ce		
Exhibit		<b>F</b>	File	T-kikia	Filing	Filed
<u>number</u> 10.30	Exhibit description Second Amendment to the Consulting Agreement by and between TapImmune Inc. and Dr. John Bonfiglio dated as of February 10, 2016*	Form	<b>no.</b> 000-27239	<u>Exhibit</u>	<u>date</u> 2/16/16	herewith
10.31	License and Assignment Agreement with Mayo Foundation for Medical Education and Research dated May 19, 2016**	10-Q	000-27239	10.7	8/15/16	
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	
10.33	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
23.2	Consent of Shumaker, Loop & Kendrick, LLP (included as part of Exhibit 5.1)					Х
24.1	Powers of Attorney (included on signature page).					X
101.INS	XBRL Instance Document	10-K	000-27239		4/14/16	
101.SCH	XBRL Taxonomy Extension Schema Document	10-K	000-27239		4/14/16	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	10-K	000-27239		4/14/16	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	10-K	000-27239		4/14/16	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	10-K	000-27239		4/14/16	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	10-K	000-27239		4/14/16	
101.INS	XBRL Instance Document	10-Q	001-37939		11/4/16	
101.SCH	XBRL Taxonomy Extension Schema Document	10-Q	001-37939		11/4/16	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	10-Q	001-37939		11/4/16	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	10-Q	001-37939		11/4/16	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	10-Q	001-37939		11/4/16	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	10-Q	001-37939		11/4/16	

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



#### ITEM 17. UNDERTAKINGS.

#### A. RULE 415 OFFERING

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b)) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

## Provided, however, That:

Paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933 each such post- effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was made in the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(7) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

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# SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Jacksonville, State of Florida, on December 22, 2016.

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)

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated. Each person in so signing also makes, constitutes and appoints Glynn Wilson and Michael J. Loiacono, and each of them with the power to act without the other, his or her true and lawful attorney-in-fact, with full power of substitution, in any and all capacities, to execute and cause to be filed with the Securities and Exchange Commission pursuant to the requirements of the Securities Act of 1933, as amended, any and all amendments to this Registration Statement, with exhibits to such registration statements and amendments and other documents in connection therewith, and hereby ratifies and confirms all that said attorney-in-fact or his or her substitute or substitutes may do or cause to be done by virtue hereof.

Signature	Title	Date
/s/ Sherry Grisewood Sherry Grisewood	Director	December 22, 2016
/s/ Glynn Wilson Dr. Glynn Wilson	Director	December 22, 2016
/s/ David Laskow-Pooley David Laskow-Pooley	Director	December 22, 2016
/s/ Mark Reddish Mark Reddish	Director	December 22, 2016
/s/ John Bonfiglio Dr. John Bonfiglio	Director	December 22, 2016
/s/ Frederick Wasserman Frederick Wasserman	Director	December 22, 2016
/s/ Joshua Silverman Joshua Silverman	Director	December 22, 2016
/s/ Michael J. Loiacono Michael J. Loiacono	Chief Financial Officer	December 22, 2016



Bank of America Plaza 813.229.7600 101 East Kennedy 813.229.1660 fax Boulevard Suite 2800 Tampa, Florida 33602

www.slk-law.com

December 22, 2016

Tapimmune, Inc. 50 N. Laura Street, Suite 2500 Jacksonville, FL

#### Re: <u>Registration Statement on Form S-3 for Tapimmune, Inc.</u>

Ladies and Gentlemen:

We have acted as counsel to Tapimmune Inc., a Nevada corporation (the "Company"), in connection with in connection with the filing, on or about the date of this letter, of a Registration Statement on Form S-3 (the "Registration Statement") under the Securities Act of 1933, as amended (the "Securities Act") registering for resale by the selling stockholders identified in the Registration Statement 7,708,935 shares of the Company's common stock, consisting of:

(i) 2,736,521 shares of Company common stock previously issued to the selling stockholders identified in the Registration Statement (the "Shares"); and

(ii) 4,972,414 shares of Company common stock issuable upon the exercise of warrants described in the Registration Statement by the selling stockholders identified in the Registration Statement ("Warrant Shares").

We have examined the originals or certified copies of such corporate records of the Company and/or public officials and such other documents and have made such other factual and legal investigations as we have deemed relevant and necessary as the basis for the opinions set forth below. In our examination, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, and the conformity to authentic original documents of all documents submitted to us as copies or as facsimiles of copies or originals, which assumptions we have not independently verified.

Based upon the foregoing and the examination of such legal authorities as we have deemed relevant, and subject to the qualifications and further assumptions set forth below, we are of the opinion that: (i) the Shares to be sold by the selling stockholders identified in the Registration Statement have been duly authorized and are validly issued, fully paid and non-assessable; and (ii) and upon exercise and payment in accordance with the terms of the warrants as described in the Registration Statement, the Warrant Shares to be sold by the selling stockholders identified in the Registration Statement will be lawfully and validly issued, fully paid and non-assessable.

We have made such inquiries with respect thereto as we consider necessary to render this opinion. The opinions expressed herein are limited to the Federal laws of the United States of America and the general corporate laws of the State of Nevada (which includes the Nevada Revised Statutes, applicable provisions of the Nevada Constitution and the reported judicial decisions interpreting those laws) currently in effect. We express no opinion with respect to the effect or applicability of the laws of any other jurisdiction. We assume no obligation to revise or supplement this opinion letter should the laws of such jurisdiction be changed after the date hereof by legislative action, judicial decision or otherwise.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and to the reference to our firm under the caption "Legal Matters" in the Registration Statement. In giving this consent, we do not represent that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the General Rules and Regulations of the Securities and Exchange Commission.

Very truly yours,

/s/Shumaker, Loop & Kendrick, LLP Shumaker, Loop & Kendrick, LLP

#### INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the inclusion in this Registration Statement of TapImmune, Inc. on Form S-3 of our report dated April 14, 2016 (except for Note 1A, as to which the date is December 22, 2016), which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of TapImmune, Inc. as of December 31, 2015 and 2014 and for the years ended December 31, 2015 and 2014, which report appears in the Prospectus, which is part of this Registration Statement. We also consent to the reference to our Firm under the heading "Experts" in such Prospectus.

/s/ Marcum LLP

Marcum LLP New York, NY December 22, 2016