

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-K**

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

For the Fiscal Year Ended December 31, 2015

OR

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

For the Transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number: 0-31265

**MABVAX THERAPEUTICS HOLDINGS, INC.**

(Exact name of Registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

93-0987903  
(I.R.S. Employer  
Identification No.)

11535 Sorrento Valley Rd., Suite 400, San Diego, CA  
(Address of principal executive offices)

92121  
(Zip Code)

Registrant's telephone number, including area code: (858) 259-9405

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

Title of Each Class  
None

Name of Each Exchange on Which Registered

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

Common Stock, \$0.01 par value per share

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES  NO

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (Sec. 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES  NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Sec.229.405 of this Chapter) is not contained herein, and will not be contained to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act.). YES  NO

The aggregate market value of the voting common stock held by non-affiliates of the Registrant was approximately \$54,552,000 as of June 30, 2015, based upon the closing sale price on the OTCQB Market of \$2.32 per share reported on such date.

As of March 14, 2016, there were 29,211,272 shares of the registrant's common stock outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III of this Annual Report on Form 10-K is incorporated by reference from the registrant's definitive proxy statement for the 2016 annual meeting of stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the close of the registrant's fiscal year ended December 31, 2015.

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**MABVAX THERAPEUTICS HOLDINGS, INC.  
2015 ANNUAL REPORT ON FORM 10-K**

**TABLE OF CONTENTS**

	<u>Page</u>
<b>PART I</b>	
<a href="#">Item 1. Business</a>	2
<a href="#">Item 1A. Risk Factors</a>	19
<a href="#">Item 1B. Unresolved Staff Comments</a>	34
<a href="#">Item 2. Properties</a>	34
<a href="#">Item 3. Legal Proceedings</a>	34
<a href="#">Item 4. Mine Safety Disclosures</a>	35
<b>PART II</b>	
<a href="#">Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity</a>	
<a href="#">Item 5. Securities</a>	35
<a href="#">Item 6. Selected Financial Data</a>	36
<a href="#">Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>	37
<a href="#">Item 7A. Quantitative and Qualitative Disclosures About Market Risk</a>	44
<a href="#">Item 8. Financial Statements and Supplementary Data</a>	44
<a href="#">Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</a>	45
<a href="#">Item 9A. Controls and Procedures</a>	45
<a href="#">Item 9B. Other Information</a>	46
<b>PART III</b>	
<a href="#">Item 10. Directors, Executive Officers and Corporate Governance</a>	46
<a href="#">Item 11. Executive Compensation</a>	46
<a href="#">Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</a>	46
<a href="#">Item 13. Certain Relationships and Related Transactions, and Director Independence</a>	46
<a href="#">Item 14. Principal Accounting Fees and Services</a>	46
<b>PART IV</b>	
<a href="#">Item 15. Exhibits and Financial Statement Schedules</a>	47

## Disclosure Regarding Forward-Looking Statements

This Annual Report on Form 10-K, including the documents that we incorporate by reference, contains statements indicating expectations about future performance and other forward-looking statements. Forward-looking statements relate to future events or our future financial performance. We generally identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar words, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements regarding our or our management’s expectations, hopes, beliefs, intentions or strategies regarding the future, such as our estimates regarding anticipated operating losses, future performance, future revenues and projected expenses; our liquidity and our expectations regarding our needs for and ability to raise additional capital; our ability to manage our expenses effectively and raise the funds needed to continue our business; our ability to retain the services of our current executive officers, directors and principal consultants; our ability to obtain and maintain regulatory approval of our existing products and any future products we may develop; the initiation, timing, progress and results of our preclinical and clinical trials, research and development programs; regulatory and legislative developments in the United States and foreign countries; the timing, costs and other limitations involved in obtaining regulatory approval for any product; the further preclinical or clinical development and commercialization of our product candidates; the potential benefits of our product candidates over other therapies; our ability to enter into any collaboration with respect to product candidates; the performance of our third-party manufacturers; our ability to obtain and maintain intellectual property protection for our products and operate our business without infringing upon the intellectual property rights of others; the successful development of our sales and marketing capabilities; the size and growth of the potential markets for our products and our ability to serve those markets; the rate and degree of market acceptance of any future products; our reliance on key scientific management or personnel; the payment and reimbursement methods used by private or governmental third-party payers; and other factors discussed elsewhere in this report or any document incorporated by reference herein or therein.

The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “plan” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this report are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (many of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled “Risk Factors.” Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. The section entitled “Risk Factors,” as well as other sections in this report or incorporated by reference into this report, discuss some of the factors that could contribute to these differences.

The forward-looking statements made in this report relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events.

This report also contains market data related to our business and industry. These market data include projections that are based on a number of assumptions. While we believe these assumptions to be reasonable and sound as of the date of this report, if these assumptions turn out to be incorrect, actual results may differ from the projections based on these assumptions. As a result, our markets may not grow at the rates projected by these data, or at all. The failure of these markets to grow at these projected rates may have a material adverse effect on our business, results of operations, financial condition and the market price of our common stock.

MabVax<sup>(R)</sup>, MabVax Therapeutics<sup>(R)</sup> and our corporate logo are trademarks or registered trademarks of MabVax Therapeutics Holdings, Inc. All other brand names or trademarks appearing in this Annual Report are the property of their respective holders.

## PART I

### Item 1. Business.

#### Company Background

We are a Delaware corporation, originally incorporated in 1988 under the name Terrapin Diagnostics, Inc. in the state of Delaware, and subsequently renamed “Telik, Inc.” in 1998, and thereafter renamed MabVax Therapeutics Holdings, Inc. in September 2014. Our principal corporate office is located at 11535 Sorrento Valley Road, Suite 400, San Diego, CA 92121 and our telephone number is (858) 259-9405. On July 8, 2014, we consummated a merger with MabVax Therapeutics, pursuant to which our subsidiary Tacoma Acquisition Corp. merged with and into MabVax Therapeutics, with MabVax Therapeutics surviving as our wholly owned subsidiary. This transaction is referred to as the “Merger.” Our internet address is [www.mabvax.com](http://www.mabvax.com). Information on our website is not incorporated into this report.

On September 8, 2014, we filed an amended and restated certificate of incorporation to increase the authorized number of shares of our common stock to 150,000,000 shares, increase the number of shares of our authorized preferred stock to 15,000,000 shares, and change our name to “MabVax Therapeutics Holdings, Inc.”

#### Overview

We are a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics and vaccines for the diagnosis and treatment of cancer. Monoclonal antibodies are produced from a single DNA sequence encoded into multiple cells that all produce the same single antibody. We generate our pipeline of antibody-based product candidates from patients who have been vaccinated with propriety vaccines licensed from Memorial Sloan Kettering Cancer Center (“MSK”). Our approach involves surveying the protective immune response from many patients to identify the ideal monoclonal antibody candidate against a specific target on the surface of a cancer cell. We believe this approach provides us with a novel next-generation human antibody technology platform. We believe our approach to antibody discovery identifies the antibody candidates with superior performance characteristics while minimizing many of the toxicity and off target binding drawbacks (phenomenon occurring when antibodies bind to non-cancer cells) of other discovery technologies. Our lead antibody candidates have been recovered from patients who have been reported to have had substantially better treatment outcomes than other patients in the clinical trials conducted by us and our partners.

Our therapeutic vaccines were developed at MSK and are exclusively licensed to us pursuant to agreements entered into in 2008. These vaccines are administered in the adjuvant setting (the period following completion of conventional treatment and consisting primarily of watchful waiting) and have been shown to elicit a protective antibody response in clinical studies. The antibodies are intended to seek out circulating tumor cells and micrometastases (small clusters of cancer cells) to kill them before they can cause cancer recurrence. Our lead cancer vaccines targeting recurrent sarcoma (soft tissue cancer) and ovarian cancer are currently in proof of concept Phase II multi-center clinical trials. Both trials have received substantial federal grant monies to support their development.

#### Recent Developments

**Phase I Clinical Trial of HuMab-5B1** – In December 2015, we received notice from the FDA authorizing the initiation of a Phase I clinical trial with HuMab-5B1 as a therapeutic treatment for pancreatic cancer. We expect to begin patient enrollment at investigational sites in the first quarter of 2016. The Phase I trial will evaluate the safety, tolerability and pharmacokinetics of HuMab 5B1 as a single agent or in combination with a standard of care chemotherapy regimen in subjects with metastatic pancreatic cancer. The first cohort of patients will be enrolled in a traditional dose escalation regimen to assess safety and determine the optimal dose of the antibody. A second patient cohort will establish the safety and optimized dose of the antibody when administered with a standard of care chemotherapy. Two additional patient cohorts will be administered the optimized dose of antibody as a single agent, or in combination with a standard of care chemotherapy regimen, for the treatment of patients with pancreatic cancer. We will also assess the antibody’s impact on tumor response rate measured by RECIST 1.1 and duration of response looking for early signals of pharmacological response.

**Phase I Clinical Trial of 89Zr-HuMab-5B1** – In December 2015, we filed an Investigation New Drug (IND) application with the FDA for 89Zr-HuMab-5B1, utilizing our fully human antibody product as a new generation PET scan cancer imaging agent. In January 2016 we received FDA authorization to proceed with a Phase I clinical trial in patients with pancreatic cancer. We plan to initiate the Phase I clinical trial in early 2016. The 89Zr-HuMab-5B1 imaging agent has demonstrated high-resolution images of tumors in xenograft animal models, potentially making it an important new tool to aid in the diagnosis, monitoring and assessment of pancreatic cancer patients and an attractive companion diagnostic for the HuMab-5B1 therapeutic product. This second planned Phase I trial will evaluate the safety, pharmacokinetics and biodistribution of 89Zr-HuMab-5B1 in cancer patients. The trial will also purport to determine the ideal dose and conditions for an optimal PET scan image using the new imaging agent.

#### **Financing Activities**

**Oxford Loan** – On January 15, 2016, we entered into a Loan and Security Agreement with Oxford Finance LLC providing for senior secured term loans to us in the aggregate principal amount of up to \$10,000,000. On January 15, 2016, we received an initial loan of \$5,000,000 under the Loan and Security Agreement.

**Underwritten Offering** – On September 30, 2015, we entered into an underwriting agreement with Laidlaw & Company (UK) Ltd. relating to the issuance and sale in a public offering of 2,500,000 shares of our common stock and 1,250,000 three-year warrants to purchase 1,250,000 shares of our common stock at an initial exercise price of \$1.32 per share. The shares of common stock were sold at a public offering price of \$1.10 per share and the warrants were sold at a price of \$0.01 per warrant. The offering closed on October 5, 2015 with total gross proceeds to us of \$2,750,000.

**April Private Placement** – On March 31, 2015 and April 10, 2015, we entered into separate subscription agreements with accredited investors relating to the issuance and sale of \$11,714,498 of units at a purchase price of \$0.75 per unit, with each unit consisting of one share of common stock (or, at the election of any investor who, as a result of receiving common stock would hold in excess of 4.99% of our issued and outstanding common stock, shares of our newly designated Series E Preferred Shares) and a thirty month warrant to purchase one half of one share of common stock at an initial exercise price of \$1.50 per share (such sale and issuance, the “April Private Placement,” or the “Private Placement”). We conducted an initial closing of the April Private Placement on March 31, 2015 in which we sold an aggregate of \$4,995,750 of units. Following the initial closing we entered into separate reconfirmation agreements with the investors in order to extend the initial closing date, increase the offering amount, and adopt a lockup agreement which was entered into by all investors who elected to continue their investment. A second closing was held on April 10, 2015 in which we entered into separate subscription agreements for the sale of an additional \$6,718,751 of units.

On April 14, 2015, as a condition to participation by OPKO Health, Inc. (“OPKO”) and Frost Gamma Investments Trust (“FGIT”) in the April Private Placement, we entered into an Escrow Deposit Agreement with Signature Bank N.A. and OPKO, as amended on June 22, 2015, pursuant to which \$3.5 million from the April Private Placement was deposited into and held at Signature Bank. The escrowed funds were released us on June 30, 2015 as part of a letter agreement giving OPKO the right, but not the obligation, until June 30, 2016, to nominate and have appointed up to two additional members of the our Board of Directors, or to approve the person(s) nominated by the Company. The nominees will be subject to satisfaction of standard corporate governance practices and any applicable national securities exchange requirements.

**Preferred and Warrant Holders Common Stock Exchange Agreements** – On March 25, 2015, we entered into separate exchange agreements (collectively, the “Exchange Agreements”) with certain holders of our Series A-1 Preferred Stock and A-1 Warrants and holders of our Series B Preferred Stock and Series B Warrants, all previously issued by us. Pursuant to the Exchange Agreements, the holders exchanged their respective preferred shares and warrants and relinquished any and all other rights they may have pursuant to such securities, their respective governing agreements and certificates of designation, including any related registration rights, in exchange for an aggregate of 2,537,502 shares of our common stock and an aggregate of 238,156 shares of our newly designated Series D Convertible Preferred Stock (collectively the “Exchange Securities”).

## Market Opportunity for Antibody-based Therapeutics and Competition

Antibodies as targeted therapeutic treatments for cancer have become a significant market accounting for more than \$34 billion in worldwide revenue in 2013. Eight of the leading twenty therapeutic products for the treatment of cancer are antibodies. There are more than 150 monoclonal antibodies in development for cancer alone (the foregoing data is according to Global Data's commercial database Pharma eTrack and MABs, 2015;7(1):9-14). The focus on the development of new monoclonal antibody based drugs is expected to continue for multiple reasons. Over the last few years much has been learned about using the human immune system to treat cancer. Several recently approved antibody therapies have demonstrated remarkable efficacy in marshaling the human immune system to treat certain cancers. Targeted therapies can attack cancer cells while minimizing damage to normal cells in the patient. Antibodies are complex molecules and are difficult and expensive to duplicate with biosimilars and therefore have a potentially longer commercial life. Currently monoclonal antibodies receive very favorable reimbursement levels from federal, state, and private insurance providers. We believe that this favorable treatment is expected to continue.

Our lead antibody candidate targets an antigen over expressed on metastatic pancreatic, colon, breast, and small cell lung cancers. The term "over expressed" refers to the antigen being present on the surface of the cancer cell in very large numbers. Patients who develop metastatic disease with these cancers have a significantly poorer prognosis. In the case of pancreatic and small cell lung cancer we believe that there are no treatments currently available that specifically focus on metastatic disease. We are developing this lead antibody as a stand-alone therapeutic agent as well as combining it with a radiolabel for use as a novel PET imaging agent. According to the National Cancer Institute's ("NCI") SEER database, there are approximately 100,000 patients annually who develop metastatic disease from these cancers who could potentially benefit from this antibody if it is successfully developed. Both of these products have completed preclinical development and GMP manufacturing of Phase I clinical material. The U.S. Food and Drug Administration (FDA) has given its authorization to allow us to proceed with Phase I clinical trials for both the stand-alone product as well as the PET imaging agent. We intend to start enrolling patients for our therapeutic product HuMab-5B1 for the treatment of pancreatic cancer in the first quarter 2016. We intend to start enrolling patients for our PET imaging agent, 89Zr-HuMab-5B1 for the diagnosis of pancreatic cancer in early 2016.

In addition to developing our HuMab-5B1 as a stand-alone therapeutic agent as well as a PET imaging agent, we have initiated development of a HuMab-5B1 based radioimmunotherapy product for the treatment of pancreatic cancer. Using what we have learned from our 89Zr-HuMab-5B1 imaging program and working with the Radiology and Nuclear Medicine Departments of MSK, we have demonstrated the feasibility and experimental proof of concept for this new product. We anticipate completing the preclinical work on this product in mid-2016 and file a third IND for a HuMab-5B1 based product before the end of 2016.

We have established a collaboration agreement with Heidelberg Pharma GmbH for the development and evaluation of a HuMab-5B1 based antibody drug conjugate (ADC) product. We think that a much more potent follow-on product to our basic antibody therapeutic product will be a key addition to the HuMab-5B1 product portfolio as well as for treatment of difficult cancers. We have supplied Heidelberg Pharma GmbH with HuMab-5B1 antibody and they have created ADC constructs using their linker and toxin technology. These constructs are being tested in both *in vitro* and animal models of disease. We believe early results from both sets of experiments have been strongly encouraging and we are continuing this development effort.

We have initiated development efforts on a second antibody that targets an antigen over expressed on the surface of sarcoma, melanoma, and neuroblastoma. The use of a targeted antibody therapy in neuroblastoma in a study sponsored by NCI and published in the New England Journal of Medicine has demonstrated that antibodies targeting this antigen can be effective. We are focused on developing an antibody-based drug for the treatment of sarcoma. We believe that there are approximately 30,000 patients who could potentially benefit from this antibody if it is successfully developed. This product is in preclinical development.

Full enrollment was achieved in both the sarcoma and ovarian cancer vaccine Phase II clinical trials. Both clinical programs are following patients to the overall survival, or OS, endpoint that we expect could be reached in late 2016 or 2017. Our discussions with the FDA at the time we developed the protocols for our vaccine trials indicated that the OS endpoint was the primary criteria for their evaluation of the efficacy and safety of the vaccines.

## Product Candidates

### *HuMab-5B1 Antibody Program*

Of the many tumor restricted monoclonal antibodies resulting from immunization of mice with human cancer cells, the majority of antibodies have been directed against carbohydrate antigens (structures consistently expressed and are targets for therapeutic intervention) expressed at the cell surface. The carbohydrate antigen sialyl Lewis<sup>x</sup> (sLe<sup>x</sup>) is the antigen recognized by monoclonal antibody CA19.9 and it is widely expressed on tumors of the gastrointestinal tract. These tumor types are generally classified as epithelial tumors (a broad classification of tumor types) and include pancreatic, colon, stomach, ovarian, breast, and small cell lung cancers. A CA19.9 serum test is the only FDA validated marker for pancreatic cancer and is a commercial test that is readily available and used frequently to aid in the diagnosis of pancreatic cancer. Circulating epithelial cancer cells over-express sLe<sup>x</sup> (abbreviation for the antigen sialyl Lewis<sup>x</sup>) and as a ligand (binding partner) for E selectin (a structure in the inner lining of blood vessels) this antigen facilitates tumor—tissue interactions that are key events for tumor metastasis. Patient outcomes appear to be worse in patients with metastatic tumors expressing higher levels of sLe<sup>x</sup> according to articles published by T. Ben-David and colleagues in *Immunology Letters* in 2008 and YI Kawamura in *Cancer Research* in 2005. Because these tumor types express very high numbers of the sLe<sup>x</sup> antigen on their cell surface, it makes the antigen an attractive target for therapeutic intervention.

We have created a series of fully human monoclonal antibodies against sLe<sup>x</sup>. One antibody in particular, HuMab-5B1, has demonstrated exceptionally high affinity and specificity for sLe<sup>x</sup>, and has very good efficacy in multiple tumor xenograft models (human cancer cells engrafted into mice) in studies conducted by MSK. Designated HuMab-5B1, this is a fully human full-length monoclonal antibody we discovered from the immune response of seven stage IV breast cancer patients who were being vaccinated in a Phase I trial in 2008 at MSK with one of our licensed vaccines.

We have conducted tissue microarray work (normal and cancer tissue samples placed on slides treated with the antibody to determine if an antibody binds to such tissue samples) with commercially available tissue samples of both normal and cancer tissues. The results of this work indicated that the HuMab-5B1 antibody bound to multiple types of epithelial tumors, including pancreatic, colon, bladder, ovarian, breast, and small cell lung cancer tissues. The antibody did not bind to normal tissues except for the exocrine cells at the ductal border of secretory cells (primarily cells in the gastrointestinal tract that face into the digestive system and not inward to the body) in epithelial tissues; those sites are less accessible to the immune system. This experimental work was confirmed in FDA mandated GLP tissue cross-reactivity studies done in both human and cynomolgus monkey tissues by an independent research organization. Both characteristics combined with the significant cytotoxicity demonstrated in *in vitro* testing led us to move to xenographic animal model testing. HuMab-5B1 has demonstrated in our pre-clinical studies good anti-tumor activity in a variety of animal models with multiple tumor types. Specifically, we have obtained positive results from animal models examining human pancreatic, colon, and small cell lung cancers.

We entered into a manufacturing agreement with Patheon Biologics LLC (f.k.a. Gallus BioPharmaceuticals) to manufacture clinical supplies of the antibody which were completed in 2015. In May of 2015 we announced the results of our GLP toxicology study for the HuMab-5B1 antibody. We challenged non-human primates in an acute dose range finding study with multiple dose levels to assess drug pharmacokinetics, as well as with repeated doses of the antibody to identify any adverse toxicology signals. These studies were conducted in the most relevant animal models with material produced by our GMP manufacturing partner. The antibody as tested is representative of the clinical supply material. The final report provided evidence that there were no significant adverse findings in the animal model which allowed the Company to move forward with our plan to enter the clinic in a Phase I study. We submitted an IND for the therapeutic product in November of 2015 and on December 24, 2015, we received FDA authorization to initiate the Phase I study. We plan to start patient enrollments in the first quarter of 2016 to determine the safety and pharmacokinetics (assessment of the distribution and metabolism of a drug) of the HuMab-5B1 antibody in patients with pancreatic cancer. We expect the preliminary results of our Phase I studies to be available in the third quarter 2016 with full Phase I results in early 2017.

### ***HuMab-5B1 Imaging Program***

Circulating biomarkers (substances released by certain cells that can be measured to assess if a patient has or is likely to have a particular type of cancer) such as CA19.9 are important clinical tools for early detection and diagnosis as well as monitoring of therapeutic progress and detection of tumor recurrence in oncology. However, false positive readings due to biomarker production from benign disorders in unrelated host tissues are a significant problem. We believe that probing the site(s) of biomarker secretion with an imaging tool could be a broadly useful strategy to enhance the fidelity of diagnosis and staging of cancers such as pancreatic ductal adenocarcinoma, or PDAC, a notoriously occult (difficult to diagnose and treat) cancer. Moreover, such a tool could guide patient stratification for directed therapeutic intervention, surgical planning and aide in the evaluation of tumor response to chemotherapy and radiation therapy. To address this opportunity clinically, together with Dr. Jason Lewis' radiochemistry laboratory at MSK, we developed 89Zr- HuMab-5B1, a fully human, antibody-based radiotracer (combined antibody and radiolabel) targeting tumor-associated CA19.9. In preclinical studies, 89Zr- HuMab-5B1 localized to tumors in multiple models representing diseases with both undetectable and clinical relevant circulating CA19.9 serum levels. Among these, 89Zr- HuMab-5B1 detected tumor in an orthotopic model (xenograph model where human cancer cells are surgically implanted in the corresponding organ of the mouse) of PDAC, an elusive cancer for which the serum assay (actual test for a biomarker) is measured in a human, but with limited specificity in part because of the frequency of CA19.9 secretion from benign hepatic pathologies (certain non-cancer conditions such as inflammation causing the production of the target biomarkers resulting in a false reading). Of further note, in preliminary experiments, 89Zr- HuMab-5B1 showed better tumor specificity (targeting only a specific type of cancer cell) compared to the commonly used 2-deoxy-2-(18F)-fluoro-D-glucose, or FDG, imaging agent, which relies on increased tumor metabolism relative to nonmalignant cells, and is known to lack sensitivity and specificity in pancreas cancers and other slow growing cancers.

To facilitate the development of the HuMab-5B1 based antibody conjugated to a radiolabel as a novel PET imaging agent for pancreatic cancer, we applied for and received a development contract from NIH pursuant to which NIH may provide up to \$1.75 million in non-dilutive funding for this project. On January 29, 2016, the FDA authorized us to proceed with the IND we filed on December 29, 2015. We intend to begin patient enrollments in a Phase I study in early 2016, and expect to have preliminary results by the third quarter 2016, with full Phase I results in 2017.

### ***HuMab-5B1 Antibody Drug Conjugate***

We observed in our clinical studies that certain types of cancer cells internalized the HuMab-5B1 antibody. These were primarily pancreatic cancer tumor types. We believe that this characteristic of the HuMab-5B1 antibody could be highly useful in constructing an antibody-drug conjugate. The development of antibody-drug conjugates is an area of intense competitive development with few companies capable of producing viable linker and toxin technologies that can be coupled with an antibody which, in this case, serves as the targeting mechanism. According to an analysis conducted utilizing the online database Global Data, over the last few years more than 21 technology access licensing deals worth more than \$6 billion have been completed by biopharmaceutical companies to gain access to these technologies.

### ***Other Research Collaborations***

We were able to identify and form collaborations with Heidelberg Pharma GmbH, which has developed its own proprietary linker and toxin technology. For the collaboration, we were able to supply the HuMab-5B1 antibody and Heidelberg has conducted both in vitro and in vivo experiments demonstrating the significant potential utility of this combination. We are hoping to expand this collaboration and continue a joint development program to bring this new product to the clinic.

### ***HuMab-5B1 Antibody Follow-On Product Opportunities***

Under our collaboration with Rockefeller University's Laboratory of Molecular Genetics and Immunology, we provided antibody material to Rockefeller for which it is exploring the mechanism of action of constant region (Fc) variants of the HuMab-5B1 in the role of tumor clearance. We will supply additional research materials as requested by the university, which is evaluating ways to optimize the function.

## **Follow-on Antibody Products from Our Discovery Library**

### ***1B7 and 31F9 Antibody Program***

We have discovered multiple fully-human antibodies to the antigen GD2, which is significantly over expressed on sarcoma, melanoma, and neuroblastoma. These are three related cancers classified as neuroectodermal cancers (sarcoma, melanoma, neuroblastoma). We discovered these antibodies by examining the immune response from more than 60 patients who participated in our sarcoma vaccine trial over the last three years. According to an article published in the New England Journal of Medicine by Alice L. Yu and colleagues in 2010, antibodies against GD2 have already been validated as effective therapeutic agents in a well-controlled Phase III clinical trial that produced statistically significant improvement in time to progression of disease in children suffering from neuroblastoma. Each of the two potential development candidates have specificity and affinity for the GD2 target and demonstrate significant ability to kill cancer cells that express GD2. Each antibody has a unique set of characteristics and, as part of the preclinical evaluation program, researchers at MSK will provide further *in vitro* and *in vivo* testing in multiple models of disease to help us decide which candidate to move forward toward clinical testing. We are currently targeting sarcoma as the primary indication for which we plan to develop an anti-GD2 antibody product.

### ***Antibody Discovery***

We have discovered and recombinantly expressed multiple fully human antibodies to eleven separate antigenic targets over expressed on multiple types of cancer. The antigenic targets are incorporated in various combinations making up the eight vaccines that were licensed from MSK and have been in at least Phase I clinical trials. To date, six separate vaccines have entered early stage clinical programs and we have received antibody discovery material from all patients who participated in five of the trials. Exclusive access to these patient samples is covered under separate licenses with MSK. We have discovered multiple antibodies to important cancer targets such as MUC1, GD3, GM2, Fucosyl-GM1, Globo-H, Tn, sTn, and TF. As we continue to raise additional capital and add capacity, it is our intention to begin moving these early product development candidates forward toward clinical evaluation.

### ***Juno Option Agreement***

In August 2014, MabVax Therapeutics entered into an option agreement with Juno Therapeutics, Inc. pursuant to which it granted Juno the option to obtain an exclusive, world-wide, royalty-bearing license authorizing Juno to develop, make, have made, use, import, have imported, sell, have sold, offer for sale and otherwise exploit certain patents MabVax Therapeutics developed with respect to fully human antibodies with binding specificity against human GD2 or sialyl-Lewis A antigens and certain MabVax Therapeutics controlled biologic materials. Juno may exercise its option to purchase the license until the earlier of June 30, 2016, or 90 days from the date MSK completes its research with respect to the patents in accordance with the terms of agreements by and between MSK and MabVax Therapeutics. As consideration for the grant of the exclusive option to purchase the license, Juno paid us a one-time up-front option fee of \$10,000. If Juno exercises the option, we intend to negotiate terms of a license that could contain license fees, milestone payments, and royalty-based compensation, if an agreement is reached.

## **Current Approach to Treatment of Pancreatic Cancer**

According to an article in the *Journal of Advanced Practitioner in Oncology*, or *Advanced Practitioner*, by Sheena Daniels, DNP, ARNP, FNP-BC and colleagues in 2011, for the more than 80% of patients diagnosed with pancreatic cancer who will not be candidates for resection and a large number (80%) of patients who were able to have resection but will develop metastases within 2 to 3 years, the drug gemcitabine has been established as the standard of care because of its documented advantage in OS and more favorable side-effect profile. In patients who are not resectable (able to remove through surgery), combination therapy with a gemcitabine-based systemic regimen followed by consolidation with chemoradiation has produced some favorable median survival durations.

## **Newer Therapeutic Agents**

According to Daniels' article in the *Advanced Practitioner*, in spite of aggressive treatment, patients with unresectable pancreatic cancer have a median survival of 10 to 14 months and an estimated 1 in 4 patients who undergo pancreatic resection do not recover sufficiently from surgery to allow administration of systemic chemotherapy. Newer targeted agents have been studied in combination with gemcitabine but did not correlate with improved OS. However, according to Daniel, the combination of gemcitabine and erlotinib did improve overall survival from 5.91 months to 6.24 months and 1-year survival improved to 23% vs 17%. These results were not duplicated using multi-targeted kinase inhibitors. There are several ongoing trials combining additional chemotherapeutic agents with gemcitabine and early results show improvements in PFS and OS but come at a significant cost of increased adverse events. Nab-paclitaxel combined with gemcitabine has produced positive results in an early Phase II trial and those results were confirmed in a subsequent Phase III trial. Nab-paclitaxel is now approved for treatment of pancreatic cancer and the combination of gemcitabine and Nab-paclitaxel is considered first line therapy in many institutions.

We believe there is a significant unmet medical need for newer agents that can treat metastatic disease. Pancreatic cancer is an area of intense research with much of the late stage clinical development efforts targeted toward advanced and metastatic disease. According to the online database BCIQ from BioCentury, to date there are 92 products in all three stages of clinical development from a total of 86 companies and there are 14 products in Phase III or pivotal trials at this time.

## **Potential Market Opportunity for the Full Length Therapeutic Antibody HuMab-5B1**

We believe there is a critical unmet medical need for new and better treatment for metastatic pancreatic and colon cancer. According to the National Cancer Institute's SEER database, the five-year survival rate for patients with metastatic pancreatic cancer is just 1.8%. There are 43,000 new pancreatic cancer patients per year and more than half of them present at initial diagnosis with metastatic disease. According to the SEER database, the five-year survival rate for patients with metastatic colon cancer is only slightly better at 12%. According to the SEER database, while most of the 141,000 new patients can be treated successfully initially, almost half of all colon cancer patients will develop metastatic disease. Thus, adding the number of metastatic disease patients for these two cancers alone represent 96,000 new metastatic cancer patients per year. Using the cost of current antibody therapies as a baseline, the market potential for an annual patient population of 96,000 is in excess of \$1 billion per year.

## **Pancreatic Cancer Imaging and Diagnosis**

We believe that the radiolabeled HuMab-5B1 antibody represents the only human derived agent in development specifically aimed at improving imaging in pancreatic cancer. Since the antigen targeted by the HuMab-5B1 antibody is significantly and preferentially over expressed on metastatic pancreatic cancer, this development effort represents a potentially important step forward in the diagnosis, staging, and assessment of the majority of pancreatic cancer patients. We believe that the market opportunity for a HuMab-5B1 antibody-based radiopharmaceutical is significant in multiple ways. The ability of physicians to accurately diagnose, stage, and assess treatment outcomes in pancreatic cancer would be very important. Accurate determinations on the extent of disease and resectability are essential to improve outcomes in this cancer. We believe almost all patients diagnosed with pancreatic cancer could potentially benefit from 89Zr-HuMab-5B1 scan. Accordingly, improvements in the sensitivity and specificity of one of the primary diagnostic tools could have a significant impact on clinical outcome.

Currently, according to Daniels' article in the *Advanced Practitioner*, all screening methods for pancreatic cancer have limitations. The symptoms associated with the disease are often vague and attributed to other more benign etiologies. Diagnosing pancreatic cancer is often challenging, as the presenting symptoms of pancreatic, hepatobiliary (portion of the liver, pancreas, and biliary tract), and upper gastrointestinal cancers are similar. Screening for pancreatic cancer, according to Daniel, is difficult primarily because there are no tumor markers that can be screened at an early stage of disease. Therefore, according to Daniel, the majority of pancreatic cancers are diagnosed at a late stage of disease hampering efforts to provide curative therapy. Pancreatic cancer is typically diagnosed by a combination of history and physical examination, coupled with CT, ultrasound, and PET imaging. In patients deemed to be at high risk for metastasis or for whom the staging is indeterminate, the diagnosis is confirmed by fine needle aspiration or laparoscopy along with FDG-PET. Accurate staging, particularly identification of distant metastases, is of paramount importance in order to properly select patients who are the most likely to benefit from surgery. Differential diagnosis between pancreatic cancer and pancreatitis (non-cancerous inflammation of the liver) is a common problem with imaging modalities.

## **Recent Developments in ImmunoPET Imaging**

2-deoxy-2-(18F)-fluoro-D-glucose, or FDG, combined with PET imaging alone, or FDG-PET, combined with CT scanning, or FDG-PET/CT, is commonly used to augment the diagnosis and staging of pancreatic cancer. According to an article in *The American Journal of Surgery* by Lan and colleagues in 2012, FDG-PET is the principal imaging agent available today for enhanced PET imaging for pancreatic cancer. FDG is a radiolabeled form of glucose and because cancer cells normally have elevated metabolic rates, highly active cells will incorporate this glucose marker and as a result can potentially help pinpoint pancreatic cancer and potential metastases.

To date, there have been 17 studies examining the accuracy of FDG-PET and the conclusions are mixed. While studies are heterogeneous (not of a similar type; not uniform), the utility of FDG-PET was reasonably established for the primary diagnosis purposes only, utility of FDG-PET/CT for determining recurrence and staging was not confirmed. Additional studies have evaluated the diagnostic thinking impact of FDG-PET with regards to patient management and diagnostic work-up of pancreatic cancer. Findings from FDG-PET lead to changes in the pre-treatment staging as well as the decisions regarding treatment management because of changes in resectability status. The majority of findings demonstrated previously unsuspected metastases and resulted in cancellation of previously planned surgical resection. Roughly half the time the newly identified metastases had not been detected by initial CT scans.

The cost-effectiveness of adding FDG-PET to the routine diagnostic procedures to determining staging and eligibility for surgery among patients with presumed resectable pancreatic cancer has been examined in a limited number of studies. Cost savings were identified primarily by identifying patients who were initially staged for surgery and later deemed ineligible because of detected metastases.

Although FDG is used extensively and successfully in many cancers, because of the targeting characteristics of this compound as a marker of glucose metabolism, the sensitivity and specificity of FDG are not optimal in all cancer types. The shortfalls of imaging with FDG, such as inadequate differentiations between post-therapy inflammation and tumor, poor imaging in slow-growing tumors, and high uptake in normal cells such as brain and gut, have remained as the justification for the development of newer PET tracers.

## **FDG-PET Reimbursement**

The Department of Health and Human Services has completed a Technology Assessment for FDG-PET in pancreatic cancer. The Centers for Medicare and Medicaid Services, or the Center, utilized the Technology Assessment and has issued a National Coverage Determination for FDG for oncologic conditions. The Center has elected to cover the expense of using FDG-PET for the diagnosis and staging of pancreatic cancer. However, the Technology Assessment found insufficient support for fully covering FDG-PET for restaging and monitoring response to treatment. Private insurance carriers follow the Center's recommendation and cover FDG-PET for diagnosis and staging.

## **Potential Market Opportunity for PET Imaging Agents**

To our knowledge, the radiolabeled HuMab-5B1 antibody represents one of the only agents in development specifically aimed at improving imaging in pancreatic cancer. Since the antigen targeted by the HuMab-5B1 antibody is significantly and preferentially over expressed on metastatic pancreatic cancer, this development effort represents a potentially important step forward in the diagnosis, staging, and assessment of the majority of pancreatic cancer patients. Using an imaging agent that is specific for a pancreatic cancer antigen would be greatly preferable to an indirect marker that can produce false positive results in high metabolic rate tissues (tissues where there is an elevated metabolism of sugar due to a variety of causes including cancer) or a false negative in slow growing cancers. We believe that the market opportunity for a HuMab-5B1 antibody-based radiopharmaceutical is significant in multiple ways. First the ability of physicians to accurately diagnose, stage, and assess treatment outcomes in pancreatic cancer would be very important. Accurate determinations on extent of disease and resectability are essential to improving outcomes in this cancer. We believe improvements in the sensitivity and specificity of one of the primary diagnostic tools would be useful and that potentially almost all patients diagnosed with pancreatic cancer could benefit from a 89Zr-HuMab-5B1 antibody scan. Using existing utilization and reimbursement rates for the current standard of care product, FDG-PET, we believe annual revenues for a HuMab-5B1 antibody-based radiopharmaceutical could exceed \$100 million per year. Since the regulatory pathway is less expensive and time consuming than a therapeutic agent, we believe that this companion diagnostic product opportunity will complement the full-length therapeutic antibody and antibody-drug conjugate products.

This project is also important to us because of the potential enablement of the full-length therapeutic antibody. The 89Zr-HuMab-5B1 antibody will be essential in the clinical development of the HuMab-5B1 antibody. It would help improve our understanding of the antibody's in vivo behavior including the interaction with its critical disease target, mechanism of action, distribution, and potential toxicities. Just as important, we believe the 5 HuMab-B1 antibody-based radiopharmaceutical would enable physicians to identify patients with the greatest chance of benefiting from treatment with the antibody and that the HuMab-5B1Db-based radiopharmaceutical would enable accurate diagnosis, staging, and assessment of treatment outcome of a new antibody treatment for advanced pancreatic cancer.

### **License Agreement with MSK**

We have licensed from MSK the exclusive world-wide developmental and commercial rights to receive biological materials from vaccinated clinical trial participants enrolled in any of the clinical trials involving the vaccines licensed to us, allowing us to discover human monoclonal antibody-based therapeutics. MSK has issued patents or has pending patent applications on the vaccine antigen conjugates, mixtures of vaccine antigen conjugates and methods of use. This patent portfolio includes 25 issued patents in the US and the rest of world along with 2 patent applications. We own all monoclonal antibodies produced by the antibody discovery program and we generally file patent applications directed to these antibodies once their potential therapeutic utility has been sufficiently demonstrated in animal models. A United States and an international patent application for each of the anti-sLea antibodies and the anti GD2 antibodies described in this document has been filed.

We are unique in that only a very small number of oncology focused companies are vaccinating patients with carbohydrate-based vaccines intended to elicit an antibody response and, to the best of our knowledge, we are the only company deriving antibodies from the lymphocytes of vaccinated patients. Since these carbohydrates are very difficult to make immunogenic and the carbohydrates cannot be easily manufactured, it is very difficult if not impossible to find a source for human antibodies to these antigens beyond that utilized by us.

### **Vaccine Program**

We have licensed exclusive rights from MSK to exploit key aspects of the work of Dr. Livingston (who is also a member of our board of directors) and colleagues, who over the last 30 years have developed a series of monovalent (targeting a single tumor cell surface antigen) cancer vaccines against cancers of neuroectodermal and epithelial (breast, ovarian colon, pancreatic) origin as well as small cell lung cancer (SCLC). These target molecules on malignant cells, known as carbohydrate antigens, are the most extensively expressed antigenic targets on the cell surface of these types of cancers and play a key role in tumor progression and metastasis. We expect to benefit from the years of work and significant expense already invested in the development and testing of the vaccines incorporating these antigens. Researchers at MSK have progressively developed highly immunogenic monovalent vaccines to each of the 11 validated target antigens that comprise the licensed vaccines. These monovalent vaccines or the combination of the monovalent forms into polyvalent vaccines (targeting multiple antigens) have been tested and refined not only in animal models but also in multiple clinical trials establishing immunogenicity, tolerability, and therapeutic utility. Our license agreement with MSK calls for MSK to complete all preclinical and Phase I clinical trial work at MSK's expense at which point the Investigational New Drug Application, or IND, would be transferred to us for continued development.

Our lead cancer vaccines targeting recurrent sarcoma and ovarian cancer are currently in proof of concept Phase II multi-center clinical trials. Both trials are fully enrolled, and have received substantial federal grant monies to support their development.

### **Our Vaccines Intend to Address Recurrent Cancer, an Unmet Medical Need**

Despite undergoing potentially curative surgical resection or combination therapy, a significant number of patients with cancer will have their cancer recur. Patients with recurrent cancer have a significantly lower survival rate and incur much higher medical costs compared to those whose disease does not recur. Multiple clinical studies have demonstrated that additional courses of chemotherapy or radiation in the adjuvant setting do not or only minimally improve outcomes for these patient groups. Thus, in the majority of cases, the current standard of care following treatment of metastatic disease and the achievement of disease-free status is watchful waiting. Sarcoma references: Potter DA, et al: J Clin Oncol 3:353-66, 1985, Rizzoni WE, et al: Arch Surg 121:1248-52, 1986, Casson AG, et al: Cancer 69:662-8, 1992. Ovarian references: Armstrong DK, et al N Engl. J Med 354:34-43, 2006, Markman M, et al: J Clin Oncol 22:3120-3125, 2004. Consequently, there is an unmet medical need for new treatments for recurrent disease.

## **Medical Solution and Rationale**

According to the article *Cancer Vaccines Targeting Carbohydrate Antigens* published in *Human Vaccines* by Livingston and colleagues in 2006, the adjuvant setting is the ideal time for immune intervention and in particular for administration of monoclonal antibodies or cancer vaccines aimed at instructing the immune system to identify and kill the few remaining circulating cancer cells. We believe that passively administered or vaccine induced antibodies against selected cell surface antigens are ideally suited for eradication of free tumor cells and micrometastases. This is the role of antibodies against most infectious diseases, which has been accomplished against cancer cells in a variety of pre-clinical models and recent clinical trials. We also believe that if antibodies of sufficient titer can be administered or induced by vaccination against tumor antigens to eliminate tumor cells from the blood and lymphatic systems and to eradicate micrometastases, this could dramatically change the approach to treating the cancer patient. If successful, establishment of new metastasis would no longer be possible, so aggressive local therapies including surgery or radiation therapy, and intralesional (injection of cancer treatment directly into a tumor) treatments, combined with our immunotherapeutic agents could result in long-term control of metastatic cancers.

## **Vaccine Purpose Determines Vaccine Design**

According to Livingston's article in *Human Vaccines*, the majority of carbohydrate antigens are recognized exclusively by B-lymphocytes and antibodies and the optimal approach for augmenting antibody responses against defined antigens involves conjugation of the antigens to a highly immunogenic carrier protein. This is the approach currently used in a variety of vaccines against bacterial pathogens and is the approach we believe to be optimal for cancer associated carbohydrate antigens (antigens/targets made of carbohydrates; also known as sugar structures) as well.

## **Previous Human Clinical Experience**

There are an increasing number of clinical trials showing that passively administered monoclonal antibodies, or mAbs, against cell surface antigens such as HER2/neu, EGF receptor, VEGF, CD20, CD33 and CD52 have demonstrated clinical efficacy against human cancers and leukemias. Specifically, according to an article titled *Adjuvant trastuzumab therapy for HER2-positive breast cancer* published in *Clinical Breast Cancer* by Mohammad Jahanzeb there is evidence from a series of recently described clinical trials with Trastuzumab (Herceptin(R), against HER2/neu) used in breast cancer patients in the adjuvant setting confirming a striking recurrence free and overall survival advantage. This is a more dramatic response than seen with the same mAb used in the more advanced disease setting. Finally, naturally acquired or vaccine induced antibodies against cancer cell surface antigens such as GM2 and sTn have correlated with improved prognosis in several different clinical settings. Murine (mouse origin) monoclonal antibodies 3F8 against GD2 and R24 against GD3 have each induced clinical responses in a significant proportion of melanoma patients in the advanced disease setting. 3F8 and R24 are murine monoclonal antibodies and so can only be administered briefly before human anti-mouse antibodies, or HAMA, induction leads to decreased clinical availability.

There has been a significant amount of clinical work in the development of the monovalent and polyvalent versions of these cancer vaccines that stretches over two decades. In the Investigator's Brochure portion of the INDs submitted to FDA on behalf of the sarcoma and ovarian cancer vaccine trials, we list the 30 Phase I clinical trials testing immunogenicity and tolerability of each of the monovalent vaccines to date. Refinements in antigen configuration, selection of carrier molecules, selection of adjuvant, vaccination schedules, and dose ranging have all lead to the optimal configuration of the current vaccines. According to Livingston's article *Cancer Vaccines Targeting Carbohydrate Antigens* published in *Human Vaccines*, the current monovalent vaccines all induce an immune response of IgM and IgG antibodies capable of killing targeted cancer cells.

## **Concern for Autoimmune Disease**

Antigens on cancer cells are generally either autoantigens or slightly modified autoantigens (antigens or targets that do not trigger an immune response) so autoimmunity is a concern with any cancer vaccine. This concern is either as a consequence of cross reactivity of the specific immune response generated against cancer antigens (also present on normal organs) or as a consequence of immune modulation resulting from the immunological adjuvant or other components of the vaccine that may generate non-specific immune modulation. These concerns are largely mitigated, however, by the extensive experience and low toxicity profile consistently observed with the individual components of this vaccine in the clinic either alone or paired up with other components of this vaccine.

## **Sarcoma Vaccine**

### ***Background***

Sarcomas are rare neoplasms (tumor that has caused a lump) that arise from the mesenchymal (connective tissue such as bone or cartilage) tissues of the body. According to the NCI's website, in the United States, there are approximately 13,000 cases diagnosed each year, representing less than 1% of all new cancers. Of these sarcomas, roughly 80% originate from soft tissue, with the remainder originating from bone. Prognosis remains poor, with more than 5,000 patients in the United States dying of disease each year. The overall prevalence of sarcoma patients in the US is thought to be approximately 100,000. All incidence and survival data from National Cancer Institute SEER data.

As in other malignancies, disease recurrence and metastasis are common in sarcoma. Metastases may involve any organ of the body, but, according to the NCI's website approximately 20% of adult patients with extremity sarcomas will have isolated lung metastasis at some point during their disease course, with some amenable to complete surgical resection. Additional patients will have solitary or oligometastatic (cancer that has spread to multiple locations throughout the body) disease affecting other sites of the body that will be amenable to complete resection. Favorable prognostic indicators in recurrent sarcoma include a long disease-free interval from the time of primary resection, the number and location of metastatic lesions, and a long tumor doubling time.

Osteosarcomas (bone based sarcomas), rhabdomyosarcomas (sarcomas arising from muscle tissue), and other non-rhabdomyosarcomas such as Ewing sarcoma (tumor arising in bone or soft tissue and primarily occurring in teenagers and young adults) are high-risk sarcomas that occur most commonly in teens and young adults. According to the NCI's website, approximately 30% of patients will present with metastases or recur following initial therapy for metastatic disease. These recurrences are generally treated with a combination of chemotherapy, surgery, and/or radiotherapy, with more than 90% of these patients achieving a complete response to therapy according to the NCI's website.

Despite undergoing potentially curative surgical resection or combination therapy, according to an article titled Patterns of recurrence in patients with high-grade soft-tissue sarcomas. J Clin Oncol 3:353-66, 1985 by DA Potter and colleagues published in the Journal of Clinical Oncology, the majority of recurrent sarcoma patients die as a result of further recurrences. The overwhelming majority of pediatric patients ultimately succumb to their disease following the development of recurrent, chemoresistant disease, and their prognosis remains unacceptably poor despite aggressive multimodality treatment. The addition of chemotherapy to surgical resection has not been shown to improve outcome in adult sarcomas. Thus, in the majority of cases, the current standard of care following treatment of metastatic disease and the achievement of disease-free status is expectant management.

### ***Sarcoma Vaccine Clinical Program***

We initiated a randomized, multicenter, double-blind Phase II clinical trial in July of 2010. A total of 136 patients were enrolled. Patients who entered the study had stage IV metastatic disease and were cleared by surgery. Patients were vaccinated 10 times over 84 weeks and monitored throughout the study period. The study was powered to show a statistical improvement in both progression free survival (measured at the mid-point of the study) and overall survival. In October of 2013, the Company presented the mid-point results to the independent Drug Safety Monitoring Board, or DSMB. The DSMB concluded that there were no unanticipated or clinically worrisome safety concerns. Injection site reactions were the most common adverse events followed by fatigue, fever, and flu-like symptoms. In addition, the DSMB recommended that investigators and patients should remain blinded as to treatment assignment and the patients should continue to be followed to assess overall survival. In addition, given the acceptable safety profile observed in both arms of the study, the DSMB recommended that after investigators and patients are informed of the (blinded) results of this analysis and with their consent, the last of the patients still receiving vaccinations should be allowed to continue treatment.

In this study, the sarcoma vaccine elicited an antibody response intended to kill circulating tumor cells and micrometastases in all but one of the vaccinated patients. However, the DSMB concluded that the study did not reach statistical significance for its primary efficacy endpoint of a 50% improvement in time to recurrence. The study has not yet accumulated a sufficient number of events to evaluate the secondary endpoint of overall survival. Based on our discussions with the FDA prior to the initiation of the study, the overall survival endpoint will be considered the primary endpoint for the measurement of efficacy. As such we plan to follow all patients in the study until sufficient numbers of events (deaths) have occurred to allow analysis of this endpoint. We expect that the event threshold will be reached in late 2016 or early 2017.

### **Potential Commercial Opportunity**

Sarcomas are a diverse group of malignant tumors that develop from fat, muscles, nerves, joints, blood vessels, bones, and deep skin tissues. Soft tissue sarcomas are more deadly in part due to the lack of detectable symptoms at early disease stages and prognosis remains poor, with more than 5,000 patients in the U.S. dying of disease each year according to the NCI. The NCI estimates 5-year survival rates of 60%. Additionally, according to the NCI, an article in *CA: A Cancer Journal for Clinicians* by A. Jemal published in 2006, and articles published by the American Cancer Society, the overall prevalence of sarcoma patients in the U.S. is thought to be approximately 100,000. Recurrence rates vary depending on the particular subtype of sarcoma but generally range from 30% to 50% and patients whose sarcoma recurs have a significantly poorer prognosis which declines even further as the number of recurrences increase over the course of the disease.

The current standard of care for patients who have been successfully treated for their cancer and rendered free of detectable disease is watchful waiting. According to The Lancet Oncology report in 2012, additional treatments of chemotherapy or radiation have not been proven to prevent or prolong the time to onset of cancer recurrence. Consequently, we anticipate that the sarcoma vaccine will be added as an additional treatment to the current treatment paradigm and not displace an existing treatment. We expect that patients who have experienced one or more recurrences will be the initial candidates for vaccine therapy. This would be consistent with the early clinical trials. Over time, as the product demonstrates utility, we anticipate that usage will migrate toward earlier and earlier treatment to include patients who have been diagnosed and treated for sarcoma but not yet experienced a recurrence in an effort to block the progress of the cancer at an earlier and more likely productive time period.

### **Ovarian Vaccine Program**

#### **Background**

According to the NCI, ovarian cancer is the most lethal gynecologic cancer. According to materials available on the NCI's website there are more than 21,800 new cases each year with almost 14,000 deaths per year. It is estimated that there are 174,000 surviving ovarian cancer patients. Recurrence rates are extremely high at 70% and 5-year survival is still very poor at just over 40%. The current standard treatment for patients with advanced ovarian cancer consists of aggressive surgical cytoreduction (resection of a tumor to the extent possible followed by radiation treatment) followed by taxane (chemical anti-cancer drug) and platinum-based chemotherapy. While the median overall survival for optimally debulked patients has increased to 65.6 months, less than 30% of patients will remain free of disease. Many patients will have chemotherapy-sensitive disease initially at recurrence, and can reenter successive remissions with additional treatment. Subsequent remissions are of progressively shorter duration until chemotherapy resistance uniformly develops. We believe that immune directed therapy is ideally suited for patients who are in clinical remission when the disease burden is lowest, and evaluating treatments designed to prolong the duration of such remissions remains a high priority. We also believe that antibodies are well suited for eradicating tumor cells from the bloodstream and eliminating early tissue invasion. Preclinical models have demonstrated the clearance of circulating tumor cells and the elimination of systemic micrometastasis through the use of both passively administered and vaccine induced antibodies.

Ovarian cancers express a rich array of cell-surface antigens. These include carbohydrate epitopes such as GM2, Globo-H, Lewis y, sialyl Tn, or STn, Tn, Thompson Friedreich antigen, or TF, and mucin 1, or MUC1. According to an article titled Tumor cell reactivity mediated by IgM antibodies in sera from melanoma patients vaccinated with GM2 ganglioside covalently linked to KLH is increased by IgG antibodies. *Cancer Immunol Immunother* 43:324-30, 1997 published in *Cancer Immunology Immunotherapy* written by Dr. Livingston., for the production of antibodies against defined cell-surface antigens such as these, the best approach has been described to include chemical conjugation of the antigen to a highly immunogenic carrier protein plus the use of a potent immunological adjuvant. The best carrier protein in our experience has been keyhole limpet hemocyanin (a sea creature such as a limpet or snail from which copper-based highly immunogenic blood is extracted), or KLH, and the best immunological adjuvant has been a saponin such as QS-21 or OPT-821. Pre-clinical data supports the hypothesis that polyvalent vaccines will likely be required due to tumor cell heterogeneity, heterogeneity of the human immune response, and the correlation between overall antibody titer against tumor cells and antibody effector mechanisms.

## ***Ovarian Vaccine Clinical Program***

A randomized, multicenter, double-blind Phase II clinical trial in ovarian cancer with a pentavalent (a vaccine that has multiple antigens) vaccine was initiated in July of 2010. While this vaccine was included in the group of vaccines exclusively licensed to us in 2008, a NIH grant award co-authored by Dr. Philip Livingston was made which fully funded the planned Phase II clinical trial. Management of the trial was assigned to the Gynecologic Oncology Group, or GOG. We contributed to the development of the Investigational New Drug Application (“IND”) and provided financial support for the manufacture of the clinical material. A total of 164 patients were enrolled. Patients who entered the study had metastatic ovarian cancer and have been treated with cytoreductive surgery and chemotherapy. They were in complete clinical remission as defined by CA-125 levels within normal, negative physical examination and no evidence of disease by CT scan. Patients were vaccinated 10 times over 84 weeks and monitored throughout the study period. The study was powered to show a statistical improvement in both progression free survival (measured at the mid-point of the study) and overall survival. The study has not achieved a sufficient number of events to trigger the mid-point analysis. Based on discussions with the principal investigator, the GOG plans to recommend that investigators and patients remain blinded as to treatment assignment and the patients should continue to be followed to assess overall survival. We anticipate that results from the overall survival endpoint will be announced in late 2016 or early 2017.

## ***Potential Commercial Opportunity***

We anticipate that the ovarian vaccine will be added as an additional treatment to the current treatment paradigm and not displace an existing treatment. We expect that patients who have experienced one or more recurrences will be the initial candidates for vaccine therapy. This would be consistent with the early clinical trials. Over time, as the product demonstrates utility, we anticipate that usage will migrate toward earlier treatment and larger numbers of patients.

## **Neuroblastoma Vaccine**

### ***Introduction and Overview***

Neuroblastoma is the most common extra-cranial solid tumor in children. According to the NCI and an article in the *Annals of Pharmacology* by Kerry Parsons and colleagues in 2013, there are approximately 700 new cases per year in the United States so it is certainly an orphan disease. According to the NCI SEER data, patients with high risk features, defined by clinical and tumor biologic parameters at diagnosis have an expected survival of only 45% despite intensive induction chemotherapy (very high dose chemotherapy), surgical resection, myeloablative consolidation chemotherapy with stem cell support, radiation, (radiation doses intended to eliminate the immune system of the patient followed by stem cell reconstitution of the system) focal radiation (precise pin-point radiation doses) and post-consolidation treatment (chemotherapy treatment post resection), with 13-cis-retinoic acid, or cisRA, and anti-GD2 mAb ch14.18 immunotherapy. We believe that these results, plus the potentially severe toxicities of chemotherapy and radiotherapy, are compelling reasons for pursuing novel therapeutic approaches.

In particular we believe that there is a need for therapies that selectively eliminate neuroblastoma cells in the setting of minimal or limited amounts of residual disease following intensive induction therapy. According to an article titled *Promising Therapeutic Targets in Neuroblastoma* published in *Clinical Cancer Research* by Katherine Matthay and Alice L. Yu in 2012, neuroblastoma is unique in its abundant expression of the gangliosides GD2 and GD3. Each of these antigenic targets is an outstanding target for immune attack against neuroblastoma cells. In experimental animal studies conducted by Philip Livingston and Govinda Ragupathi, administered or vaccine-induced antibodies against GD2, GD3 and other cell surface antigens were able to eliminate micrometastasis in settings similar to the treatment of patients in complete remission but with a high likelihood of relapse. The basis for emphasis on a bivalent (having two antigens raising an immune response to two targets) vaccine containing each of these agents are tumor cell heterogeneity, heterogeneity of the human immune response and the correlation between overall antibody titer against the tumor cell surface and effector mechanisms such as opsonization, complement-dependent cytotoxicity (how antibodies marshal other immune system cells to kill the cells to which they have attached, or CDC, or antibody dependent cellular cytotoxicity, or ADCC).

In a Phase I trial of a bivalent vaccine containing GD2-KLH, GD3-KLH and escalating doses of saponin adjuvant co-administered with oral beta-glucan in children with neuroblastoma has been completed (Kushner, et. al.) Safety, immunogenicity and the optimal saponin adjuvant dose were determined and the vaccinated subjects in this study were noted to have an unexpectedly favorable outcome. We believe that this experience provides the rationale for undertaking a study in high-risk neuroblastoma subjects who are in second or subsequent complete remission or have only limited residual disease.

### **Results of a Recent Phase I Trial of Bivalent Vaccine in Combination with Oral $\beta$ -glucan**

MSK carried out a Phase I trial in subjects with high-risk neuroblastoma to assess the toxicity of escalating doses of the immunological adjuvant OPT-821 in a bivalent vaccine containing fixed doses of GD2L and GD3L, each covalently attached to the immunological carrier protein KLH (Kushner, 2012). The study subjects were in second (or later) complete, very good partial, or partial remission. Subjects received seven subcutaneous injections over 52 weeks,

Thirteen of the 15 subjects received the entire 12 months of protocol treatment. No dose limiting toxicity was noted in any of the subjects. Most subjects had detectable anti-GD2 or anti-GD3 antibodies. Twelve remain relapse-free at 21+-36+ (median 29+) months. One had a focal relapse (recurrence of the cancer at a specific spot) (supraclavicular node) at 21 months. Two other subjects had early focal relapses (2.3 and 4.6 months). PFS was 87+9% at 12 months and 78+11% at 24 months. Overall survival is 100% (follow-up >22months). These results are in marked contrast to the expected relapse rate at 12 months of 50% to 60%.

### **Clinical Plan**

We have received the Phase I portion of an SBIR grant for support in production of the clinical trial material required for a planned Phase II clinical trial. Because the market opportunity for a vaccine to treat recurrent neuroblastoma is very small, we have worked to bring in additional non-dilutive financing. We hope to expand the SBIR award to the Phase II portion of the grant which could offset \$1 million in Phase II clinical expenses. We are currently evaluating the resource and capital requirements to file an IND to be able to initiate the Phase II clinical trial. No timing can be given at this time regarding the filing of an IND.

### **Patents**

We strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining patents intended to cover our vaccines and monoclonal antibody-based candidates, their methods of use and processes for their manufacture and any other inventions that are commercially important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

We are currently, as of March 1, 2016, the exclusive licensee, sole assignee or co-assignee of 11 granted United States patents, 3 pending United States patent applications, 14 international patents and 3 pending international patent applications. The patents and patent applications include claims to vaccine antigen conjugates, mixtures of vaccine antigen conjugates that makeup polyvalent vaccine candidates, processes for their preparation and their use as a vaccine. Two of the pending patent applications in the United States and 2 international patent applications have claims to human anti-sLea and anti-GD2 monoclonal antibodies, nucleic acids encoding the human anti-sLea and anti-GD2 monoclonal antibodies, processes for their preparation and their use as therapeutic agents.

Our success will depend significantly on our ability to obtain and maintain patents and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the field of anti-fungal agents.

We believe that we have a sufficient intellectual property position and substantial know-how relating to the development and commercialization of our vaccine and monoclonal antibody-based candidates in the markets described herein, consisting of patents or patent applications that we have licensed from MSK or that we have filed ourselves. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology.

Our objective is to continue to expand our intellectual property estate by filing patent applications directed to our vaccine and monoclonal antibody programs. We intend to pursue, maintain, and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions, and improvements that are commercially important to the development of our business.

## Government Regulation

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Drug and Cosmetic Act and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. The FDA has very broad enforcement authority and failure to abide by applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions, restitution, disgorgement of profits, recall or seizure of products, total or partial suspension of production or distribution, withdrawal of approval, refusal to approve pending applications, and criminal prosecution.

### *FDA Approval Process*

We believe that our product candidates will be regulated by the FDA as drugs. No manufacturer may market a new drug until it has submitted a New Drug Application, or NDA, to the FDA, and the FDA has approved it. The steps required before the FDA may approve an NDA generally include:

- preclinical laboratory tests and animal tests conducted in compliance with FDA's good laboratory practice requirements;
- development, manufacture and testing of active pharmaceutical product and dosage forms suitable for human use in compliance with current good manufacturing practices, or GMP;
- the submission to the FDA of an investigational new drug application, or IND, for human clinical testing, which must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its specific intended use(s);
- the submission to the FDA of a New Drug Application, or NDA; and
- FDA review and approval of the NDA.

Preclinical tests include laboratory evaluation of the product candidate, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the pre-clinical tests must comply with federal regulations and requirements including good laboratory practices. We must submit the results of the preclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol to the FDA as part of an IND, which must become effective before we may commence human clinical trials. The IND will automatically become effective 30 days after its receipt by the FDA, unless the FDA raises concerns or questions before that time about the conduct of the proposed trials. In such a case, we must work with the FDA to resolve any outstanding concerns before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board for approval. An institutional review board may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the institutional review board's requirements or may impose other conditions.

Clinical trials involve the administration of the product candidate to humans under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are typically conducted in three sequential phases, though the phases may overlap or be combined. In Phase 1, the initial introduction of the drug into healthy human subjects, the drug is usually tested for safety (adverse effects), dosage tolerance and pharmacologic action, as well as to understand how the drug is taken up by and distributed within the body. Phase 2 usually involves studies in a limited patient population (individuals with the disease under study) to:

- evaluate preliminarily the efficacy of the drug for specific, targeted conditions;
- determine dosage tolerance and appropriate dosage as well as other important information about how to design larger Phase 3 trials; and
- identify possible adverse effects and safety risks.

Phase 3 trials generally further evaluate clinical efficacy and test for safety within an expanded patient population. The conduct of the clinical trials is subject to extensive regulation, including compliance with good clinical practice regulations and guidance.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. We may also suspend clinical trials at any time on various grounds.

The results of the preclinical and clinical studies, together with other detailed information, including the manufacture and composition of the product candidate, are submitted to the FDA in the form of an NDA requesting approval to market the drug. FDA approval of the NDA is required before marketing of the product may begin in the U.S. If the NDA contains all pertinent information and data, the FDA will “file” the application and begin review. The FDA may “refuse to file” the NDA if it does not contain all pertinent information and data. In that case, the applicant may resubmit the NDA when it contains the missing information and data. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for non-priority drug products are reviewed within 10 months. The review process, however, may be extended by FDA requests for additional information, preclinical or clinical studies, clarification regarding information already provided in the submission, or submission of a risk evaluation and mitigation strategy. The FDA may refer an application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA will typically inspect the facilities at which the product candidate is manufactured and will not approve the product candidate unless GMP compliance is satisfactory. FDA also typically inspects facilities responsible for performing animal testing, as well as clinical investigators who participate in clinical trials. The FDA may refuse to approve an NDA if applicable regulatory criteria are not satisfied, or may require additional testing or information. The FDA may also limit the indications for use and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The testing and approval process requires substantial time, effort and financial resources, and our product candidates may not be approved on a timely basis, if at all. The time and expense required to perform the clinical testing necessary to obtain FDA approval for regulated products can frequently exceed the time and expense of the research and development initially required to create the product. The results of preclinical studies and initial clinical trials of our product candidates are not necessarily predictive of the results from large-scale clinical trials, and clinical trials may be subject to additional costs, delays or modifications due to a number of factors, including difficulty in obtaining enough patients, investigators or product candidate supply. Failure by us to obtain, or any delay in obtaining, regulatory approvals or in complying with requirements could adversely affect the commercialization of product candidates and our ability to receive product or royalty revenues.

#### *Other Regulatory Requirements*

After approval, drug products are subject to extensive continuing regulation by the FDA, which include company obligations to manufacture products in accordance with Good Manufacturing Practice, or GMP, maintain and provide to the FDA updated safety and efficacy information, report adverse experiences with the product, keep certain records and submit periodic reports, obtain FDA approval of certain manufacturing or labeling changes, and comply with FDA promotion and advertising requirements and restrictions. Failure to meet these obligations can result in various adverse consequences, both voluntary and FDA-imposed, including product recalls, withdrawal of approval, restrictions on marketing, and the imposition of civil fines and criminal penalties against the NDA holder. In addition, later discovery of previously unknown safety or efficacy issues may result in restrictions on the product, manufacturer or NDA holder.

We and any manufacturers of our products are required to comply with applicable FDA manufacturing requirements contained in the FDA's GMP regulations. GMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facilities for our products must meet GMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and any third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

Outside the United States, our ability to market a product is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from jurisdiction to jurisdiction. At present, foreign marketing authorizations are applied for at a national level, although within the European Union registration procedures are available to companies wishing to market a product in more than one European Union member state.

We are also subject to various environmental, health and safety regulations including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials. From time to time, and in the future, our operations may involve the use of hazardous materials.

## **Item 1A. Risk Factors.**

*Our business faces significant risks, some of which are set forth below to enable readers to assess, and be appropriately apprised of, many of the risks and uncertainties applicable to the forward-looking statements made in this Annual Report. You should carefully consider these risk factors as each of these risks could adversely affect our business, operating results and financial condition. If any of the events or circumstances described in the following risks actually occurs, our business may suffer, the trading price of our common stock could decline and our financial condition or results of operations could be harmed. Given these risks and uncertainties, you are cautioned not to place undue reliance on forward-looking statements. These risks should be read in conjunction with the other information set forth in this Annual Report. There may be additional risks faced by our business, though we do believe that the risks set forth below reflect the more important ones.*

***We will be required to raise additional funds to finance our operations and remain a going concern; we may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us.***

Our operations to date have consumed substantial amounts of cash. Negative cash flows from our operations are expected to continue over at least the next several years. Our cash utilization amount is highly dependent on the progress of our product development programs, particularly, the results of our preclinical and clinical studies and those of our partners, the cost, timing and outcomes of regulatory approval for our product candidates, and the rate of recruitment of patients in our human clinical trials. In addition, the further development of our ongoing clinical trials will depend on upcoming analysis and results of those studies and our financial resources at that time.

We will require future additional capital infusions including public or private financing, strategic partnerships or other arrangements with organizations that have capabilities and/or products that are complementary to our own capabilities and/or products, in order to continue the development of our product candidates. However, there can be no assurances that we will complete any financings, strategic alliances or collaborative development agreements, and the terms of such arrangements may not be advantageous to us. Any additional equity financing will be dilutive to our current stockholders and debt financing, if available, may involve restrictive covenants. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize. Our failure to raise capital when needed could materially harm our business, financial condition and results of operations.

Additionally, we are prohibited from issuing any shares of common stock or securities convertible into common stock, enter into any equity line of credit or issue any floating or variable priced equity linked instrument without the consent of a certain recipient of Exchange Securities until the earlier to occur of: (a) April 1, 2017; (b) the date on which the Company has raised \$10 million in equity financing; (c) the date on which the Company has closed one or more licensing agreements with corporate partners pursuant to which the Company is entitled to receive in total a minimum of \$10,000,000 in initial licensing or equity investments under such agreements; and (d) the date on which shares of the Company's common stock are listed on a national securities exchange. These arrangements may make it difficult for us to raise or borrow additional funds.

Our ongoing capital requirements will depend on numerous factors, including: the progress and results of preclinical testing and clinical trials of our product candidates under development; the costs of complying with the FDA and other domestic and foreign regulatory agency requirements, the progress of our research and development programs and those of our partners; the time and costs expended and required to obtain any necessary or desired regulatory approvals; the resources that we devote to manufacturing expenditures; our ability to enter into licensing arrangements, including any unanticipated licensing arrangements that may be necessary to enable us to continue our development and clinical trial programs; the costs and expenses of filing, prosecuting and, if necessary, enforcing our patent claims, or defending against possible claims of infringement by third-party patent or other technology rights; the cost of commercialization activities and arrangements, if any, that we undertake; and, if and when approved, the demand for our products, which demand depends in turn on circumstances and uncertainties that cannot be fully known, understood or quantified unless and until the time of approval, including the range of indications for which any product is granted approval.

***We have a history of losses, and we anticipate that we will continue to incur losses in the future; our auditors have included in their audit report an explanatory paragraph as to substantial doubt as to our ability to continue as a going concern.***

We have experienced net losses every year since our inception and, as of December 31, 2015, had an accumulated deficit of \$60,601,778. Our auditors have included in their audit report a “going concern” explanatory paragraph as to substantial doubt as to our ability to continue as a going concern that assumes the realization of our assets and the satisfaction of our liabilities and commitments in the normal course of business. We anticipate continuing to incur substantial additional losses over at least the next several years due to, among other factors, expenses related to the following: conducting Phase I clinical trials with the HuMab-5B1 antibody, preclinical testing of follow-on antibody candidates, investor and public relations, SEC compliance efforts, anticipated research and development activities and the general and administrative expenses associated with each of these activities. We have not yet commercialized any product candidates. Our ability to attain profitability will depend upon our ability to develop and commercialize products that are effective and commercially viable, to obtain regulatory approval for the manufacture and sale of our products and to license or otherwise market our products successfully. We may never achieve profitability, and even if we do, we may not be able to sustain being profitable.

***If we are unable to obtain required regulatory approvals, we will be unable to market and sell our product candidates.***

Our product candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing, oversight of clinical investigators, recordkeeping and commercialization. Rigorous preclinical testing and clinical trials and an extensive regulatory review and approval process are required to be successfully completed in the United States and in each foreign jurisdiction in which we offer our products before a new drug or other product can be sold in such jurisdictions. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain, and subject to unanticipated delays. The time required to obtain approval by the FDA, or the regulatory authority in such other jurisdictions is unpredictable and often exceeds five years following the commencement of clinical trials, depending upon the complexity of the product candidate and the requirements of the applicable regulatory agency.

In connection with the clinical development of our product candidates, we face risks that:

- the product candidate may not prove to be safe and efficacious;
- patients may die or suffer serious adverse effects for reasons that may or may not be related to the product candidate being tested;
- we may fail to maintain adequate records of observations and data from our clinical trials, to establish and maintain sufficient procedures to oversee, collect data from, and manage clinical trials, or to monitor clinical trial sites and investigators to the satisfaction of the FDA or other regulatory agencies;
- the results of later-phase clinical trials may not confirm the results of earlier clinical trials; and
- the results from clinical trials may not meet the level of statistical significance or clinical benefit-to-risk ratio required by the FDA or other regulatory agencies for marketing approval.

Only a small percentage of product candidates for which clinical trials are initiated receive approval for commercialization. Furthermore, even if we do receive regulatory approval to market a product candidate, any such approval may be subject to limitations such as those on the indicated uses for which we may market a particular product candidate.

***Our management and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting upon completion of our audit in May of 2014 that were not fully remediated as of December 31, 2014. We have implemented certain internal controls to address the material weaknesses, which no longer existed as of December 31, 2015. However, our efforts to maintain an effective control environment may not be sufficient to prevent future significant deficiencies from occurring, which could adversely impact investor confidence and our stock price.***

In connection with the audit of our financial statements as of and for the year ended December 31, 2014, our management and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting relating to (1) the reporting of non-routine complex transactions and (2) the lack of segregation of duties. These material weaknesses were primarily the result of a limited number of employees in our accounting department. In June 2014, we added an assistant controller, a person dedicated solely to processing accounts payable, and another person dedicated to reviewing and reporting on clinical trials progress and expenses. In April 2015, the assistant controller was promoted to controller and we hired a Senior Director of Finance to take over some of the responsibilities of the controller and Chief Financial Officer, so that the Chief Financial Officer is able to perform review functions on significant transactions on a going forward basis. We believe that the additional resources and controls added helped ensure that the material weaknesses noted above have been resolved. During 2015 we hired an independent consulting firm to document, test and evaluate our internal controls. Following the consulting firm's review and discussion with management and the Audit Committee, we have concluded that the two material weaknesses in our internal control have been remediated as of December 31, 2015. Our management is responsible for maintaining an effective control environment, and implementing and testing our internal controls over financial reporting; and our efforts to maintain an effective control environment may not be sufficient to prevent future significant deficiencies from occurring.

***Our product candidates have not completed clinical trials, and may never demonstrate sufficient safety and efficacy in order to do so.***

Our product candidates are in the clinical and pre-clinical stages of development. In order to achieve profitable operations, we alone, or in collaboration with others, must successfully develop, manufacture, introduce and market our products. The time frame necessary to achieve market success for any individual product is long and uncertain. The products we are currently developing will require significant additional research, development and preclinical and clinical testing prior to application for commercial use or sale. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after showing promising results in early or later-stage studies or clinical trials. Although we have obtained some favorable results to-date in preclinical studies and clinical trials of certain of our potential products, such results may not be indicative of results that will ultimately be obtained in or throughout such clinical trials, and clinical trials may not show any of our products to be safe or capable of producing a desired result. Additionally, we may encounter problems in our clinical trials that may cause us to delay, suspend or terminate those clinical trials.

Further, our research or product development efforts may not be successfully completed, any compounds we currently have under development may not be successfully developed into drugs, may not receive regulatory approval on a timely basis, if at all, and competitors may develop and bring to market products or technologies that render our potential products obsolete. If any of these events occur, our business would be materially and adversely affected.

***If clinical trials or regulatory approval processes for our product candidates are prolonged, delayed or suspended, we may be unable to commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any revenue from potential product sales.***

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials or delay the analysis of data derived from them. A number of events, including any of the following, could delay the completion of our ongoing and planned clinical trials and negatively impact our ability to obtain regulatory approval for, and to market and sell, a particular product candidate:

- conditions imposed on us by the FDA or another foreign regulatory authority regarding the scope or design of our clinical trials;
- delays in obtaining, or our inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply of our product candidates or other materials necessary to conduct and complete our clinical trials;
- slow enrollment and retention rate of subjects in our clinical trials;
- serious and unexpected drug-related side effects related to the product candidate being tested; and
- delays in meeting manufacturing and testing standards required for production of clinical trial supplies.

Commercialization of our product candidates may be delayed by the imposition of additional conditions on our clinical trials by the FDA or any other applicable foreign regulatory authority or the requirement of additional supportive studies by the FDA or such foreign regulatory authority. In addition, clinical trials require sufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, the conduct of other clinical trials that compete for the same patients as our clinical trials, and the eligibility criteria for our clinical trials. Our failure to enroll patients in our clinical trials could delay the completion of the clinical trial beyond its expectations. In addition, the FDA could require us to conduct clinical trials with a larger number of subjects than we may have projected for any of our product candidates. We may not be able to enroll a sufficient number of patients in a timely or cost-effective manner. Furthermore, enrolled patients may drop out of our clinical trials, which could impair the validity or statistical significance of the clinical trials.

We do not know whether our clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, if at all. Delays in our clinical trials will result in increased development costs for our product candidates, and our financial resources may be insufficient to fund any incremental costs. In addition, if our clinical trials are delayed, our competitors may be able to bring products to market before we do and the commercial viability of our product candidates could be limited. In cases where an outside party, such as the NCI conducts a clinical trial on our behalf, we may not have direct involvement in discussions with the FDA regarding the factors discussed above.

***Our product candidates will remain subject to ongoing regulatory review even if they receive marketing approval, and if we fail to comply with continuing regulations, we could lose these approvals and the sale of any of our approved commercial products could be suspended.***

Even if we receive regulatory approval to market a particular product candidate, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, and record keeping related to the product will remain subject to extensive regulatory requirements. If we fail to comply with the regulatory requirements of the FDA and other applicable domestic and foreign regulatory authorities or discover any previously unknown problems with any approved product, manufacturer, or manufacturing process, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers, or manufacturing processes;
- warning letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;
- pressure to initiate voluntary product recalls;
- suspension or withdrawal of regulatory approvals; and
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications.

***Our industry is highly competitive, and our product candidates may become obsolete.***

We are engaged in a rapidly evolving field. Competition from other pharmaceutical companies, biotechnology companies and research and academic institutions is intense and likely to increase. Many of those companies and institutions have substantially greater financial, technical and human resources than we do. Those companies and institutions also have substantially greater experience in developing products, conducting clinical trials, obtaining regulatory approval and in manufacturing and marketing pharmaceutical products. Our competitors may succeed in obtaining regulatory approval for their products more rapidly than we do. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. We are aware of potential competitors developing products similar to our sarcoma vaccine, ovarian cancer vaccine and pancreatic cancer antibodies product candidates. Our competitors may succeed in developing products that are more effective and/or cost competitive than those we are developing, or that would render our product candidates less competitive or even obsolete. In addition, one or more of our competitors may achieve product commercialization or patent protection earlier than we do, which could materially adversely affect our business.

***If physicians and patients do not accept our future products or if the market for indications for which any product candidate is approved is smaller than expected, we may be unable to generate significant revenue, if any.***

Even if any of our product candidates obtain regulatory approval, they may not gain market acceptance among physicians, patients, and third-party payers. Physicians may decide not to recommend our treatments for a variety of reasons including:

- timing of market introduction of competitive products;
- demonstration of clinical safety and efficacy compared to other products;
- cost-effectiveness;
- limited or no coverage by third-party payers;
- convenience and ease of administration;
- prevalence and severity of adverse side effects;
- restrictions in the label of the drug;
- other potential advantages of alternative treatment methods; and
- ineffective marketing and distribution support of its products.

If any of our product candidates are approved, but fail to achieve market acceptance or such market is smaller than anticipated, we may not be able to generate significant revenue and our business would suffer.

***As we evolve from a company that is primarily involved in clinical development to a company that is also involved in commercialization, we may encounter difficulties in expanding our operations successfully.***

As we advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities and may need to further contract with third parties to provide these capabilities. As our operations expand, we likely will need to manage additional relationships with such third parties, as well as additional collaborators, distributors, marketers and suppliers.

Maintaining third party relationships for these purposes will impose significant added responsibilities on members of our management and other personnel. We must be able to: manage our development efforts effectively; recruit and train sales and marketing personnel; manage our participation in the clinical trials in which our product candidates are involved effectively; and improve our managerial, development, operational and finance systems, all of which may impose a strain on our administrative and operational infrastructure.

If we enter into arrangements with third parties to perform sales, marketing or distribution services, any product revenues that we receive, or the profitability of these product revenues to us, are likely to be lower than if we were to market and sell any products that we develop without the involvement of these third parties. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or in doing so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our products.

***The uncertainty associated with pharmaceutical reimbursement and related matters may adversely affect our business.***

Market acceptance and sales of any one or more of our product candidates will depend on reimbursement policies and may be affected by future healthcare reform measures in the United States and in foreign jurisdictions. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for any of our product candidates. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any product candidates that we develop.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs.

The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of any products that it develops due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, ACA, became law in the U.S. The goal of ACA is to reduce the cost of health care and substantially change the way health care is financed by both government and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of, and the price we charge for, any products we develop that receive regulatory approval. We also cannot predict the impact of ACA on our business, as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions, which have not yet been fully promulgated and implemented.

***We only have a limited number of employees to manage and operate our business.***

As of March 1, 2016, we had a total of 15 full-time employees and two part-time employees. Our focus on limiting cash utilization requires us to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to retain adequate staffing levels to run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

***We depend heavily on our executive officers, directors, and principal consultants and the loss of their services would materially harm our business.***

We believe that our success depends, and will likely continue to depend, upon our ability to retain the services of our current executive officers, directors, principal consultants and others. In addition, we have established relationships with universities, hospitals and research institutions, which have historically provided, and continue to provide, us with access to research laboratories, clinical trials, facilities and patients. The loss of the services of any of these individuals or institutions would have a material adverse effect on our business.

***Due in part to our limited financial resources, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable indications or therapeutic areas for our product candidates or those that are in-licensed, and/or we may be unable to pursue the clinical trials that we would like to pursue.***

We have limited technical, managerial and financial resources to determine the indications on which we should focus the development efforts related to our product candidates. Due to our limited available financial resources, we may have curtailed clinical development programs and activities that might otherwise have led to more rapid progress of our product candidates through the regulatory and development processes.

We may make incorrect determinations with regard to the indications and clinical trials on which to focus the available resources that we do have. Furthermore, we cannot assure you that we will be able to retain adequate staffing levels to run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish. Our decisions to allocate our research, management and financial resources toward particular indications or therapeutic areas for our product candidates may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate drug development programs may also cause us to miss valuable opportunities.

***If the third parties on which we rely for the conduct of our clinical trials and results do not perform our clinical trial activities in accordance with good clinical practices and related regulatory requirements, we may be unable to obtain regulatory approval for or commercialize our product candidates.***

We use independent clinical investigators and other third-party service providers to conduct and/or oversee the clinical trials of our product candidates and expect to continue to do so for the foreseeable future. We rely heavily on these parties for successful execution of our clinical trials. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with the FDA's requirements and our general investigational plan and protocol.

The FDA requires us and our clinical investigators to comply with regulations and standards, commonly referred to as good clinical practices, for conducting and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the respective trial plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates or result in enforcement action against us.

***We have limited manufacturing capacity and have relied on, and expect to continue to rely on, third-party manufacturers to produce our product candidates.***

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely, and expect to rely for the foreseeable future, on third-party manufacturers to supply our product candidates. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our product candidates or products ourselves, including:

- reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance;
- limitations on supply availability resulting from capacity and scheduling constraints of third-parties;
- the possible breach of manufacturing agreements by third-parties because of factors beyond our control; and
- the possible termination or non-renewal of the manufacturing agreements by the third-party, at a time that is costly or inconvenient to us.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products and substantially increases our costs or deplete profit margins, if any. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with current cGMPs. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop our product candidates and commercialize any products that receive regulatory approval on a timely basis.

***It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.***

We have been issued patents, applied for other patents, and intend on continuing to seek additional patent protection for our families of antibodies from our antibody development program, our vaccines, and other compounds that we discover. However, any or all of such compounds or new uses may not be subject to effective patent protection. Further, the development of regimens for the administration of our vaccines, which involve specifications for the frequency, timing and amount of dosages, has been, and we believe may continue to be, important to our efforts, although those processes, as such, may not be patentable. In addition, our issued patents may be declared invalid or our competitors may find ways to avoid the claims in the patents.

Our commercial success will depend, in part, on our ability to obtain and maintain patent protection, protect our trade secrets and operate without infringing on the proprietary rights of others. Our commercial success will also depend, in part, on our ability to market our product candidates during the term of our patent protection. For example, certain patents primarily in foreign countries within our portfolio expired in 2014 and can no longer be relied on for protection in those countries. As of March 1, 2016, we were the exclusive licensee, sole assignee or co-assignee of 11 granted United States patents, 3 pending United States patent applications, 14 international patents and 3 pending international patent applications. The patent position of pharmaceutical and biotechnology firms like us are generally highly uncertain and involves complex legal and factual questions, resulting in both an apparent inconsistency regarding the breadth of claims allowed in United States patents and general uncertainty as to their legal interpretation and enforceability. No absolute policy regarding the breadth of claims allowed in biopharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. Changes in either the patent laws or in interpretations of patent laws in the United States and foreign jurisdictions may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that we currently own or that may be issued from the applications we have filed or may file in the future or that we have licensed or may license from third parties, including MSK for the vaccine antigen patents. Further, if any patents we obtain or license are deemed invalid or unenforceable, it could impact our ability to commercialize or license our technology. Thus, patent applications assigned or exclusively licensed to us may not result in patents being issued, any issued patents assigned or exclusively licensed to us may not provide us with competitive protection or may be challenged by others, and the current or future granted patents of others may have an adverse effect on our ability to do business and achieve profitability.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are similar to our vaccines and monoclonal antibody-based candidates and any future product candidates we may seek to develop but that are not covered by the claims of our patents;
- if we encounter delays in our clinical trials, the period of time during which we could market our vaccines and monoclonal antibody-based candidates under patent protection would be reduced;
- we might not have been the first to conceive, make or disclose the inventions covered by our patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- any patents that we obtain may be invalid or unenforceable or otherwise may not provide us with any competitive advantages;  
or
- the patents of others may have a material adverse effect on our business.

Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of the product candidates that may be disclosed or methods involving these candidates that may be disclosed in the parent patent application. We plan to pursue divisional patent applications and/or continuation patent applications in the United States and many other countries to obtain claim coverage for inventions that were disclosed but not claimed in the parent patent application, but may not succeed in these efforts.

Composition of matter patents on the active biological component are generally considered to be the strongest form of intellectual property protection for biopharmaceutical products, as such patents generally provide protection without regard to any method of use. We cannot be certain that the claims in our patent applications covering composition-of-matter of our candidates will be considered patentable by the U.S. Patent and Trademark Office, or USPTO, courts in the United States or by the patent offices and courts in foreign countries. Method of use patents protect the use of a product for the method recited in the claims. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to or induce the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail, resulting in harm to our business, and, even if successful, may result in substantial costs and distract our management and other employees.

There have been numerous changes to the patent laws and proposed changes to the rules of the USPTO, which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, in September 2011, President Obama signed the America Invents Act that codifies several significant changes to the U.S. patent laws, including, among other things, changing from a “first to invent” to a “first inventor to file” system, limiting where a patent holder may file a patent suit, replacing interference or “first to invent” proceedings with derivation proceedings and creating inter partes review and post-grant opposition proceedings to challenge the validity of patents after they have been issued. The effects of these changes are currently unclear as the USPTO only recently has adopted regulations implementing the changes, the courts have yet to address most of these provisions, and the applicability of the act and new regulations on specific patents and patent applications discussed herein have not been determined and would need to be reviewed.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, licensees, licensors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information such that our competitors may obtain it. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how, such as new therapies, including therapies for the indications we are targeting. If others seek to develop similar therapies, their research and development efforts may inhibit our ability to conduct research in certain areas and to expand our intellectual property portfolio, and also have a material adverse effect on our business.

Moreover, because some of the basic research relating to one or more of our patent applications and/or patents were performed at various universities and/or funded by grants, one or more universities, employees of such universities and/or grantors could assert that they have certain rights in such research and any resulting products. Further, others may independently develop similar products, may duplicate our products, or may design around our patent rights. In addition, as a result of the assertion of rights by a third-party or otherwise, we may be required to obtain licenses to patents or other proprietary rights of others in or outside of the United States. Any licenses required under any such patents or proprietary rights may not be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we could encounter delays in product market introductions during our attempts to design around such patents or could find that the development, manufacture or sale of products requiring such licenses is foreclosed. In addition, we could incur substantial costs in defending suits brought against us or in connection with patents to which we hold licenses or in bringing suit to protect our own patents against infringement.

We require employees and the institutions that perform our preclinical and clinical trials to enter into confidentiality agreements with us. Those agreements provide that all confidential information developed or made known to a party to any such agreement during the course of the relationship with us be kept confidential and not be disclosed to third-parties, except in specific circumstances. Any such agreement may not provide meaningful protection for our trade secrets or other confidential information in the event of unauthorized use or disclosure of such information.

With respect to our vaccine programs we have in-licensed rights from third parties. If these license agreements terminate or expire, we may lose the licensed rights to some or all of our vaccine product candidates. We may not be able to continue to develop them or, if they are approved, market or commercialize them.

We depend on license agreements with third-parties for certain intellectual property rights relating to our product candidates, including, but not limited to, the license of certain intellectual property rights from MSK. In general, our license agreements require us to make payments and satisfy performance obligations in order to keep these agreements in effect and retain our rights under them. These payment obligations can include upfront fees, maintenance fees, milestones, royalties, patent prosecution expenses, and other fees. These performance obligations typically include diligence obligations. If we fail to pay, be diligent or otherwise perform as required under our license agreements, we could lose the rights under the patents and other intellectual property rights covered by these agreements. If disputes arise under any of our in-licenses, including our in-licenses from MSK, we could lose our rights under these agreements. Any such dispute may not be resolvable on favorable terms, or at all. Whether or not any disputes of this kind are favorably resolved, our management's time and attention and our other resources could be consumed by the need to attend to these disputes and our business could be harmed by the emergence of such a dispute.

If we lose our rights under these agreements, we might not be able to develop any related product candidates further, or following regulatory approval, if any, we might be prohibited from marketing or commercializing these product candidates. In particular, patents previously licensed to us might, after termination of an agreement, be used to stop us from conducting these activities.

***We are dependent on MSK for the establishment of our intellectual property rights related to the vaccine program, and if MSK has not established our intellectual property rights with sufficient scope to protect our vaccine candidates, we may have limited or no ability to assert intellectual property rights to our vaccine candidates.***

Under our agreement with MSK, MSK was responsible for establishing the intellectual property rights to the vaccine antigen conjugates, mixtures of vaccine antigen conjugates that make up polyvalent vaccine candidates and methods of use. As we were not responsible for the establishment of our intellectual property rights to these vaccine antigen conjugates, mixtures of vaccine antigen conjugates and methods of use, we have less visibility into the strength of our intellectual property rights to our vaccine candidates than if we had been responsible for the establishment of these rights. If MSK did not establish those rights so they are of sufficient scope to protect the vaccine candidates, then we may not be able to prevent others from using or commercializing some or all of our vaccine candidates, and others may be able to assert intellectual property rights in our vaccine candidates and prevent us from further pursuing the development and commercialization of our vaccine candidates.

***We may not obtain exclusive rights to intellectual property created as a result of our strategic collaborative agreements.***

We are party to collaborative research agreements with Heidelberg Pharma GmbH and Rockefeller University, and expect to enter into agreements with other parties in the future, each of which involve research and development efforts. Under our existing agreements, we do not have exclusive rights to jointly developed intellectual property and would have to license the collaborative partner's interest in the jointly developed intellectual property to obtain exclusive rights. We may not be able to license our collaborative partner's interest or license their interest at reasonable terms. If we are unable to license their interest we would not have exclusive rights to the jointly developed intellectual property and, in some collaborations, the collaborative partner may be free to license their interest in the jointly developed intellectual property to a competitor. In other collaborations, if we are unable to license the collaborative partner's interest we may not have sufficient rights to practice the jointly developed intellectual property. Such provisions to the jointly developed intellectual property may limit our ability to gain commercial benefit from some of or all of the intellectual property we jointly develop with our collaborative partners and may lead to costly or time-consuming disputes with parties with whom we have collaborative relationships over rights to certain innovations or with other third parties that may result from the activities of the collaborative arrangements.

***We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to enforce or protect our rights to, or use, our technology.***

If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced. These lawsuits are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents or sustaining their validity and enforceability. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to enforce them. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the grounds that such other party's activities do not infringe such patents. In addition, the United States Court of Appeals for the Federal Circuit and the Supreme Court of the United States continue to address issues under the United States patent laws, and the decisions of those and other courts could adversely affect our ability to sustain the validity of our issued or licensed patents and obtain new patents.

Furthermore, a third party may claim that we or our manufacturing or commercialization partners or customers are using inventions covered by the third party's patent rights and may go to court to stop us or our partners and/or customers from engaging in our operations and activities, including making or selling our vaccine and monoclonal antibody-based candidates and any future product candidates we may seek to develop. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. There is a risk that a court would decide that we or our commercialization partners or customers are infringing the third party's patents and would order us or our partners or customers to stop the activities covered by the patents. In that event, we or our commercialization partners or customers may not have a viable way around the patent and may need to halt commercialization or use of the relevant product. In addition, there is a risk that a court will order us or our partners or customers to pay the other party damages for having violated the other party's patents or obtain one or more licenses from third parties, which may be impossible or require substantial time and expense. We cannot predict whether any license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In such events, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. In the future, we may agree to indemnify our commercial partners and/or customers against certain intellectual property infringement claims brought by third parties which could increase our financial expense, increase our involvement in litigation and/or otherwise materially adversely affect our business.

Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation, which could adversely affect our intellectual property rights and our business. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, because searches and examinations of patent applications by the USPTO and other patent offices may not be comprehensive, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our patents or pending applications. Our competitors may have filed, and may in the future file, patent applications and may have obtained patents covering technology similar to ours. Any such patents or patent application may have priority over our patent applications, which could further require us to obtain or license rights to issued patents covering such technologies. If another party has obtained a U.S. patent or filed a U.S. patent application on inventions similar to ours, we may have to participate in a proceeding before the USPTO or in the courts to determine which patent or application has priority. The costs of these proceedings could be substantial, and it is possible that our application or patent could be determined not to have priority, which could adversely affect our intellectual property rights and business.

We have received confidential and proprietary information from collaborators, prospective licensees and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have improperly used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If we are not successful, our ability to continue our operations and our business could be materially, adversely affected.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations, on our ability to hire or retain employees, or otherwise on our business.

***If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates and any products that we may develop.***

The testing and marketing of medical products entail an inherent risk of product liability. Although we are not aware of any historical or anticipated product liability claims or specific causes for concern, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates and any products that we may develop. In addition, product liability claims may also result in withdrawal of clinical trial volunteers, injury to our reputation and decreased demand for any products that we may commercialize. We currently carry product liability insurance that covers our clinical trials up to a \$5.0 million annual aggregate limit. We will need to increase the amount of coverage if and when we have a product that is commercially available. If we are unable to obtain sufficient product liability insurance at an acceptable cost, potential product liability claims could prevent or inhibit the commercialization of any products that we may develop, alone or with corporate partners.

***Our restated certificate of incorporation, our amended and restated by-laws and Delaware law could deter a change of our management which could discourage or delay offers to acquire us; certain restrictions in our agreements with existing stockholders could also discourage or delay offers to acquire us.***

Certain provisions of Delaware law and of our restated certificate of incorporation, as amended, and amended and restated by-laws, could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or in our best interests. These provisions include:

- establishing a classified board of directors requiring that members of the board be elected in different years, which lengthens the time needed to elect a new majority of the board;
- authorizing the issuance of “blank check” preferred stock that could be issued by our board of directors to increase the number of outstanding shares or change the balance of voting control and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;
- limiting the ability of stockholders to call special meetings of the stockholders;
- prohibiting stockholder action by written consent and requiring all stockholder actions to be taken at a meeting of our stockholders; and
- establishing 90 to 120 day advance notice requirements for nominations for election to the board of directors and for proposing matters that can be acted upon by stockholders at stockholder meetings.

Additionally, the Company is prohibited from issuing any shares of common stock or securities convertible into common stock, enter into any equity line of credit or issue any floating or variable priced equity linked instrument without the consent of a certain recipient of Exchange Securities until the earlier to occur of: (a) April 1, 2017; (b) the date on which the Company has raised \$10 million in equity financing; (c) the date on which the Company has closed one or more licensing agreements with corporate partners pursuant to which the Company is entitled to receive in total a minimum of \$10,000,000 in initial licensing or equity investments under such agreements; and (d) the date on which shares of the Company's common stock are listed on a national securities exchange. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or in our best interests.

***The price of our common stock is volatile, and is likely to continue to fluctuate due to reasons beyond our control.***

The market price of our common stock has been, and likely will continue to be, highly volatile. Factors, including our financial results or our competitors' financial results, clinical trial and research development announcements and government regulatory action affecting our potential products in both the United States and foreign countries, have had, and may continue to have, a significant effect on our results of operations and on the market price of our common stock. We cannot assure you that any investment in our common stock will not fluctuate significantly. One or more of these factors could significantly harm our business and cause a decline in the price of our common stock in the public market. Sales of shares of common stock registered for resale or eligible for resale pursuant to Rule 144 under the Securities Act as amended, as well as future sales of our common stock by existing stockholders, or the perception that sales may occur at any time, could adversely affect the market price of our common stock.

***Substantial future sales of our common stock by us or by our existing stockholders could cause our stock price to fall.***

Additional equity financings or other share issuances by us, including shares issued in connection with strategic alliances and corporate partnering transactions, could adversely affect the market price of our common stock. Sales by existing stockholders of a large number of shares of our common stock in the public market or the perception that additional sales could occur could cause the market price of our common stock to drop.

***If we do not progress in our programs as anticipated, our stock price could decrease.***

For planning purposes, we estimate the timing of a variety of clinical, regulatory and other milestones, such as when a certain product candidate will enter clinical development, when a clinical trial will be completed or when an application for regulatory approval will be filed. Our estimates are based on present facts and a variety of assumptions. Many of the underlying assumptions are outside of our control. If milestones are not achieved when we estimated that they would be, investors could be disappointed, and our stock price may decrease.

***Our common stock is deemed a “penny stock,” which would make it more difficult for our investors to sell their shares.***

Our common stock is subject to the “penny stock” rules adopted under Section 15(g) of the Exchange Act. The penny stock rules generally apply to companies whose common stock is not listed on the NASDAQ Stock Market or other national securities exchange and trades at less than \$4.00 per share, other than companies that have had average revenue of at least \$6,000,000 for the last three years or that have tangible net worth of at least \$5,000,000 (\$2,000,000 if the company has been operating for three or more years). These rules require, among other things, that brokers who trade penny stock to persons other than “established customers” complete certain documentation, make suitability inquiries of investors and provide investors with certain information concerning trading in the security, including a risk disclosure document and quote information under certain circumstances. Many brokers have decided not to trade penny stocks because of the requirements of the penny stock rules and, as a result, the number of broker-dealers willing to act as market makers in such securities is limited. If we remain subject to the penny stock rules for any significant period, it could have an adverse effect on the market, if any, for our securities. If our securities are subject to the penny stock rules, investors will find it more difficult to dispose of our securities.

***Our stock price may be volatile, you may not be able to resell your shares at or above your purchase price.***

Our stock prices and the market prices for securities of biotechnology companies in general have been highly volatile, with recent significant price and volume fluctuations, and may continue to be highly volatile in the future. For example, during the year ended December 31, 2015, our common stock traded between \$0.61 per share and \$4.94 per share. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock, some of which are beyond our control:

- developments regarding, or the results of, our clinical trials;
- announcements of technological innovations or new commercial products by our competitors or us;
- our issuance of equity or debt securities, or disclosure or announcements relating thereto;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- publicity regarding actual or potential medical results relating to products under development by our competitors or us;
- regulatory developments in the United States and foreign countries;
- litigation;
- economic and other external factors or other disaster or crisis; or
- period-to-period fluctuations in our financial results.

***We have been, and in the future may be, subject to securities class action lawsuits and shareholder derivative actions. These, and potential similar or related litigation, could result in substantial damages and may divert management’s time and attention from our business.***

We have been, and may in the future be, the target of securities class actions or shareholder derivative claims. Any such actions or claims could result in substantial damages and may divert management’s time and attention from our business.

***The rights of our common stockholders are limited by and subordinate to the rights of the holders of Series D Preferred Stock and Series E Preferred Stock; these rights may have a negative effect on the value of shares of our common stock.***

The holders of the Series D Preferred Stock and Series E Preferred Stock have rights and preferences generally superior to those of the holders of common stock. The existence of these superior rights and preferences may have a negative effect on the value of shares of our common stock. These rights are more fully set forth in the Series D certificate of designations and Series E certificate of designations, respectively, and include, but are not limited to the right to receive a liquidation preference, prior to any distribution of our assets to the holders of our common stock, in an amount equal to \$0.01 per share or \$1,915 for the Series D Convertible Preferred Stock and \$0.01 per share or \$333 for the Series E Convertible Preferred Stock.

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

Our common stock is currently quoted on the OTCQB marketplace. The quotation of our common stock on the OTCQB marketplace does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is 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. Because our common stock does not trade on a national securities exchange, our common stock is subject to the securities laws of the various states and jurisdictions of the United States in addition to federal securities law. While we may register our common stock or qualify for exemptions for our common stock in one of more states, if we fail to do so the investors in those states where we have not taken such steps may not be allowed to purchase our stock or those who presently hold our stock may not be able to resell their shares without substantial effort and expense. These restrictions and potential costs could be significant burdens on our stockholders.

***We may not be able to achieve secondary trading of our stock in certain states because our common stock is no longer nationally traded, which could subject our stockholders to significant restrictions and costs.***

Our common stock is not currently eligible for trading on the NASDAQ Capital Market or on a national securities exchange. Therefore, our common stock is subject to the securities laws of the various states and jurisdictions of the United States in addition to federal securities law. While we may register our common stock or qualify for exemptions for our common stock in one of more states, if we fail to do so the investors in those states where we have not taken such steps may not be allowed to purchase our stock or those who presently hold our stock may not be able to resell their shares without substantial effort and expense. These restrictions and potential costs could be significant burdens on our stockholders.

***Reverse Stock Split; Uplisting Risk.***

On August 26, 2015, stockholders of the Company approved a proposal to grant the Board of Directors authority to effect a reverse stock split of the Company's issued and outstanding common stock by a range of 1 share for every 2 shares of common stock outstanding and up to 1 share for every 4 shares of common stock outstanding. The Board of Directors has not determined a date for approving any reverse split. NASDAQ and other national securities exchanges require a minimum price per share of common stock for listing of the Company's common stock and approval of a reverse split is in the discretion of the Board of Directors. Accordingly, the price of the Company's common stock would have an impact on the Company's ability to list or timing of such listing on any national securities exchange.

***The number of shares of issued and outstanding common stock represents approximately 45% of our fully diluted shares of common stock. Additional issuances of shares of common stock upon conversion and/or exercise of preferred stock, options to purchase common stock and warrants to purchase common stock will cause substantial dilution to existing stockholders.***

At March 1, 2016, we had 29,211,272 shares of common stock issued and outstanding. Up to an additional 21,662,200 shares may be issued upon conversion of our Series D and Series E Convertible Preferred Stock; 8,876,336 shares issuable upon exercise of warrants at a weighted average price of \$1.33; 3,263,041 shares upon exercise of all outstanding options to purchase our common stock at an weighted average price of \$2.36; and 2,300,850 shares issuable upon vesting of restricted stock units granted, which amounts include all reserves, resulting in a total of up to 65,313,699 shares that may be issued and outstanding, assuming conversion of all outstanding convertible preferred stock, and exercise of all outstanding option and warrants to purchase our common stock. The issuance of any and all of the 36,102,427 shares issuable upon exercise or conversion of our outstanding convertible securities will cause substantial dilution to existing stockholders and may depress the market price of our common stock.

***You may experience future dilution in the event of future equity offerings***

We may in the future offer shares of our common stock or other securities convertible into or exchangeable for our common stock. Although no assurances can be given that we will consummate a financing, in the event we do, or in the event we sell shares of common stock or other securities convertible into shares of our common stock in the future, additional and substantial dilution will occur. In addition, investors purchasing shares or other securities in the future could have rights superior to our current shareholders.

**Item 1B. Unresolved Staff Comments.**

None

**Item 2. Properties.**

MabVax Therapeutics entered into a lease agreement in August 2012, with a lease term that ended on July 31, 2015, for 5,955 square feet of office space at 11588 Sorrento Valley Road in San Diego, California. Upon expiration of the lease in July 2015, prior to the availability of our new facility, we continued to lease this space on a month-to-month basis from August 2015 through January 2016 at the rate of \$11,017 per month.

In September 2015 we entered into a lease agreement with AGP Sorrento Business Complex, L.P. for a lease of approximately 14,971 rentable square feet of office and research facilities located at 11535 Sorrento Valley Road, San Diego, California 92121 to serve as our corporate offices and laboratories. Due to the fact that certain tenant improvements needed to be made to the premises before we could take occupancy, the facilities were not ready until early 2016. We moved from our previous facility at 11588 Sorrento Valley Road, into our new space in early February 2016. Monthly rent commenced upon occupancy at \$2.38 per square foot, totaling \$35,631, and will escalate at an annual rate of 3% a year over the six-year term of the lease as set forth in the Lease.

**Item 3. Legal Proceedings.**

On May 30, 2014, a class action lawsuit was commenced in Santa Clara County Superior Court, State of California, on behalf of Cadillac Partners and others similarly situated, naming as defendants, MabVax Therapeutics, the Company and the Company's directors, Hudson Bay Capital Management LP, Bio IP Ventures LLC, Hudson Bay Master Fund Ltd., and Hudson Bay IP Opportunities Master Fund LP, together the "Parties". The suit alleged the defendants breached certain fiduciary duties, or aided and abetted a breach of fiduciary duties, in connection with the Company's merger with MabVax Therapeutics. In support of their purported claims, the plaintiff alleged, among other things, that the Company's board has historically failed to fulfill its fiduciary duty to its stockholders, and claiming with respect to the Series B Private Placement and the Merger, that such transactions involved an inadequate sales process and included preclusive deal protection devices, and that the Company's board of directors would receive personal benefits not available to its public stockholders as a result of the Merger. The plaintiff sought to enjoin the Merger and obtain damages as well as attorneys' and expert fees and costs.

On June 29, 2014, the parties entered into a Stipulation and Settlement (the “Settlement”), pursuant to which the Company agreed to file with the SEC certain supplemental disclosures in connection with the merger. The Settlement was subject to certain confirmatory discovery to be undertaken by the plaintiff and to the Parties’ agreement on the payment of the plaintiff’s attorneys’ fees and expenses.

On July 16, 2014, the Company and all other parties to the litigation entered into an agreement which, if consummated, would settle the litigation (the “Proposed Settlement”). Among many other terms, under the Proposed Settlement the Company and all defendants will receive a broad release of any and all claims pertaining to the Series B Private Placement, the Merger, the prior disclosure and a wide variety of other matters. The Proposed Settlement also calls for the parties to ask the court to, among other things, enter orders enjoining other stockholders from bringing similar actions, certifying the putative settlement class, and approving the Proposed Settlement as a fair, final, and binding resolution of the litigation. Under the Proposed Settlement, the Company and the other defendants have expressly denied the allegations of the complaint and denied engaging in any other misconduct, nor will any of them make any payment or in any respect amend the negotiated terms of the since-consummated Series B Private Placement and merger. Finally, under the Proposed Settlement, the Company and the other defendants have not agreed to pay any legal fees, or reimburse any expenses, allegedly incurred by the plaintiffs who filed the complaint; instead, the Company expects that counsel for those plaintiffs will present any such disputed claim for legal fees and expenses to the court for resolution.

On April 20, 2015, the Parties made an application for an Order for Notice and Scheduling of Hearing of Settlement in accordance with a Stipulation of Settlement dated as of April 20, 2015 (the “Action”), which sets forth the terms and conditions for settlement and which provides for dismissal of the Action with prejudice. The Order after Hearing on June 12, 2015, provided preliminary approval of the settlement that was agreed to by the Parties, in which the Company provided supplemental disclosures in the definitive proxy filed with the SEC on June 30, 2014. Notice of the action as a class action was sent to class members in July 2015.

On September 18, 2015, an Order and Final Judgment was entered by the Superior Court of the State of California, approving the settlement that was agreed upon by both parties and closing the case. The Company anticipates that there will be no additional future expenses incurred in this action by the Company after the December 31, 2015 balance sheet date which would not be offset by insurance.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**PART II**

**Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.**

Our common stock trades on the OTCQB under the symbol “MBVX”. The following table sets forth the high and low sales prices for our common stock for each quarterly period within the two most recent fiscal years. All stock prices included in the following table are adjusted for the 1 for 8 reverse stock split which occurred on September 8, 2014.

	<u>High</u>	<u>Low</u>
<b>2015</b>		
Quarter ended March 31, 2015	\$ 2.67	\$ 0.83
Quarter ended June 30, 2015	\$ 4.94	\$ 1.80
Quarter ended September 30, 2015	\$ 2.82	\$ 1.05
Quarter ended December 31, 2015	\$ 1.12	\$ 0.61
<b>2014</b>		
Quarter ended March 31, 2014	\$ 15.20	\$ 9.52
Quarter ended June 30, 2014	\$ 16.48	\$ 9.68
Quarter ended September 30, 2014	\$ 15.00	\$ 5.00
Quarter ended December 31, 2014	\$ 6.70	\$ 1.51

## Holders

As of March 1, 2016, there were 151 stockholders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC. Shares of common stock that are held by financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are considered to be held of record by Cede & Co. as one stockholder.

## Dividends

We have never paid our stockholders cash dividends, and we do not anticipate paying any cash dividends in the foreseeable future as we intend to retain any earnings for use in our business. Any future determination to pay dividends will be at the discretion of our board of directors.

## Securities Authorized for Issuance under Equity Compensation Plans

The following table provides certain information with respect to all of the Company's equity compensation plans in effect as of December 31, 2015.

<b>Plan Category</b>	<b>(a)</b>	<b>(b)</b>	<b>(c)</b>
	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>Weighted-average Exercise Price of Outstanding Options, Warrants and Rights</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))</b>
Equity compensation plans approved by security holders	3,243,041	\$ 2.36	2,970,012
Equity compensation plans not approved by security holders	—	N/A	—
<b>Total</b>	<b>3,243,041</b>		<b>2,970,012</b>

## Item 6. Selected Financial Data.

The information under this Item is not required to be provided by smaller reporting companies.

## **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

You should read the following discussion and analysis in conjunction with "Item 8. Financial Statements and Supplementary Data" included in this Annual Report on Form 10-K, or Annual Report. Operating results are not necessarily indicative of results that may occur in future periods.

This discussion and analysis contains forward-looking statements that involve a number of risks, uncertainties and assumptions. Actual events or results may differ materially from our expectations. Important factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements include, but are not limited to, those set forth in "Item 1A. Risk Factors" in this Annual Report. All forward-looking statements included in this Annual Report are based on information available to us as of the time we file this Annual Report and, except as required by law, we undertake no obligation to update publicly or revise any forward-looking statements.

### ***Overview***

We have been engaged in the discovery, development and commercialization of proprietary human monoclonal antibody products and vaccines for the diagnosis and treatment of a variety of cancers. We have discovered a pipeline of human monoclonal antibody products based on the protective immune responses generated by patients who have been immunized against targeted cancers. Therapeutic vaccines under development were discovered at Memorial Sloan Kettering Cancer Center, or MSK, and are exclusively licensed to MabVax Therapeutics. We operate in only one business segment. We have incurred net losses since inception, and we expect to incur substantial losses for the foreseeable future as we continue our research and development activities. To date, we have funded operations primarily through government grants, the sale of preferred stock, equity securities, non-equity payments from collaborators and interest income. The process of developing our products will require significant additional research and development, preclinical testing and clinical trials, as well as regulatory approval. We expect these activities, together with general and administrative expenses, to result in substantial operating losses for the foreseeable future. We will not receive product revenue unless we, or our collaborative partners, complete clinical trials, obtain regulatory approval and successfully commercialize one or more of our products.

During the year ended December 31, 2015, our loss from operations was \$18,124,895 and our net loss was \$18,105,315. Net cash used in operating activities for the year ended December 31, 2015 was \$10,525,182 and cash and cash equivalents at December 31, 2015 were \$4,084,085. As of December 31, 2015, we had an accumulated deficit of \$60,601,778.

We are subject to risks common to biopharmaceutical companies, including the need for capital, risks inherent in our research, development and commercialization efforts, preclinical testing, clinical trials, uncertainty of regulatory and marketing approvals, enforcement of patent and proprietary rights, potential competition and retention of key employees. In order for a product to be commercialized, it will be necessary for us to conduct preclinical tests and clinical trials, demonstrate efficacy and safety of our product candidates to the satisfaction of regulatory authorities, obtain marketing approval, enter into manufacturing, distribution and marketing arrangements, obtain market acceptance and, in many cases, obtain adequate reimbursement from government and private insurers. We cannot provide assurance that we will ever generate revenues or achieve and sustain profitability in the future or obtain the necessary working capital for our operations.

### ***2014 Merger Agreement***

On July 8, 2014, we consummated a merger with MabVax Therapeutics, pursuant to which our subsidiary Tacoma Acquisition Corp. merged with and into MabVax Therapeutics, with MabVax Therapeutics surviving as our wholly owned subsidiary.

As a result of the consummation and upon the closing of the Merger, the former stockholders, option holders and warrant holders of MabVax Therapeutics were issued, based on the methodology set forth in the merger agreement (which excluded certain out-of-the-money convertible securities and calculated others on a net-exercise or cashless basis under the terms of the convertible securities), approximately 85% of the outstanding shares of our common stock on a fully diluted basis and our stockholders, option holders and warrant holders immediately prior to the Merger owned approximately 15% of the outstanding shares of our common stock on a fully diluted basis (such percentages calculated based on the methodology set forth in the merger agreement). As a result of the Merger, a change of control of MabVax Therapeutics Holdings occurred.

The total consideration for the transaction was approximately \$6,416,000, based on the market price of MabVax Therapeutics Holdings common stock, since management has determined that this was the most reliable measure of fair value.

The issuance of shares of our common stock and preferred stock in the Merger were approved by our stockholders in the stockholders' meeting held on July 7, 2014.

For accounting purposes, because a change in control took place with a business, the Merger is treated as a "reverse acquisition" and MabVax Therapeutics is considered the accounting acquirer. As a result, the historical financial statements of the private company MabVax Therapeutics constitute the historical financial statements of the merged companies. The transaction is considered a business combination as the accounting acquirer, MabVax Therapeutics Holdings, is considered an operating entity. For accounting purposes, the private company MabVax Therapeutics is treated as the continuing reporting entity.

#### ***Reverse Stock Split, Name Change and Increase in Authorized Shares***

On September 8, 2014, we amended our amended and restated articles of incorporation to change our name from "Telik, Inc." to "MabVax Therapeutics Holdings, Inc." and to increase the authorized number of our common shares from 100,000,000 to 150,000,000 and our authorized number of preferred shares from 5,000,000 to 15,000,000. Also on September 8, 2014, we filed an amendment to our amended and restated articles of incorporation in order to effect a reverse split of our common stock on a 1-for-8 basis.

Shares of our common stock began to trade on the OTCQB marketplace on a post-split basis under the name "MabVax Therapeutics Holdings, Inc." on September 10, 2014 under the new CUSIP number 55414P108. Commencing on October 10, 2014, shares of our common stock begin trading on the OTCQB marketplace under the trading symbol "MBVX."

#### ***Clinical Product Development – Recent Updates***

**Phase I Clinical Trial of HuMab-5B1** – In December 2015, we received notice from the FDA authorizing the initiation a Phase I clinical trial with HuMab-5B1 as a therapeutic treatment for pancreatic cancer. We expect to begin patient enrollment at investigational sites in the first quarter of 2016. The Phase I trial will evaluate the safety, tolerability and pharmacokinetics of HuMab-5B1 as a single agent or in combination with a standard of care chemotherapy regimen in subjects with metastatic pancreatic cancer. The first cohort of patients will be enrolled in a traditional dose escalation regimen to assess safety and determine the optimal dose of the antibody. A second patient cohort will establish the safety and optimized dose of the antibody when administered with a standard of care chemotherapy. Two additional patient cohorts will be administered the optimized dose of antibody as a single agent, or in combination with a standard of care chemotherapy regimen, for the treatment of patients with pancreatic cancer.

**Phase I Clinical Trial of 89Zr-HuMab-5B1** – In December 2016, we filed an IND application with the FDA for 89Zr-HuMab-5B1, utilizing our fully human antibody product as a new generation PET scan cancer imaging agent. In January 2016 we received FDA authorization to proceed with a Phase I clinical trial in patients with pancreatic cancer. We plan to initiate the Phase I clinical trial in early 2016. The 89Zr-HuMab-5B1 imaging agent has demonstrated high-resolution images of tumors in xenograft animal models, potentially making it an important new tool to aid in the diagnosis, monitoring and assessment of pancreatic cancer patients and an attractive companion diagnostic for the HuMab-5B1 therapeutic product. This second planned Phase I trial will evaluate the safety, pharmacokinetics and biodistribution of 89Zr-HuMab-5B1 in cancer patients. The trial will also determine the ideal dose and conditions for an optimal PET scan image using the new imaging agent.

**Vaccines** – Our therapeutic vaccines were developed at MSK and are exclusively licensed to MabVax Therapeutics pursuant to agreements entered into by and between MabVax Therapeutics and MSK in 2008. These vaccines are administered in the adjuvant setting and have shown to elicit a protective antibody response in clinical studies. The antibodies are intended to seek out circulating tumor cells and micrometastases to kill them before they can cause cancer recurrence. Our lead cancer vaccines targeting recurrent sarcoma and ovarian cancer are currently in proof of concept Phase II multi-center clinical trials. Both trials have received substantial federal grant monies to support their development.

#### ***Preclinical Drug Product Development***

Our lead antibody candidate, HuMab-5B1, is being developed as a therapeutic product and as a diagnostic imaging product. The antibody targets carbohydrate antigen sialyl Lewis, which is widely expressed on tumors of the gastrointestinal tract, including pancreatic, colon and stomach cancers, as well as ovarian, breast, and small cell lung cancers. We are also developing the HuMab-5B1 antibody conjugated to a radiolabel as a novel PET imaging agent to assist in the diagnosis of pancreatic cancer. The advanced preclinical study results of our work in tumor imaging using our HuMab-5B1 antibody conjugated to a radiolabel were published in the *Journal of Nuclear Medicine*. We subsequently applied for and received a contract from the National Institutes of Health (the “NIH”) for the development of the HuMab-5B1 based PET imaging agent. We also discovered and are developing multiple fully-human antibodies to the antigen GD2.

#### ***Results of Operations***

##### *Revenues*

Revenues for the years ended December 31, 2015 and 2014 were \$1,267,036 and \$314,175, respectively, primarily from grant revenues. Future revenues will depend upon the extent to which we obtain approval of new grants or enter into new collaborative research agreements and the amounts of payments relating to such agreements.

	<b>Years Ended December 31,</b>		<b>% change</b>
	<b>2015</b>	<b>2014</b>	<b>2014 to 2015</b>
Revenues	\$ 1,267,036	\$ 314,175	303%

For the year ended December 31, 2015, MabVax Therapeutics recognized revenues of \$1,267,036, as compared to \$314,175 for the same period in the prior year. This increase was primarily due to more work performed on grant contracts in 2015 as compared to work performed on grants in 2014. Revenues earned in 2015 and 2014 were from different phases of the NIH Imaging Contract, which began on September 20, 2013 and continued in 2014 and 2015 with a Phase II portion of the SBIR contract from NCI being awarded for \$1.5 million.

##### *Research and Development Expenses*

Research and development expenses for the years ended December 31, 2015 and 2014 were \$9,596,768 and \$3,502,730, respectively. Our research and development costs consist primarily of clinical trial site costs, clinical data management and statistical analysis support, drug manufacture, storage and distribution, regulatory services and other outside services related to drug development.

	<b>Years Ended December 31,</b>		<b>% change</b>
	<b>2015</b>	<b>2014</b>	<b>2014 to 2015</b>
Research and development	\$ 9,596,768	\$ 3,502,730	174%

[Table of Contents](#)

Total research and development expenses for the year ended December 31, 2015 increased by 174%, or \$6,094,038, compared to the same period in 2014 were primarily related to GMP manufacturing development of our lead antibody candidate HuMab-5B1 at Patheon (f.k.a. Gallus BioPharmaceuticals), clinical consulting costs for use of outside experts in our antibody programs, cell line licensing costs during the quarter, increased staffing to support in-house management of patient monitoring for the sarcoma clinical trial, as well as increased stock based compensation costs due to annual grant to employees during the current quarter. Expenses in the same period a year ago were primarily for direct labor, supplies and third party costs in connection with the sarcoma vaccine trial, antibody manufacturing costs, as well as the initial contract expenses under the imaging contract with NIH.

Stock-based compensation expense included in research and development expenses for the years ended December 31, 2015 and 2014 was \$929,633 and \$163,019, respectively.

We expect our total research and development expenditures in the next twelve months to increase as we begin to fund the initial clinical study of HuMab-5B1 in humans intended to start in early 2016. Our current funds enable us to fund approximately the first half of phase I clinical trials for HuMab-5B1 until we receive interim clinical trial results. In the event we are unable to obtain sufficient funding for clinical development of HuMab-5B1, we will need to defer completion of clinical trials until such funding is in place. If we are unable to obtain additional funding for HuMab-5B1 to complete clinical development, our total research and development expenditures will decrease substantially until the additional funding is raised.

The process of conducting the clinical research necessary to obtain FDA approval is costly and time consuming. Current FDA requirements for a new human drug to be marketed in the United States include:

- the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety;
- filing with the FDA of an IND, to conduct initial human clinical trials for drug candidates;
- the successful completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate; and
- filing by the company and acceptance and approval by the FDA of an NDA for a product candidate to allow commercial distribution of the drug, which is beyond the scope of our financial resources. We intend on licensing or selling the technology prior to filing an NDA.

We consider the active management and development of our clinical pipeline to be crucial to our long-term success. The actual probability of success for each product candidate and clinical program may be impacted by a variety of factors, including, among others, the quality of the candidate, the validity of the target and disease indication, early clinical data, investment in the program, competition, manufacturing capability and commercial viability. Due to these and other factors, it is difficult to give accurate guidance on the anticipated proportion of our research and development investments or the future cash inflows from these programs.

*General and Administrative Expenses*

General and administrative expenses for the years ended December 31, 2015 and 2014 were \$9,795,163 and \$5,204,341, respectively.

	<u>Years Ended December 31,</u>		<u>% change</u>
	<u>2015</u>	<u>2014</u>	<u>2014 to 2015</u>
General and administrative	\$ 9,795,163	\$ 5,204,341	88%

The increase in general and administrative expenses of 88%, or \$4,590,822 in 2015, compared to the same period in 2014, was primarily due to an increase of approximately \$2,470,000 in business development expenses primarily related to restricted stock grants to consultants for services, \$1,460,000 in investor relations expenses related to restricted stock grants, \$782,000 in salaries and wages related to increased headcount primarily in finance and accounting areas, and \$1,326,000 in employee benefit and stock based compensation costs. The increase in general and administrative expenses was partially offset by lower legal costs of approximately \$1,278,000 compared to the same period in the prior year primarily resulting from legal costs related to the merger being recorded in the previous year.

[Table of Contents](#)

Stock-based compensation expense included in general and administrative expenses for the years ended December 31, 2015 and 2014 was \$3,534,062 and \$441,957, respectively.

We expect future general and administrative expenses to decrease in 2016 primarily as a result of lower anticipated stock based compensation expenses, partially offset by increased rent and facility expenses.

*Interest Income and Interest Expense*

	<u>Years Ended December 31,</u>		<u>% change</u>
	<u>2015</u>	<u>2014</u>	<u>2014 to 2015</u>
Interest and other income (expense), net	\$ (227)	\$ (379)	-40%

Interest and other income and expense, net was \$227 and \$379 for the years ended December 31, 2015 and 2014, respectively.

*Warrant Liability*

Change in fair value of warrant liability for the years ended December 31, 2015 and 2014 was 19,807 and \$475,422, respectively. The decrease was mainly due to the restructuring the Company's capital structure resulting in the elimination of the warrant liability as of December 31, 2015. We calculate the value of our warrant liability on a quarterly basis, or when other events and circumstances occur, using the Black-Scholes-Merton valuation model.

*Critical Accounting Policies and Significant Judgments and Estimates*

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements as well as the reported revenues and expenses during the reporting periods. On an on-going basis, we evaluate our estimates and judgments related to our operating costs. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates under different assumptions or conditions.

*Our critical accounting policies include:*

**Revenue recognition.** Revenue from grants is based upon internal and subcontractor costs incurred that are specifically covered by the grant, including a facilities and administrative rate that provides funding for overhead expenses. NIH grants are recognized when MabVax Therapeutics incurs internal expenses that are specifically related to each grant, in clinical trials at the clinical trial sites, by subcontractors who manage the clinical trials, and provided the grant has been approved for payment. U.S. grant awards are based upon internal research and development costs incurred that are specifically covered by the grant, and revenues are recognized when MabVax Therapeutics incurs internal expenses that are related to the approved grant.

Any amounts received by MabVax Therapeutics pursuant to the NIH grants prior to satisfying our revenue recognition criteria are recorded as deferred revenue.

**Clinical trial expenses.** We accrue clinical trial expenses based on work performed. In determining the amount to accrue, we rely on estimates of total costs incurred based on the enrollment of subjects, the completion of trials and other events defined in contracts. We follow this method because we believe reasonably dependable estimates of the costs applicable to various stages of a clinical trial can be made. However, the actual costs and timing of clinical trials are highly uncertain, subject to risks, and may change depending on a number of factors. Differences between the actual clinical trial costs and the estimated clinical trial costs that we have accrued in any prior period are recognized in the subsequent period in which the actual costs become known. Historically, these differences have not been material; however, material differences could occur in the future.

**Stock-based compensation.** Our stock-based compensation programs include grants of stock options and restricted stock to employees, non-employee directors and non-employee consultants. Stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense, under the straight-line method, over the employee, non-employee director or non-employee consultant's requisite service period (generally the vesting period of the equity grant).

We account for equity instruments, including stock options and restricted stock, issued to employees and non-employees in accordance with authoritative guidance for equity based payments. Stock options issued are accounted for at their estimated fair value determined using the Black-Scholes-Merton option-pricing model and restricted stock is accounted for using the grant date fair value of our common stock granted. The fair value of options and restricted stock granted to non-employees is re-measured as they vest, and the resulting increase in value, if any, is recognized as expense during the period the related services are rendered.

**Warrant liability.** We calculate the value of our warrant liability on a quarterly basis, or when other events and circumstances occur, using as a first step the Black-Scholes-Merton valuation model, taking into consideration the warrant exercise price, the probability of certain exercise price re-pricing scenarios, the market price for the common stock on the date of measurement, the risk-free interest rate, the dividend yield, the volatility of a comparable period in which the warrant may be exercised, and the remaining life of the warrant, and then as a second step we test our valuation for reasonableness based on settlement offers we have received from the holder of the warrant. If the settlement offer is within a reasonable period of time from when we do our calculation, and is not materially different from the value we recorded using the Black-Scholes-Merton model, then we retain the value established with our model. If the settlement offer were to reflect a materially different amount near the date of our calculation, then we would record the settlement offer.

**Income taxes.** Significant judgment is required by management to determine our provision for income taxes, our deferred tax assets and liabilities, and the valuation allowance to record against our net deferred tax assets, which are based on complex and evolving tax regulations throughout the world. Our tax calculation is impacted by tax rates in the jurisdictions in which we are subject to tax and the relative amount of income earned in each jurisdiction. Our deferred tax assets and liabilities are determined using the enacted tax rates expected to be in effect for the years in which those tax assets are expected to be realized.

The effect of an uncertain income tax position is recognized as the largest amount that is “more-likely-than-not” to be sustained under audit by the taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The realization of our deferred tax assets is dependent upon our ability to generate sufficient future taxable income. We establish a valuation allowance when it is more-likely-than-not that the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available evidence, both positive and negative. As of December 31, 2015, MabVax Therapeutics concluded that it was more-likely-than-not that its deferred tax assets would not be realized, and a full valuation allowance has been recorded.

#### **Liquidity and Capital Resources**

From inception to December 31, 2015, we have financed our operations principally through net proceeds received from private equity and preferred stock financings, and grants through the NIH and SBIR programs. We have experienced negative cash flows from operations each year since our inception. As of December 31, 2015, we had an accumulated deficit of \$60,601,778. We expect to continue to incur increased expenses, resulting in losses, over at least the next several years due to, among other factors, our continuing and planned clinical trials and anticipated research and development activities. We had cash and cash equivalents of \$4,084,085 as of December 31, 2015.

	<u>2015</u>	<u>2014</u>
<b>December 31:</b>		
Cash and cash equivalents	\$ 4,084,085	\$ 1,477,143
Working capital/(deficit)	\$ 350,621	\$ (1,055,335)
Current ratio	1.07:1	0.64:1
<b>December 31:</b>		
Cash provided by (used in):		
Operating activities	\$ (10,525,182)	\$ (7,662,019)
Investing activities	\$ (78,416)	\$ 1,452,476
Financing activities	\$ 13,210,540	\$ 7,332,432

## **Sources and Uses of Cash**

Due to the significant research and development expenditures and the lack of any approved products to generate revenue, we have not been profitable and have generated operating losses since we incorporated in 1988. As such, we have funded our research and development operations through government grants and contracts, sales of equity, collaborative arrangements with corporate partners, and interest earned on investments. At December 31, 2015, we had available cash and cash equivalents of \$4,084,085. Our cash and cash equivalents balances are held primarily in checking accounts. Cash in excess of immediate requirements is invested with regard to liquidity and capital preservation. Wherever possible, we seek to minimize the potential effects of concentration and degrees of risk.

**Cash Flows from Operating Activities.** Cash used in operating activities for 2015 was \$10,525,182 compared to \$7,662,019 for the same period in 2014. Net loss of \$18,105,315 in 2015 included non-cash charges of \$4,463,695 for stock-based compensation and \$21,360 in depreciation, partially offset by a \$19,807 reduction in fair value of the Series B warrants. Cash used in 2014 resulted from net loss of \$7,917,853 and included non-cash charges of \$604,976 for stock-based compensation and \$12,241 for depreciation, partially offset by a \$475,422 reduction in fair value of the Series B warrants.

**Cash Flows from Investing Activities.** Cash provided by (used in) investing activities for 2015 was \$(78,416) compared to \$1,452,476 during the same period in 2014. Cash used in 2015 was primarily used to purchase property and equipment. Cash provided in 2014 was primarily from \$1,497,283 in cash received in the Merger, offset by \$44,807 used to purchase property and equipment.

**Cash Flows from Financing Activities.** Cash provided by financing activities for 2015 was \$13,210,540 compared to \$7,332,432 provided in 2014. Cash provided by financing activities in 2015 included \$10,709,740 from net proceeds from the sale of common stock and warrants in a private placement completed in April 2015, as well as a public offering completed in October 2015 for \$2,750,000. Cash provided by financing activities in 2014 included \$2,884,333 from sales of our common stock, \$2,973,655 from sales of preferred stock, and \$1,472,502 from exercises of Series C-1 warrants.

**Working Capital.** Working capital increased to \$350,621 at December 31, 2015 compared to a working capital deficit of \$1,055,335 at December 31, 2014. The increase in working capital was primarily due an increase in the amount of capital raised from sales of our common stock and preferred stock partially offset by 2014 costs related to the completion of the merger and costs associated with becoming a public company.

After giving effect to the net proceeds received from the January 2016 Term Loan, we believe our cash and cash equivalents as of December 31, 2015 will be sufficient to fund our projected operating requirements through approximately September 2016. In order to continue our current and future operations and continue our clinical product development programs through 2016, we will depend on our ability to obtain additional funding in a timely manner or if at all. We are uncertain about our ability to raise sufficient funds to continue our existing operations beyond 2016. We continue to explore alternatives that could include partnerships involving one or more of our product candidates, licensing arrangements with one or more of our product development candidates, merger with or acquisition by another company, or some other arrangement through which the value of our assets to stockholders could be enhanced. We may raise funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently. Our failure to raise capital when needed could materially harm our business, financial condition and results of operations. See Risk Factors.

Our future capital uses and requirements depend on numerous factors, including the following:

- the progress and success of preclinical studies and clinical trials of our product candidates;
- the progress and number of research programs in development;
- the costs associated with conducting Phase I and II clinical trials;
- the costs and timing of obtaining regulatory approvals;
- our ability to establish, and the scope of, any new collaborations;
- our ability to meet the milestones identified in our collaborative agreements that trigger payments;
- the costs and timing of obtaining, enforcing and defending our patent and intellectual property rights; and
- competing technological and market developments.

### ***Future Contractual Obligations***

MabVax Therapeutics had rental payment obligations under an operating lease that expired on July 31, 2015 related to its facility at 11588 Sorrento Valley Road. During the quarter ended December 31, 2015, the Company continued to occupy the current premises and continued the lease on a month-to-month basis.

On September 2, 2015, the Company entered into a lease (the "Lease") with AGP Sorrento Business Complex, L.P., for certain premises consisting of a total of approximately 14,971 square feet of office and laboratory space in buildings located at 11535-11585 Sorrento Valley Rd., San Diego, California, to serve as the Company's corporate offices and laboratories (the "New Premises"). Due to the fact that certain tenant improvements needed to be made to the New Premises before the Company could occupy the New Premises, the term of the Lease commenced on February 5, 2015. The Lease terminates six years after such term commencement date, unless earlier terminated in accordance with the Lease. Pursuant to the terms of the Lease, the monthly base rent will be \$35,631, subject to annual increases as set forth in the Lease.

The Company has an option to extend the Lease term for a single, five-year period. If the Lease term is extended for the optional five-year period, the monthly base rent will be adjusted based on fair market rental value. In addition to rent, the Company agreed to pay a portion of the taxes and utility, maintenance and other operating costs paid or accrued in connection with the ownership and operation of the property.

Our master lease and sublease of our facility located at 3165 Porter Drive in Palo Alto, California (the "Porter Drive Facility") were terminated on February 28, 2013 and we entered into a termination agreement with ARE on February 19, 2013 to voluntarily surrender its premises. As a result of the termination agreement, we were relieved of further obligations under the master lease and further rights to rental income under the sublease and paid a termination fee of approximately \$700,000. In addition to the termination fee, if we receive \$15 million or more in additional financing in the aggregate, an additional termination fee of \$590,504 will be due to ARE, but will otherwise be forgiven.

We anticipate that we will continue to incur substantial net losses into the foreseeable future as we: (i) initiate in the first quarter 2016 Phase I clinical trials planned for our stand-alone therapeutic HuMab 5b-1 and our PET imaging agent 89Zr-HuMab-5B1, (ii) continue to conduct preclinical development activities related to other product development candidates in our library, and (iii) monitor patients in clinical trials that have already completed their treatment regimens. Based on management's assumptions for continuing to develop its existing pipeline of products without additional funding, we expect we will have sufficient funds to meet our obligations through September 2016.

We plan to continue to fund our research and development and operating activities through equity or debt financings, strategic collaborations, licensing arrangements, government grants or other arrangements. However, we cannot be sure that such additional funds will be available on reasonable terms, or at all. If we are unable to secure adequate additional funding, we may be forced to reduce spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. In addition, if we do not meet our payment obligations to third parties as they come due, we may be subject to litigation claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management. Any of these actions could materially harm our business, results of operations, and future prospects.

If we raise additional funds by issuing equity securities, substantial dilution to our existing stockholders would result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

### ***Off-Balance Sheet Arrangements***

We have no material off-balance sheet arrangements as defined in Regulation S-K 303(a)(4)(ii).

### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

We do not hold any derivative financial instruments, commodity-based instruments or other long-term debt obligations.

### **Item 8. Financial Statements and Supplementary Data.**

All information required by this item is included in Item 15 of Part IV of this Annual Report and is incorporated into this item by reference.

**Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.**

None

**Item 9A. Controls and Procedures.**

***a) Disclosure Controls and Procedures***

Our principal executive officer and principal financial officer evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective, at the reasonable assurance level, in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

For the year ended December 31, 2014, we identified two material weaknesses in our internal controls over financial reporting and have taken measures in 2015 to mitigate both material weaknesses. In June 2014, we hired an Assistant Controller to prepare many of the accounting transactions so that the Chief Financial Officer is in a position to timely review the transactions in preparation for issuing the financial statements. In April 2015, the Assistant Controller was promoted to controller and we hired a Senior Director of Finance to take over some of the responsibilities of the controller and Chief Financial Officer, so that the Chief Financial Officer is able to perform review functions on significant transactions on a going forward basis. In July 2015, we hired a Staff Accountant further enabling us to enhance controls by segregating certain additional responsibilities within the accounting function. Also in 2015, we hired an independent consultant to document, test and evaluate our internal controls.

***b) Management’s Report on Internal Control over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, as a process designed by, or under the supervision of, a company’s principal executive and principal financial officer and effected by the our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
- (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made in accordance with authorizations of management and directors of the company; and
- (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible enhancements to controls and procedures.

We conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our principal executive officer and principal financial officer conclude that, at December 31, 2015, our internal control over financial reporting was effective.

This annual report does not include an attestation report of the company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the company's independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the company to provide only management's report in this annual report.

#### **CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING**

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded that, other than as discussed above, there were no such changes during the quarter ended December 31, 2015.

#### **Item 9B. Other Information.**

None.

### **PART III**

#### **Item 10. Directors, Executive Officers and Corporate Governance.**

Information responsive to this Item will be included in our definitive proxy statement relating to our 2016 annual meeting of stockholders to be filed by us with the Securities and Exchange Commission no later than 120 days after the close of our fiscal year ended December 31, 2015 and is incorporated herein by reference.

#### **Item 11. Executive Compensation.**

Information responsive to this Item will be included in our definitive proxy statement relating to our 2016 annual meeting of stockholders to be filed by us with the Securities and Exchange Commission no later than 120 days after the close of our fiscal year ended December 31, 2015 and is incorporated herein by reference.

#### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

Information responsive to this Item will be included in our definitive proxy statement relating to our 2016 annual meeting of stockholders to be filed by us with the Securities and Exchange Commission no later than 120 days after the close of our fiscal year ended December 31, 2015 and is incorporated herein by reference.

#### **Item 13. Certain Relationships and Related Transactions, and Director Independence.**

Information responsive to this Item will be included in our definitive proxy statement relating to our 2016 annual meeting of stockholders to be filed by us with the Securities and Exchange Commission no later than 120 days after the close of our fiscal year ended December 31, 2015 and is incorporated herein by reference.

#### **Item 14. Principal Accounting Fees and Services**

Information responsive to this Item will be included in our definitive proxy statement relating to our 2016 annual meeting of stockholders to be filed by us with the Securities and Exchange Commission no later than 120 days after the close of our fiscal year ended December 31, 2015 and is incorporated herein by reference.

**PART IV****Item 15. Exhibits and Financial Statement Schedules.**

The following documents are filed as part of this Annual Report:

1. *Financial Statements.* Our consolidated financial statements and the Report of Independent Registered Public Accounting Firm are included in Part IV of this Report on the pages indicated:
2. *Financial Statement Schedules.* All schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or the notes thereto.
3. *Exhibits:*

<b>Exhibit No.</b>	<b>Description</b>	<b>Form</b>	<b>Filing Date/Period End</b>	<b>Exhibit Number</b>
2.1	Agreement and Plan of Merger and Reorganization, dated May 12, 2014, between the Company, Tacoma Acquisition Corp., Inc. and MabVax Therapeutics, Inc.	8-K	5/12/2014	2.1
2.2	Amendment No.1, dated as of June 30, 2014, by and between the Company and MabVax Therapeutics, Inc.	8-K	7/1/2014	2.1
2.3	Amendment No.2 to the Agreement and Plan of Merger, dated July 7, 2014, by and among the Company, Tacoma Acquisition Corp. and MabVax Therapeutics, Inc.	8-K	7/9/2014	2.1
3.1	Certificate of Designations, Preferences and Rights of Series C Convertible Preferred Stock	8-K	9/3/2014	3.1
3.2	Amended and Restated Certificate of Incorporation	8-K	9/9/2014	3.1
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation	8-K	9/9/2014	3.2
3.4	Amended and Restated Bylaws	8-K	12/14/2007	3.2
3.5	Certificate of Designations, Preferences and Rights of Series D Convertible Preferred Stock	8-K	3/26/2015	3.1
3.6	Certificate of Designations, Preferences and Rights of Series E Convertible Preferred Stock	10-K	3/31/2015	3.8

Table of Contents

4.1	Securities Purchase Agreement, dated as of February 12, 2014, between MabVax Therapeutics, Inc. and the purchasers set forth on the signature pages thereto including that certain Amendment No. 1 to Securities Purchase Agreement, dated as of May 12, 2014, between MabVax Therapeutics, Inc. and the persons and entities identified on the signature pages thereto	8-K	5/12/2014	10.3
4.2	Registration Rights Agreement, dated as of February 12, 2014, between MabVax Therapeutics, Inc. and the persons and entities identified on the signature pages thereto	8-K	5/12/2014	10.2
4.3	Form of Exchange Agreement	8-K	9/3/2014	10.1
4.4	Form of Waiver Letter	8-K	9/3/2014	10.2
4.5	Form of Common Stock Certificate	S-1	9/29/2014	4.1
4.6	Form of Waiver Extension Letter	8-K	9/30/2014	10.1
4.7	Form of Subscription Agreement, dated March 31, 2015, between the Company and the subscribers set forth on the signature pages thereto	10-K	3/31/2015	4.11
4.8	Form of Common Stock Purchase Warrant	10-K	3/31/2015	4.12
4.9	Form of Registration Rights Agreement, dated March 31, 2015, between the Company and the persons and entities identified on the signature pages thereto	10-K	3/31/2015	4.13
4.10	Form of Secured Promissory Note	8-K	1/19/2016	4.1
4.11	Form of Warrant	8-K	1/19/2016	4.2
10.1	Separation Agreement and Release, dated May 12, 2014, between Michael M. Wick and the Company	8-K	5/12/2014	10.4
10.2	Separation Agreement and Release, dated May 12, 2014, between William P. Kaplan and the Company	8-K	5/12/2014	10.5
10.3	Separation Agreement and Release, dated May 12, 2014, between Steven R. Schow and the Company	8-K	5/12/2014	10.6
10.4	Separation Agreement and Release, dated May 12, 2014, between Wendy K. Wee and the Company	8-K	5/12/2014	10.7
10.5	Michael Wick Resignation Letter, dated July 7, 2014	8-K	7/9/2014	99.1
10.6	Edward W. Cantrall Resignation Letter, dated July 7, 2014	8-K	7/9/2014	99.2
10.7	Steven R. Goldring Resignation Letter, dated July 7, 2014	8-K	7/9/2014	99.3

Table of Contents

10.9	Richard B. Newman Resignation Letter, dated July 7, 2014	8-K	7/9/2014	99.4
10.10	Employment Agreement, dated July 1, 2014, by and between MabVax Therapeutics, Inc. and J. David Hansen	10-Q	8/8/2014	10.9
10.11	Employment Agreement, dated July 1, 2014, by and between MabVax Therapeutics, Inc. and Gregory P. Hanson	10-Q	8/8/2014	10.10
10.12	Employment Agreement, dated July 1, 2014, by and between MabVax Therapeutics, Inc. and Wolfgang W. Scholz, Ph.D.	10-Q	8/8/2014	10.11
10.13	Securities Purchase Agreement, dated July 8, 2014, by and between MabVax Therapeutics, Inc. and certain institutional investors set forth therein	10-Q	8/8/2014	10.12
10.14	Form of Indemnification Agreement	8-K	9/9/2014	10.1
10.15	Second Amended and Restated MabVax Therapeutics Holdings, Inc. 2014 Employee, Director and Consultant Equity Incentive Plan	10-K	3/31/2015	10.15
10.16	Non-Employee Director Compensation Policy	10-Q/A	8/12/2015	10.1
10.17	Standard Industrial Net Lease, dated as of May 23, 2008, by and between MabVax Therapeutics, Inc. and Sorrento Square	10-Q/A	8/12/2015	10.2
10.18	First Amendment to that Standard Industrial Net Lease, dated May 6, 2010, by and between MabVax Therapeutics, Inc. and Sorrento Square	10-Q/A	8/12/2015	10.3
10.19	Second Amendment to that Standard Industrial Net Lease, dated August 1, 2012, by and between the Company and Sorrento Square	10-Q/A	8/12/2015	10.4
10.20	Employment Agreement, dated July 21, 2014, 2014, by and between MabVax Therapeutics, Inc. and Paul Maffuid, Ph.D.	10-Q/A	8/12/2015	10.5
10.21	Development and Manufacturing Services Agreement, dated April 15, 2014, by and between MabVax Therapeutics, Inc. and Gallus BioPharmaceuticals NJ, LLC	10-Q/A	8/12/2015	10.6
10.22	Exclusive License Agreement for “Polyvalent Conjugate Vaccines for Cancer” (SK#14491), dated as of June 30, 2008, by and between MabVax Therapeutics, Inc. and Sloan-Kettering Institute for Cancer Research	10-Q/A	8/12/2015	10.7
10.23	Research and License Agreement, dated as of April 7, 2008, by and between MabVax Therapeutics, Inc. and Sloan-Kettering Institute for Cancer Research	10-Q/A	8/12/2015	10.8
10.24	Exclusive License to Unimolecular Antibodies, dated October 13, 2011, by and between MabVax Therapeutics, Inc. and Sloan-Kettering Institute for Cancer Research	10-Q/A	8/12/2015	10.9

Table of Contents

10.25	Option Agreement, dated August 29, 2014, by and between MabVax Therapeutics, Inc. and Juno Therapeutics, Inc.	10-Q/A	8/12/2015	10.10
10.26	SBIR Contract from National Cancer Institute	10-Q/A	8/12/2015	10.
10.27	Form of Exchange Agreement (Series A-1 Preferred Stock and Series A-1 Warrants).	8-K	3/26/2015	10.1
10.28	Form of Exchange Agreement (Series B Preferred Stock and Series B Warrants).	8-K	3/26/2015	10.2
10.29	2008 Equity Incentive Plan	10-K	3/31/2015	10.29
10.30	Form of Option Agreement, 2008 Equity Incentive Plan	10-K	3/31/2015	10.30
10.31	Form of Lockup Agreement dated as of April 3, 2015	8-K	4/6/2015	10.3
10.32	Consulting Agreement with The Del Mar Consulting Group, Inc. and Alex Partners, LLC dated as of April 5, 2015	8-K	4/6/2015	10.4
10.33	Form of Escrow Deposit Agreement dated as of April 14, 2015	8-K	4/15/2015	10.1
10.34	Form of Amendment Agreement to Registration Rights Agreement	8-K	6/10/2015	10.1
10.35	Amendment to Escrow Deposit Agreement dated June 22, 2015	8-K	6/24/2015	10.1
10.36	Letter Agreement dated June 30, 2015 between MabVax Therapeutics, Inc. and OPKO Health, Inc.	8-K	7/1/2015	10.1
10.37	Form of Proposed Lease Agreement with AGP Sorrento Business Complex, L.P	S-1	8/25/2015	10.37
10.38	Form of Amendment Agreement No. 2 to Registration Rights Agreement	8-K	8/4/2015	10.1
10.39	Non-Employee Director Compensation Policy	10-Q/A	8/12/2015	10.1
10.41	Standard Industrial Net Lease, dated as of May 23, 2008, by and between MabVax Therapeutics, Inc. and Sorrento Square	10-Q/A	8/12/2015	10.2
10.42	First Amendment to that Standard Industrial Net Lease, dated May 6, 2010, by and between MabVax Therapeutics, Inc. and Sorrento Square	10-Q/A	8/12/2015	10.3
10.43	Second Amendment to that Standard Industrial Net Lease, dated August 1, 2012, by and between the Company and Sorrento Square	10-Q/A	8/12/2015	10.4

Table of Contents

10.44	Employment Agreement, dated July 21, 2014, by and between MabVax Therapeutics, Inc. and Paul Maffuid, Ph.D.	10-Q/A	8/12/2015	10.5
10.45	Development and Manufacturing Services Agreement, dated April 15, 2014, by and between MabVax Therapeutics, Inc. and Gallus BioPharmaceuticals NJ, LLC	10-Q/A	8/12/2015	10.6
10.46	Exclusive License Agreement for “Polyvalent Conjugate Vaccines for Cancer” (SK#14491), dated as of June 30, 2008, by and between MabVax Therapeutics, Inc. and Sloan-Kettering Institute for Cancer Research	10-Q/A	8/12/2015	10.7
10.47	Research and License Agreement, dated as of April 7, 2008, by and between MabVax Therapeutics, Inc. and Sloan-Kettering Institute for Cancer Research	10-Q/A	8/12/2015	10.8
10.48	Exclusive License to Unimolecular Antibodies, dated October 13, 2011, by and between MabVax Therapeutics, Inc. and Sloan-Kettering Institute for Cancer Research	10-Q/A	8/12/2015	10.9
10.49	Option Agreement, dated August 29, 2014, by and between MabVax Therapeutics, Inc. and Juno Therapeutics, Inc.	10-Q/A	8/12/2015	10.10
10.50	SBIR Contract from National Cancer Institute	10-Q/A	8/12/2015	10.11
10.51	Lease by and between AGP Sorrento Business Complex, L.P., and MabVax Therapeutics Holdings, Inc., dated as of September 2, 2015	8-K	9/3/2015	10.1
10.52	Form of Amendment Agreement No.3 to Registration Rights Agreement	8-K	10/13/2015	10.1
10.53	Loan and Security Agreement dated as of January 15, 2016	8-K	1/19/2016	10.1
10.54*	Form of Amendment Agreement			
11.1	Statement of per share earnings	S-1	9/29/2014	11.1
21.1	Subsidiaries of the Registrant	S-1	9/29/2014	21.1
23.1*	Consent of Independent Registered Public Accounting Firm			
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
32.2 *	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
101*	Interactive data file			
*	Filed herewith			

**MABVAX THERAPEUTICS HOLDINGS, INC.  
INDEX TO FINANCIAL STATEMENTS**

<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-1
<a href="#">Consolidated Balance Sheets</a>	F-2
<a href="#">Consolidated Statements of Operations</a>	F-3
<a href="#">Consolidated Statements of Redeemable Convertible Preferred Stock, Convertible Preferred Stock and Stockholders' Equity (Deficit)</a>	F-4
<a href="#">Consolidated Statements of Cash Flows</a>	F-13
<a href="#">Notes to Consolidated Financial Statements</a>	F-14

## SIGNATURES

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

Date: March 14, 2016

MABVAX THERAPEUTICS HOLDINGS, INC

By: /s/ J. David Hansen  
J. David Hansen  
President and Chief Executive Officer (Principal executive officer)

By: /s/ Gregory P. Hanson  
Gregory P. Hanson  
Chief Financial Officer (Principal financial and accounting officer)

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ J. David Hansen</u> J. David Hansen	Chairman of the Board, President and Chief Executive Officer (Principal executive officer)	March 14, 2016
<u>/s/ Gregory P. Hanson</u> Gregory P. Hanson	Chief Financial Officer (Principal financial and accounting officer)	March 14, 2016
<u>/s/ J. Kenneth M. Cohen</u> Kenneth M. Cohen	Director	March 14, 2016
<u>/s/ Jeffrey F. Eisenberg</u> Jeffrey F. Eisenberg	Director	March 14, 2016
<u>/s/ J. Robert E. Hoffman</u> Robert E. Hoffman	Director	March 14, 2016
<u>/s/ Phillip O. Livingston</u> Philip O. Livingston, M.D.	Director	March 14, 2016
<u>/s/ Paul V. Maier</u> Paul V. Maier	Director	March 14, 2016
<u>/s/ J. Jeffrey V. Ravetch</u> Jeffrey V. Ravetch, M.D., Ph.D.	Director	March 14, 2016
<u>/s/ Thomas C. Varvaro</u> Thomas C. Varvaro	Director	March 14, 2016

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders  
MabVax Therapeutics Holdings, Inc.

We have audited the accompanying consolidated balance sheets of MabVax Therapeutics Holdings, Inc. (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, redeemable convertible preferred stock, convertible preferred stock and stockholders' equity (deficit), and cash flows for the years then ended. MabVax Therapeutics Holdings, Inc.'s management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of MabVax Therapeutics Holdings, Inc. as of December 31, 2015 and 2014, and the 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 consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring operating losses and is dependent on additional financing to fund operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ CohnReznick LLP

San Diego, California  
March 14, 2016

**MABVAX THERAPEUTICS HOLDINGS, INC.**  
**Consolidated Balance Sheets**

	<b>December 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 4,084,085	\$ 1,477,143
Grants receivable	757,562	84,344
Prepaid expenses	419,751	334,629
Other current assets	47,586	14,675
<b>Total current assets</b>	<b>5,308,984</b>	<b>1,910,791</b>
Property and equipment, net	135,486	57,053
Goodwill	6,826,003	6,826,003
Other long-term assets	126,654	11,017
<b>Total assets</b>	<b>\$ 12,397,127</b>	<b>\$ 8,804,864</b>
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,002,497	\$ 1,313,247
Accrued compensation	562,755	230,381
Accrued clinical operations and site costs	391,041	494,110
Accrued lease contingency fee	590,504	590,504
Other accrued expenses	411,566	245,421
Warrant liability	—	92,463
<b>Total current liabilities</b>	<b>4,958,363</b>	<b>2,966,126</b>
Commitments and contingencies		
Redeemable convertible preferred stock:		
MabVax Therapeutics Holdings Series B redeemable convertible preferred stock, 1,250,000 shares authorized, none and 1,250,000 issued and outstanding as of December 31, 2015 and 2014, respectively, with a liquidation preference of \$2,627,123 as of December 31, 2014	—	1,838,025
<b>Total redeemable convertible preferred stock</b>	<b>—</b>	<b>1,838,025</b>
Stockholders' equity (deficit):		
Series A-1 convertible preferred stock, 2,763,000 shares authorized, none and 1,593,389 shares issued and outstanding as of December 31, 2015 and 2014, respectively, with a liquidation preference of \$2,860,233 as of December 31, 2014	—	4,029,576
Series C convertible preferred stock, 200,000 shares authorized, none and 96,571 shares issued and outstanding as of December 31, 2015 and 2014, respectively, with no liquidation preference	—	966
Series D convertible preferred stock, \$0.01 par value, 1,000,000 shares authorized, 191,491 and no shares issued and outstanding as of December 31, 2015 and 2014, respectively, with a liquidation preference of \$1,915 as of December 31, 2015	1,915	—
Series E convertible preferred stock, \$0.01 par value, 100,000 shares authorized, 33,333 and no shares issued and outstanding as of December 31, 2015 and 2014, respectively, with a liquidation preference of \$333 as of December 31, 2015	333	—
Common stock, \$0.01 par value; 150,000,000 shares authorized as of December 31, 2015, 28,391,072 and 2,802,867 shares issued and outstanding as of December 31, 2015 and 2014, respectively	283,911	28,029
Additional paid-in capital	67,754,383	24,492,450
Accumulated deficit	(60,601,778)	(24,550,308)
<b>Total stockholders' equity</b>	<b>7,438,764</b>	<b>4,000,713</b>
<b>Total liabilities, redeemable convertible preferred stock and stockholders' equity</b>	<b>\$ 12,397,127</b>	<b>\$ 8,804,864</b>

See Accompanying Notes to Consolidated Financial Statements.

**MABVAX THERAPEUTICS HOLDINGS, INC.**  
**Consolidated Statements of Operations**

	<b>For the Years Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
Revenues:		
Grants	\$ 1,267,036	\$ 304,175
Other	—	10,000
Total revenues	<u>1,267,036</u>	<u>314,175</u>
Operating costs and expenses:		
Research and development	9,596,768	3,502,730
General and administrative	9,795,163	5,204,341
Total operating costs and expenses	<u>19,391,931</u>	<u>8,707,071</u>
Loss from operations	(18,124,895)	(8,392,896)
Interest and other income (expense)	(227)	(379)
Change in fair value of warrant liability	19,807	475,422
Net loss	(18,105,315)	(7,917,853)
Deemed dividend on Series A-1 preferred stock	(9,017,512)	(2,214,911)
Deemed dividend on Series A-1 warrant	(179,411)	—
Deemed dividend on Series B preferred stock	(8,655,998)	—
Accretion of preferred stock dividends	(93,234)	(444,992)
Net loss allocable to common stockholders	<u>\$ (36,051,470)</u>	<u>\$ (10,577,756)</u>
Basic and diluted net loss per share	<u>\$ (1.82)</u>	<u>\$ (9.51)</u>
Shares used to calculate basic and diluted net loss per share	<u>19,844,875</u>	<u>1,112,481</u>

See Accompanying Notes to Consolidated Financial Statements.

**MABVAX THERAPEUTICS HOLDINGS, INC.**

**Consolidated Statements of Redeemable Convertible Preferred Stock, Convertible Preferred Stock and Stockholders' Equity  
(Deficit)**

	Redeemable Convertible Preferred Stock								
	MabVax Series A		MabVax Series B		MabVax Series C-1		Series B		Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	
<b>Balance at</b>									
<b>December 31, 2013</b>	<b>956,240</b>	<b>\$5,787,906</b>	<b>891,485</b>	<b>\$ 6,737,276</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>\$12,525,182</b>
Exercise of Series B warrant in January at \$0.01 per share	—	—	194,281	1,942	—	—	—	—	1,942
Conversion of \$240,000 in accounts payable into 44,466 shares of common stock on February 12, 2014	—	—	—	—	—	—	—	—	—
Issuance of MabVax Series C-1 preferred stock in February at \$0.84 per share, net of issuance costs of \$126,345	—	—	—	—	3,697,702	2,973,655	—	—	2,973,655
Deemed dividend related to beneficial conversion feature of MabVax Series C-1 preferred	—	—	—	—	—	2,214,911	—	—	2,214,911
Issuance of common stock at \$9.32 per share, net of issuance costs of \$156,303 in June and July	—	—	—	—	—	—	—	—	—
Reclassification of Series A and Series B to equity in June	(956,240)	(5,787,906)	(1,085,766)	(6,739,218)	—	—	—	—	(12,527,124)
Conversion of Series A to common stock on July 8, 2014	—	—	—	—	—	—	—	—	—
Conversion of Series B to common stock on July 8, 2014	—	—	—	—	—	—	—	—	—
Accretion of redemption value for Series C-1 to July 8, 2014	—	—	—	—	—	99,200	—	—	99,200
Exercise of Series C-1 warrant on July 7, 2014	—	—	—	—	1,827,979	1,472,502	—	—	1,472,502
Accretion of redemption value for Series C-1 warrant to July 8, 2014	—	—	—	—	—	47,120	—	—	47,120
Conversion of Series C-1 into Series A-1 on July 8, 2014	—	—	—	—	(5,525,681)	(6,807,388)	—	—	(6,807,388)
Accretion of redemption value for Series A-1 from July 8 to December 31, 2014	—	—	—	—	—	—	—	—	—

Acquisition of MabVax Therapeutics Holdings (f.k.a. Telik, Inc.) at exchange ratio of 2.223284 shares of MabVax Therapeutics Holdings for every share of MabVax, including 4,205,411 common and 1,250,000 Series B preferred stock outstanding in July	—	—	—	—	—	—	1,250,000	1,710,902	1,710,902
Accretion of redemption value for Series B from May 12, 2014	—	—	—	—	—	—	—	127,123	127,123
Exchange of common stock for Series C on September 3, 2014	—	—	—	—	—	—	—	—	—
Elimination of fractional shares resulting from Reverse Split on September 8, 2014	—	—	—	—	—	—	—	—	—
Shares issued in connection with exercise of warrants on a cashless basis in September and October	—	—	—	—	—	—	—	—	—
Conversion of Series A-1 into common stock from November 13 to December 31, 2014	—	—	—	—	—	—	—	—	—
Conversion of Series C into common stock from October to December 2014	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—
<b>Balance at December 31, 2014</b>	—	—	—	—	—	—	<b>1,250,000</b>	<b>1,838,025</b>	<b>1,838,025</b>
Conversion of Series A-1 into common stock on January 10 and February 25, 2015	—	—	—	—	—	—	—	—	—
Conversion of Series C into common stock on January 10, 2015	—	—	—	—	—	—	—	—	—
Conversion of Series B into common stock between March 3 and March 20, 2015	—	—	—	—	—	—	(106,437)	(160,380)	(160,380)
Accretion of redemption value for Series A-1 from January 1 to March 25, 2015	—	—	—	—	—	—	—	—	—
Accretion of redemption value for Series B from January 1 to March 25, 2015	—	—	—	—	—	—	—	45,485	45,485
Deemed dividend related to exchange of common stock for Series A-1, Series A-1 Warrants, and Series B on March 25, 2015	—	—	—	—	—	—	—	8,655,998	8,655,998

Exchange of Series A-1 and Series A-1 Warrants into common and Series D on March 25, 2015	—	—	—	—	—	—	—	—	—	—
Exchange of Series B into Common and Series D on March 25, 2015	—	—	—	—	—	—	(1,143,563)	(10,379,128)	(10,379,128)	
Private Placement Issuance of 6,661,000 shares at \$0.75 per share, net of issuance costs of \$281,023 on March 31, 2015	—	—	—	—	—	—	—	—	—	—
Issuance of additional common stock in March 2015 under common stock Purchase Agreement in relation to financing on July 7, 2014	—	—	—	—	—	—	—	—	—	—
Private Placement Issuance of 5,624,998 shares at \$0.75 per share, net of issuance costs of \$387,127 on April 10, 2015	—	—	—	—	—	—	—	—	—	—
Private Placement Issuance of 33,333 shares at \$75 per share of Series E Preferred Stock on April 10, 2015	—	—	—	—	—	—	—	—	—	—
Issuance of restricted common stock in April 2015 for services	—	—	—	—	—	—	—	—	—	—
Issuance of restricted common stock to former board member on April 3, 2015 upon termination	—	—	—	—	—	—	—	—	—	—
Conversion of Series D Preferred Stock to common stock	—	—	—	—	—	—	—	—	—	—
Stock option exercise	—	—	—	—	—	—	—	—	—	—
Shares issued in connection with exercise of warrants on a cashless basis	—	—	—	—	—	—	—	—	—	—
Elimination of warrant liability in exchange transaction	—	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—
<b>Balance at December 31, 2015</b>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>\$ —</u>

See Accompanying Notes to Consolidated Financial Statements.

MABVAX THERAPEUTICS HOLDINGS, INC.

Consolidated Statements of Redeemable Convertible Preferred Stock, Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Convertible Preferred Stock							
	MabVax Series A		MabVax Series B		Series A-1		Series C	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
<b>Balance at December 31, 2013</b>	—	\$ —	—	\$ —	—	\$ —	—	\$ —
Exercise of Series B warrant in January at \$0.01 per share	—	—	—	—	—	—	—	—
Conversion of \$240,000 in accounts payable into 44,466 shares of common stock on February 12, 2014	—	—	—	—	—	—	—	—
Issuance of MabVax Series C-1 preferred stock in February at \$0.84 per share, net of issuance costs of \$126,345	—	—	—	—	—	—	—	—
Deemed dividend related to beneficial conversion feature of MabVax Series C-1 preferred	—	—	—	—	—	—	—	—
Issuance of common stock at \$9.32 per share, net of issuance costs of \$156,303 in June and July	—	—	—	—	—	—	—	—
Reclassification of Series A and Series B to equity in June	956,240	5,787,906	1,085,766	6,739,218	—	—	—	—
Conversion of Series A to common stock on July 8, 2014	(956,240)	(5,787,906)	—	—	—	—	—	—
Conversion of Series B to common stock on July 8, 2014	—	—	(1,085,766)	(6,739,218)	—	—	—	—
Accretion of redemption value for Series C-1 to July 8, 2014	—	—	—	—	—	—	—	—
Exercise of Series C-1 warrant on July 7, 2014	—	—	—	—	—	—	—	—
Accretion of redemption value for Series C-1 warrant to July 8, 2014	—	—	—	—	—	—	—	—
Conversion of Series C-1 into Series A-1 on July 8, 2014	—	—	—	—	2,762,841	6,807,388	—	—
Accretion of redemption value for Series A-1 from July 8 to December 31, 2014	—	—	—	—	—	171,549	—	—
Acquisition of MabVax Therapeutics Holdings (f.k.a. Telik, Inc.) at exchange ratio of 2.223284 shares of MabVax Therapeutics Holdings for every share of MabVax, including 4,205,411 common and 1,250,000 Series B preferred stock outstanding in July	—	—	—	—	—	—	—	—
Accretion of redemption value for Series B from May 12, 2014	—	—	—	—	—	—	—	—
Exchange of common stock for Series C on September 3, 2014	—	—	—	—	—	—	118,970	1,190
Elimination of fractional shares resulting from reverse split on September 8, 2014	—	—	—	—	—	—	—	—

[Table of Contents](#)

Shares issued in connection with exercise of warrants on a cashless basis in September and October	—	—	—	—	—	—	—	—
Conversion of Series A-1 into common stock from November 13 to December 31, 2014	—	—	—	—	(1,169,452)	(2,949,361)	—	—
Conversion of Series C into common stock from October to December 2014	—	—	—	—	—	—	(22,399)	(224)
Stock-based compensation	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—
<b>Balance at December 31, 2014</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>1,593,389</b>	<b>4,029,576</b>	<b>96,571</b>	<b>966</b>
Conversion of Series A-1 into common stock on January 10 and February 25, 2015	—	—	—	—	(64,019)	(162,968)	—	—
Conversion of Series C into common stock on January 10, 2015	—	—	—	—	—	—	(96,571)	(966)
Conversion of Series B into common stock between March 3 and March 20, 2015	—	—	—	—	—	—	—	—
Accretion of redemption value for Series A-1 from January 1 to March 25, 2015	—	—	—	—	—	47,749	—	—
Accretion of redemption value for Series B from January 1 to March 25, 2015	—	—	—	—	—	—	—	—
Deemed dividend related to exchange of common stock for Series A-1, Series A-1 Warrants, and Series B on March 25, 2015	—	—	—	—	—	9,196,923	—	—
Exchange of Series A-1 and Series A-1 Warrants into common and Series D on March 25, 2015	—	—	—	—	(1,529,370)	(13,111,280)	—	—
Exchange of Series B into common and Series D on March 25, 2015	—	—	—	—	—	—	—	—
Private Placement Issuance of 6,661,000 shares at \$0.75 per share, net of issuance costs of \$281,023 on March 31, 2015	—	—	—	—	—	—	—	—
Issuance of additional common stock in March 2015 under common stock Purchase Agreement in relation to financing on July 7, 2014	—	—	—	—	—	—	—	—
Private Placement Issuance of 5,624,998 shares at \$0.75 per share, net of issuance costs of \$387,127 on April 10, 2015	—	—	—	—	—	—	—	—
Private Placement Issuance of 33,333 shares at \$75 per share of Series E Preferred Stock on April 10, 2015	—	—	—	—	—	—	—	—

[Table of Contents](#)

Issuance of restricted common stock in April 2015 for services	—	—	—	—	—	—	—	—	—
Issuance of restricted common stock to former board member on April 3, 2015 upon termination	—	—	—	—	—	—	—	—	—
Conversion of Series D Preferred Stock to common stock	—	—	—	—	—	—	—	—	—
Stock option exercise	—	—	—	—	—	—	—	—	—
Shares issued in connection with exercise of warrants on a cashless basis	—	—	—	—	—	—	—	—	—
Elimination of warrant liability in exchange transaction	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—
<b>Balance at December 31, 2015</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>						

See Accompanying Notes to Consolidated Financial Statements.

MABVAX THERAPEUTICS HOLDINGS, INC.

Consolidated Statements of Redeemable Convertible Preferred Stock, Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Series D & E Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
<b>Balance at December 31, 2013</b>	—	\$ —	230,503	\$ 2,305	\$ 607,913	\$ (13,972,552)	\$ (13,362,334)
Exercise of Series B warrant in January at \$0.01 per share	—	—	—	—	—	—	—
Conversion of \$240,000 in accounts payable into 44,466 shares of common stock on February 12, 2014	—	—	44,466	445	239,555	—	240,000
Issuance of MabVax Series C-1 preferred stock in February at \$0.84 per share, net of issuance costs of \$126,345	—	—	—	—	—	—	—
Deemed dividend related to beneficial conversion feature of MabVax Series C-1 preferred	—	—	—	—	—	(2,214,911)	(2,214,911)
Issuance of common stock at \$9.32 per share, net of issuance costs of \$156,303 in June and July	—	—	326,264	3,263	2,881,070	—	2,884,333
Reclassification of Series A and Series B to equity in June	—	—	—	—	—	—	12,527,124
Conversion of Series A to common stock on July 8, 2014	—	—	265,749	2,657	5,785,249	—	—
Conversion of Series B to common stock on July 8, 2014	—	—	301,746	3,017	6,736,201	—	—
Accretion of redemption value for Series C-1 to July 8, 2014	—	—	—	—	—	(99,200)	(99,200)
Exercise of Series C-1 warrant on July 7, 2014	—	—	—	—	—	—	—
Accretion of redemption value for Series C-1 warrant to July 8, 2014	—	—	—	—	—	(47,120)	(47,120)
Conversion of Series C-1 into Series A-1 on July 8, 2014	—	—	—	—	—	—	6,807,388
Accretion of redemption value for Series A-1 from July 8 to December 31, 2014	—	—	—	—	—	(171,549)	—

[Table of Contents](#)

Acquisition of MabVax

Therapeutics Holdings (f.k.a. Telik, Inc.) at exchange ratio of 2.223284 shares of MabVax Therapeutics Holdings for every share of MabVax, including 4,205,411 common and 1,250,000 Series B preferred stock outstanding in July	—	—	572,858	5,729	4,699,997	—	4,705,726
Accretion of redemption value for Series B from May 12, 2014	—	—	—	—	—	(127,123)	(127,123)
Exchange of common stock for Series C on September 3, 2014	—	—	(148,713)	(1,487)	297	—	—
Elimination of fractional shares resulting from Reverse Split on September 8, 2014	—	—	—	—	(293)	—	(293)
Shares issued in connection with exercise of warrants on a cashless basis in September and October	—	—	488,659	4,887	(4,887)	—	—
Conversion of Series A-1 into common stock from November 13 to December 31, 2014	—	—	693,335	6,933	2,942,428	—	—
Conversion of Series C into common stock from October to December 2014	—	—	28,000	280	(56)	—	—
Stock-based compensation	—	—	—	—	604,976	—	604,976
Net loss	—	—	—	—	—	(7,917,853)	(7,917,853)
<b>Balance at December 31, 2014</b>	<b>—</b>	<b>—</b>	<b>2,802,867</b>	<b>28,029</b>	<b>24,492,450</b>	<b>(24,550,308)</b>	<b>4,000,713</b>
Conversion of Series A-1 into common stock on January 10 and February 25, 2015	—	—	38,456	384	162,584	—	—
Conversion of Series C into common stock on January 10, 2015	—	—	120,714	1,207	(241)	—	—
Conversion of Series B into common stock between March 3 and March 20, 2015	—	—	276,883	2,769	157,611	—	160,380
Accretion of redemption value for Series A-1 from January 1 to March 25, 2015	—	—	—	—	—	(47,749)	—
Accretion of redemption value for Series B from January 1 to March 25, 2015	—	—	—	—	—	(45,485)	(45,485)

[Table of Contents](#)

Deemed dividend related to exchange of common stock for Series A-1, Series A-1 Warrants, and Series B on March 25, 2015	—	—	—	—	—	(17,852,921)	(8,655,998)
Exchange of Series A-1 and Series A-1 Warrants into common and Series D on March 25, 2015	117,583	1,176	2,213,407	22,134	13,087,970	—	—
Exchange of Series B into common and Series D on March 25, 2015	120,573	1,206	324,095	3,241	10,374,681	—	10,379,128
Private Placement Issuance of 6,661,000 shares at \$0.75 per share, net of issuance costs of \$281,023 on March 31, 2015	—	—	6,661,000	66,610	4,648,116	—	4,714,726
Issuance of additional common stock in March 2015 under common stock Purchase Agreement in relation to financing on July 7, 2014	—	—	88,093	881	(881)	—	—
Private Placement Issuance of 5,624,998 shares at \$0.75 per share, net of issuance costs of \$387,127 on April 10, 2015	—	—	5,624,998	56,250	3,775,372	—	3,831,622
Private Placement Issuance of 33,333 shares at \$75 per share of Series E Preferred Stock on April 10, 2015	33,333	333	—	—	2,499,667	—	2,500,000
Issuance of restricted common stock in April 2015 for services	—	—	1,831,500	18,315	1,894,135	—	1,912,450
Issuance of restricted common stock to former board member on April 3, 2015 upon termination	—	—	20,000	200	45,800	—	46,000
Conversion of Series D Preferred Stock to common stock	(46,665)	(467)	4,666,500	46,665	(46,198)	—	—
Stock option exercise	—	—	2,779	28	772	—	800
Shares issued in connection with exercise of warrants on a cashless basis	—	—	1,219,780	12,198	(12,198)	—	—
Elimination of warrant liability in exchange transaction	—	—	—	—	72,656	—	72,656
Issuance of shares in registered offering in October 2015, net of issuance costs	—	—	2,500,000	25,000	2,138,392	—	2,163,392
Stock-based compensation	—	—	—	—	4,463,695	—	4,463,695
Net loss	—	—	—	—	—	(18,105,315)	(18,105,315)
<b>Balance at December 31, 2015</b>	<b>224,824</b>	<b>\$ 2,248</b>	<b>28,391,072</b>	<b>\$283,911</b>	<b>\$ 67,754,383</b>	<b>\$(60,601,778)</b>	<b>\$ 7,438,764</b>

See Accompanying Notes to Consolidated Financial Statements.

**MABVAX THERAPEUTICS HOLDINGS, INC.**  
**Consolidated Statements of Cash Flows**

	<b>For the Years Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Operating activities</b>		
Net loss	\$ (18,105,315)	\$ (7,917,853)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	21,360	12,241
Stock-based compensation	4,463,695	604,976
Change in fair value of warrants	(19,807)	(475,422)
Issuance of restricted common stock for services	1,958,450	—
Increase (decrease) in operating assets and liabilities excluding effects of the Merger:		
Grants receivable	(673,218)	(84,344)
Other receivables	2,275	28,316
Prepaid expenses and other	(199,377)	(117,004)
Accounts payable	1,631,305	1,246,270
Accrued clinical operations and site costs	(103,069)	(279,413)
Accrued compensation	332,374	(789,014)
Other accrued expenses	166,145	109,228
Net cash used in operating activities	<u>(10,525,182)</u>	<u>(7,662,019)</u>
<b>Investing activities</b>		
Purchases of property and equipment	(78,416)	(44,807)
Proceeds from acquisition of Telik, Inc.	—	1,497,283
Net cash provided by (used in) investing activities	<u>(78,416)</u>	<u>1,452,476</u>
<b>Financing activities</b>		
Issuances of preferred stock, net of issuance costs	2,500,000	2,973,655
Proceeds from exercise of MabVax Series B warrant	—	1,942
Proceeds from exercise of MabVax Series C-1 warrants	—	1,472,502
Proceeds from exercise of stock options	800	—
Proceeds from issuance of common stock, net of issuance costs	10,709,740	2,884,333
Net cash provided by financing activities	<u>13,210,540</u>	<u>7,332,432</u>
Net change in cash and cash equivalents	2,606,942	1,122,889
Cash and cash equivalents at beginning of year	1,477,143	354,254
Cash and cash equivalents at end of year	<u>\$ 4,084,085</u>	<u>\$ 1,477,143</u>
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid during the year for income taxes	<u>\$ 1,600</u>	<u>\$ 800</u>
<b>Supplemental disclosures of non-cash investing and financing information:</b>		
Deemed dividend on beneficial conversion feature for preferred stock	<u>\$ 17,852,921</u>	<u>\$ 2,214,911</u>
Goodwill on acquisition of Telik, Inc.	<u>\$ —</u>	<u>\$ 6,826,003</u>
Warrant liability upon acquisition of Telik, Inc.	<u>\$ —</u>	<u>\$ 567,885</u>
Accretion of redemption value for Series A-1, B and C-1 preferred stock	<u>\$ 93,234</u>	<u>\$ 444,992</u>
Issuance of common stock for accounts payable	<u>\$ —</u>	<u>\$ 240,000</u>
Conversion of Series A and Series B redeemable preferred stock into common stock	<u>\$ 160,380</u>	<u>\$ 12,527,124</u>
Conversion of Series C-1 redeemable preferred stock into Series A-1 preferred stock	<u>\$ —</u>	<u>\$ 6,807,388</u>
Conversion of Series D preferred stock into common stock	<u>\$ 467</u>	<u>\$ —</u>
Conversion of Series A-1 preferred stock and warrants into common stock and Series D preferred stock	<u>\$ 162,968</u>	<u>\$ —</u>
Acquisition of MabVax Therapeutics Holdings in relation to the merger	<u>\$ —</u>	<u>\$ 4,705,726</u>
Exchange of Series A-1 preferred stock and warrants to common stock and Series D convertible preferred stock	<u>\$ 13,111,280</u>	<u>\$ 2,949,361</u>
Exchange of Series B preferred stock and warrants to common stock and Series D convertible preferred stock	<u>\$ 10,451,784</u>	<u>\$ —</u>
Warrants exercised to purchase common stock on a cashless basis to purchase 488,659 shares of common stock.	<u>\$ 12,198</u>	<u>\$ 4,887</u>
Conversion of common stock to Series C preferred stock	<u>\$ —</u>	<u>\$ 1,190</u>
Elimination of warrant liability in exchange transaction	<u>\$ 72,656</u>	<u>\$ —</u>
Financing transaction not yet paid	<u>\$ 36,570</u>	<u>\$ —</u>
Conversion of Series C preferred stock to common stock	<u>\$ 966</u>	<u>\$ 224</u>
Property and equipment accrued in accounts payable	<u>\$ 21,376</u>	<u>\$ —</u>

See Accompanying Notes to Consolidated Financial Statements.

**MABVAX THERAPEUTICS HOLDINGS, INC.**  
**Notes to Consolidated Financial Statements**

**1. Nature of Operations and Basis of Presentation**

MabVax Therapeutics Holdings, Inc. (f.k.a. Telik, Inc. and referred to herein as “MabVax Therapeutics Holdings” or the “Company”) (OTCQB: MBVX) was incorporated in the state of Delaware on October 20, 1988. On July 8, 2014, Tacoma Acquisition Corp., a Delaware corporation and wholly owned subsidiary of MabVax Therapeutics Holdings (“Tacoma Corp.”) merged with MabVax Therapeutics, Inc., a Delaware corporation (“MabVax Therapeutics”) pursuant to an Agreement and Plan of Merger, dated May 12, 2014, by and among MabVax Therapeutics Holdings, Tacoma Corp. and MabVax Therapeutics, as amended by that certain Amendment No. 1 to the Merger Agreement, dated June 30, 2014, by and among the parties thereto and by that certain Amendment No. 2 to the Merger Agreement, dated July 7, 2014, by and among the parties thereto (such agreement as amended, the “Merger Agreement”; such Merger, the “Merger”). Unless the context otherwise requires, references to “we,” “our,” “us,” or the “Company” in this Annual Report mean MabVax Therapeutics Holdings on a consolidated financial statement basis with our wholly owned subsidiary following the Merger, MabVax Therapeutics, as applicable. On October 9, 2014 FINRA approved The Company’s stock symbol change request and the Company began trading under the symbol MBVX (OTCQB: MBVX) on October 10, 2014.

The Company is a clinical stage biopharmaceutical company engaged in the discovery, development and commercialization of proprietary human monoclonal antibody products and vaccines for the treatment of a variety of cancers. The Company has discovered a pipeline of human monoclonal antibody products based on the protective immune responses generated by patients who have been immunized against targeted cancers. Therapeutic vaccines under development were discovered at Memorial Sloan Kettering Cancer Center (“MSK”) and are exclusively licensed to MabVax Therapeutics. The Company operates in only one business segment.

The Company has incurred net losses since inception and expects to incur substantial losses for the foreseeable future as it continues its research and development activities. To date, the Company has funded operations primarily through government grants, the sale of preferred stock and equity securities, non-equity payments from collaborators and interest income. The process of developing products will require significant additional research and development, preclinical testing and clinical trials, as well as regulatory approvals. The Company expects these activities, together with general and administrative expenses, to result in substantial operating losses for the foreseeable future. The Company will not receive substantial revenue unless the Company or its collaborative partners complete clinical trials, obtain regulatory approvals and successfully commercialize one or more products; or the Company licenses its technology after achieving one or more milestones of interest to a potential partner.

***Liquidity and Going Concern***

The accompanying consolidated financial statements have been prepared on the going concern basis, which assumes that the Company will continue to operate as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. As reflected in the accompanying consolidated financial statements, the Company had a net loss of \$18,105,315, net cash used in operating activities of \$10,525,182 and net cash used by investing activities of \$78,416, for the year ended December 31, 2015. As of December 31, 2015, the Company had \$4,084,085 in cash and cash equivalents and an accumulated deficit of \$60,601,778.

On March 31, 2015 and April 10, 2015, we closed on a financing transaction by entering into separate subscription agreements with accredited investors relating to the issuance and sale of an aggregate of \$11,714,498 of units (the “Units”) at a purchase price of \$0.75 per Unit, with each Unit consisting of one share of common stock, par value \$0.01 per share (or, at the election of any investor who, as a result of receiving common stock would hold in excess of 4.99% of the Company’s issued and outstanding common stock, shares of the Company’s newly designated 0% Series E Convertible Preferred Stock) and a thirty-month warrant to purchase one half of one share of common stock at an initial exercise price of \$1.50 per share, as further described in the Notes to Financial Statements – Equity, (the “April 2015 Private Placement”).

The initial closing of the April 2015 Private Placement took place on March 31, 2015, in which the Company sold an aggregate of \$4,995,749 of Units. Following the initial closing The Company entered into separate reconfirmation agreements with the investors in order to extend the initial closing date, increase the offering amount, and adopt a lockup agreement, which was entered by all investors who elected to continue their investment. The second closing was completed on April 10, 2015 for an additional \$6,718,751 of Units. The Company issued \$2,500,000 of Units consisting of Series E Convertible Preferred Stock on April 10, 2015 and the remainder of Units issued in the April

2015 Private Placement were in the form of common stock Units. Of the total cash received in the second closing on April 10, 2015, \$3,500,000 was initially held in escrow under the terms of an escrow agreement with Signature Bank, N.A for a period of 10 weeks pending the approval of a representative of one of the lead investors to release the funds. On June 22, 2015, the Company, Signature Bank, N.A. and OPKO Health, Inc. (“OPKO”) extended the term of the escrow to 16 weeks from the closing of the April 2015 Private Placement. As further consideration for the amendment, on June 30, 2015, the Company and OPKO entered into a letter agreement pursuant to which the Company granted OPKO the right, but not the obligation, until June 30, 2016, to nominate and appoint up to two additional members of the Company’s board of directors (the “Board” or the “Board of Directors”), or to approve the person(s) nominated by the Company pursuant to the agreement in consideration for the release of the escrowed funds. The nominees will be subject to the satisfaction of standard corporate governance practices and any applicable national securities exchange requirements. Upon signing the agreement, the escrowed funds were released to the Company.

On October 5, 2015, we closed a public offering of 2,500,000 shares of common stock and warrants to purchase 1,250,000 shares of common stock, at an offering price of \$1.10 per share. For every two shares of common stock sold, the Company issued one warrant to purchase one share of common stock. The Company received \$2,750,000 in gross proceeds, before underwriting discounts and commissions and offering expenses totaling approximately \$586,608, and without giving effect to the exercise of the underwriters’ over-allotment option. The Company intends to use the net proceeds from this offering to fund the HuMab-5B1 human antibody program through Phase I clinical development and for working capital and general corporate purposes.

The shares and warrants were separately issued and sold in equal proportions. The warrants are immediately exercisable, expire September 30, 2018, and have an exercise price of \$1.32 per share. The warrants will not be listed on any securities exchange or other trading market. The underwriters did not exercise a 30-day option to purchase up to an additional 375,000 shares of common stock and up to an additional 187,500 warrants at the same price to cover over-allotments, if any.

Under the terms of the underwriting agreement entered into between the Company and the underwriter in the public offering, the Company, without the prior written consent of the underwriter, was prohibited, for a period of 90 days after execution of the underwriting agreement, from issuing any equity securities, subject to certain exceptions.

On October 12, 2015, the Company and investors holding over 60% of the outstanding Registerable Securities (as such term is defined in the Registration Rights Agreements) issued in the April 2015 Private Placement entered into a third amendment agreement to the Registration Rights Agreements to suspend the Company’s registration obligations under the Registration Rights Agreements and related subscription agreements during any period when the “Standstill” provision set forth in 5(u) of the related subscription agreements is in effect. On January 28, 2016, we filed a registration statement with the SEC; and we gave notification of effectiveness of the registration statement on February 10, 2016.

On January 15, 2016, the Company and Oxford Finance LLC, as collateral agent and lender, entered into a Loan and Security Agreement providing for senior secured term loans to the Company in an aggregate principal amount of up to \$10,000,000, subject to the terms and conditions set forth in the Loan Agreement (the “January 2016 Term Loan”). On January 15, 2016, the Company received an initial loan of \$5,000,000 under the Loan Agreement, before fees and issuance costs of approximately \$381,000.

We anticipate that the Company will continue to incur net losses into the foreseeable future as we: (i) initiate in the first quarter 2016 Phase I clinical trials planned for our stand-alone therapeutic HuMab 5b-1 and early in 2016 our PET imaging agent 89Zr-HuMab-5B1, (ii) continue to conduct preclinical efforts on several other programs, and (iii) continue operations as a public company. After giving effect to the net proceeds received from the January 2016 Term Loan, management believes that the Company has sufficient funds to meet its obligations through September 2016. These conditions give rise to substantial doubt as to the Company’s ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We plan to continue to fund the Company's losses from operations and capital funding needs through equity or debt financings, strategic collaborations, licensing arrangements, asset sales, government grants or other arrangements. However, we cannot be sure that such additional funds will be available on reasonable terms, or at all. If we are unable to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. In addition, if the Company does not meet its payment obligations to third parties as they come due, it may be subject to litigation claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Any of these actions could materially harm the Company's business, results of operations, and future prospects.

If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict the Company's ability to operate its business.

## **2. Summary of Significant Accounting Policies**

### ***Basis of Presentation***

The accompanying consolidated financial statements reflect all of our activities, including those of our wholly owned subsidiaries. All material intercompany accounts and transactions have been eliminated in consolidation.

### ***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Management believes that these estimates are reasonable; however, actual results may differ from these estimates.

### ***Cash and Cash Equivalents***

We consider all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. The Company minimizes its credit risk associated with cash and cash equivalents by periodically evaluating the credit quality of its primary financial institution. The balance at times may exceed federally insured limits. The Company has not experienced any losses on such accounts.

### ***Fair Value of Financial Instruments***

The Company's financial instruments consist of cash and cash equivalents, grants receivable, other receivable, accounts payable, all of which are generally considered to be representative of their respective fair values because of the short-term nature of those instruments.

### ***Grants Receivable***

Grants receivable at December 31, 2015 represent amounts due under the NIH Imaging Contract Phase II with the National Cancer Institute (the "NCI"), a division of the National Institutes of Health, or NIH (collectively, the "NIH Grants"). The Company considers the grants receivable to be fully collectible; accordingly, no allowance for doubtful accounts has been established. Grants receivable balances may include unbilled amounts for which work was completed by the Company as of the balance sheet date. If amounts become uncollectible, they are charged to operations.

### ***Property and Equipment***

Property and equipment are carried at cost less accumulated depreciation. Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the assets, which are generally three to five years. Leasehold improvements are amortized over the lesser of the life of the lease or the life of the asset.

### ***Impairment of Long-lived Assets***

We evaluate the Company's long-lived assets with definite lives, such as property and equipment, for impairment. We record impairment losses on long-lived assets used for operations when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the carrying value of the assets. There have not been any impairment losses of long-lived assets for the years ended December 31, 2015 and 2014.

### ***Impairment of Goodwill***

We apply Generally Accepted Accounting Principles ("GAAP") related to Intangibles – Goodwill and Other to test for goodwill impairment annually. The Company has conducted the annual impairment test and evaluated goodwill as of December 31, 2015, and concluded that no impairment of goodwill has taken place for the year ended December 31, 2015.

### ***Revenue Recognition***

Revenue from grants is based upon internal and subcontractor costs incurred that are specifically covered by the grant, including a facilities and administrative rate that provides funding for overhead expenses. NIH Grants are recognized when the Company incurs internal expenses that are specifically related to each grant, in clinical trials at the clinical trial sites, by subcontractors who manage the clinical trials, and provided the grant has been approved for payment. U.S. Treasury grant awards are based upon internal research and development costs incurred that are specifically covered by the grant, and revenues are recognized when the Company incurs internal expenses that are related to the approved grant. The Company records revenue associated with the NIH Grants as the related costs and expenses are incurred. Any amounts received by the Company pursuant to the NIH Grants prior to satisfying the Company's revenue recognition criteria are recorded as deferred revenue.

### ***Research and Development Costs***

Research and development expenses, which consist primarily of salaries and other personnel costs, clinical trial costs and preclinical study fees, manufacturing costs for non-commercial products, and the development of earlier-stage programs and technologies, are expensed as incurred when these expenditures have no alternative future uses. A significant portion of the development activities are outsourced to third parties, including contract research organizations. In such cases, the Company may be required to estimate related service fees incurred.

### ***Stock-based Compensation***

The Company's stock-based compensation programs include grants of stock options to employees, non-employee directors and non-employee consultants. Stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense, under the straight-line method, over the employee's requisite service period (generally the vesting period of the equity grant).

The Company accounts for equity instruments, including stock options, issued to non-employees in accordance with authoritative guidance for equity based payments to non-employees. Stock options issued to non-employees are accounted for at their estimated fair value determined using the Black-Scholes-Merton option-pricing model. The fair value of options granted to non-employees is re-measured as they vest, and the resulting increase in value, if any, is recognized as expense during the period the related services are rendered.

### ***Income Taxes***

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to basis differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. As of December 31, 2015 and 2014, all deferred tax assets were fully offset by a valuation allowance.

The Company accrues interest and penalties, if any, on underpayment of income taxes related to unrecognized tax benefits as a component of income tax expense in its consolidated statements of operations.

### ***Fair Value Measurements***

Level 1 fair value inputs are quoted prices for identical items in active, liquid and visible markets such as stock exchanges. Level 2 fair value inputs are observable information for similar items in active or inactive markets, and appropriately consider counterparty creditworthiness in the valuations. Level 3 fair value inputs reflect our best estimate of inputs and assumptions market participants would use in pricing an asset or liability at the measurement date. The inputs are unobservable in the market and significant to the valuation estimate.

### **3. Recent Accounting Pronouncements**

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers” (Topic 606). ASU No. 2014-09 supersedes the revenue recognition requirements in Topic 605, “Revenue Recognition,” and most industry-specific revenue recognition guidance throughout the Industry Topics of the Accounting Standards Codification. Additionally, this update supersedes some cost guidance included in Subtopic 605-35, “Revenue Recognition-Construction-Type and Production-Type Contracts.” The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. It is effective for the first interim period within annual reporting periods beginning after December 15, 2016, and early adoption is not permitted. In July 2015, the FASB affirmed its proposal to defer the effective date of this standard to annual reporting periods (and interim reporting periods within those years) beginning after December 15, 2017. Entities are permitted to apply the new revenue standard early, but not before the original effective date of annual periods beginning after December 15, 2016. Entities may choose from two adoption methods, with certain practical expedients. The Company is currently reviewing this standard to assess the impact on its future financial statements and evaluating the available adoption methods.

In June 2014, the FASB issued ASU No. 2014-12, “Compensation—Stock Compensation” (Topic 718): “Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period,” which requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. ASU No. 2014-12 is effective for annual reporting periods beginning after December 15, 2015, including interim periods within that reporting period, although early adoption is permitted. We are currently reviewing this standard to assess the impact on the Company’s future financial statements.

In August 2014, the FASB issued ASU No. 2014-15, (“ASU 2014-15”), “Disclosure of Uncertainties About an Entity’s Ability to Continue as a Going Concern”. ASU 2014-15 requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date the financial statements are issued and provides guidance on determining when and how to disclose going concern uncertainties in the financial statements. Certain disclosures will be required if conditions give rise to substantial doubt about an entity’s ability to continue as a going concern. ASU 2014-15 applies to all entities and is effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. Management is currently evaluating the impact of the adoption of the updated standard on the financial statements and disclosures.

In February 2016, the FASB issued ASU 2016-2, "Leases (Topic 842)". This update will increase transparency and comparability by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Under the new guidance, lessees will be required to recognize the following for all leases (with the exception of short-term leases) at the commencement date (i) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and (ii) a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. Under the new guidance, lessor accounting is largely unchanged, and it simplified the accounting for sale and leaseback transactions. Lessees will no longer be provided with a source of off-balance sheet financing. Lessees (for capital and operating leases) and lessors (for sales-type, direct financing, and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Lessees and lessors may not apply a full retrospective transition approach. The standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We are currently in the process of assessing what impact this new standard may have on our consolidated financial statements.

Management does not believe that any other recently issued, but not yet effective, accounting standards if currently adopted would have a material effect on the accompanying consolidated financial statements.

#### 4. Property and Equipment, Net

Property and equipment consisted of the following as of December 31, 2015 and 2014:

	December 31,	
	2015	2014
Furniture and fixtures	\$ 8,979	\$ 8,979
Office equipment	52,547	31,170
Lab equipment	400,301	321,884
	461,827	362,033
Less accumulated depreciation and amortization	(326,341)	(304,980)
Totals	\$ 135,486	\$ 57,053

Depreciation expense for the years ended December 31, 2015 and 2014 was \$21,360 and \$12,241, respectively.

#### 5. Reverse Stock Split, Name Change and Increase in Authorized Shares

On September 8, 2014, MabVax Therapeutics Holdings filed an amended and restated certificate of incorporation to increase the authorized number of shares of our common stock to a new total of 150,000,000 shares, increase the number of shares of our preferred stock to a new total of 15,000,000 shares, and change the name of the Company from "Telik, Inc." to "MabVax Therapeutics Holdings, Inc." The amendment and restatement of the certificate of incorporation effectuating the name change and above authorized share increases were approved by our stockholders at the special stockholder meeting on September 8, 2014 and by our Board of Directors at a meeting of the Board held on September 8, 2014.

On September 8, 2014, following the filing of the amended and restated certificate disclosed above, MabVax Therapeutics Holdings filed a certificate of amendment to the amended and restated certificate of incorporation to effect an 8-for-1 reverse stock split on common stock (the "Reverse Split"), effective as of 4:01 p.m. Eastern Time (the "Effective Time") on September 8, 2014 (the "Effective Date"). The Reverse Split was approved by our stockholders at the special stockholder meeting held on September 8, 2014 and by the Board of Directors at a meeting of the Board held on September 8, 2014.

On the Effective Date, immediately and without further action by our stockholders, every 8 shares of our common stock, issued and outstanding immediately prior to the Effective Time, were automatically converted into 1 share of our common stock. As a result of the Reverse Split and calculated as of the Record Date, the number of outstanding shares of our common stock was reduced from 13,932,937 to 1,741,617, excluding outstanding and unexercised share options and warrants and subject to adjustment for fractional shares. No fractional shares were issued as a result of the Reverse Split and, in lieu of these fractional shares, any holder of less than 1 share of our common stock was entitled to receive cash for such holder's fractional share equal to the product of such fraction multiplied by the average of the last reported bid and ask prices of our common stock at 4:00 p.m., Eastern time, end of regular trading hours on OTCQB marketplace, during the 10 consecutive trading days ending on the last trading day prior to the Effective Date. Further, any options, warrants and contractual rights outstanding as of the Effective Date that were subject to adjustment were adjusted in accordance with their terms. These adjustments included, without limitation, changes to the number of shares of our common stock that may be obtained upon exercise or conversion of these securities, and changes to the applicable exercise or purchase price of such securities.

Shares of our common stock began to trade on the OTCQB marketplace on a post-split basis under the name MabVax Therapeutics Holdings, Inc. on September 10, 2014 under the new CUSIP number 55414P108. MabVax Therapeutics Holdings retained the same CUSIP number when its common stock began trading on the OTCQB marketplace under the trading symbol MBVX on October 10, 2014.

All prior periods in these consolidated financial statements have been adjusted to reflect the effects of the Merger and the Reverse Split, unless otherwise indicated.

## **6. Merger with MabVax Therapeutics, Inc.**

On May 12, 2014, the Company entered into a Merger Agreement. Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, Tacoma Corp. was merged with and into private company MabVax Therapeutics on July 8, 2014, with MabVax Therapeutics surviving the Merger as a wholly owned subsidiary of MabVax Therapeutics Holdings. The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

On July 7, 2014, the stockholders of MabVax Therapeutics Holdings approved the Merger, and the Merger closed and became effective on July 8, 2014. At the effective date of the Merger: (a) all shares of MabVax Therapeutics Series A preferred stock and all shares of MabVax Therapeutics Series B preferred stock were automatically converted into shares of MabVax Therapeutics Holdings common stock, (b) all outstanding shares of MabVax Therapeutics common stock were converted into and exchanged for shares of MabVax Therapeutics Holdings common stock at an exchange rate calculated in accordance with the methodology set forth in the Merger Agreement, which resulted in 2.223284 shares of MabVax Therapeutics Holdings common stock for every share of MabVax Therapeutics common stock, (c) all outstanding shares of MabVax Therapeutics Series C-1 preferred stock were converted into and exchanged for shares of MabVax Therapeutics Holdings Series A-1 preferred stock at a rate of two shares of MabVax Therapeutics Series C-1 per each share of MabVax Therapeutics Holdings Series A-1 preferred stock, (d) each outstanding MabVax Therapeutics option and warrant to purchase MabVax Therapeutics common stock became options and warrants to purchase shares of MabVax Therapeutics Holdings common stock (and the number of such shares and exercise price was adjusted as calculated in accordance with the methodology set forth in the Merger Agreement), and (e) each outstanding MabVax Therapeutics warrant to purchase MabVax Therapeutics preferred stock was cancelled for no consideration.

As a result of the consummation of the Merger, as of the closing date, the former stockholders, option holders and warrant holders of MabVax Therapeutics were issued, based on the methodology set forth in the Merger Agreement (which excluded certain out-of-the-money convertible securities and calculated others on a net-exercise or cashless basis under the terms of the convertible securities) approximately 85% of the outstanding shares of MabVax Therapeutics Holdings common stock on a fully diluted basis and the stockholders, option holders and warrant holders of MabVax Therapeutics Holdings prior to the Merger owned approximately 15% of the outstanding shares of MabVax Therapeutics Holdings common stock on a fully diluted basis (such percentages calculated based on the methodology set forth in the Merger Agreement). As a result of the Merger, a change of control of MabVax Therapeutics Holdings occurred.

[Table of Contents](#)

For accounting purposes, the Merger is treated as a “reverse acquisition”. The private company MabVax Therapeutics is considered the accounting acquirer, and the public company MabVax Therapeutics Holdings is considered the legal acquirer and accounting acquiree. The private company MabVax Therapeutics is the accounting acquirer because it owns a majority of the merged company (approximately 85%). As a result, the historical financial statements of the private company MabVax Therapeutics constitute the historical financial statements of the merged companies. The transaction is considered a business combination as MabVax Therapeutics Holdings is considered an operating entity. For accounting purposes, MabVax Therapeutics is treated as the continuing reporting entity.

The issuance of shares of our common stock and preferred stock in the Merger was approved by our stockholders in the annual stockholder meeting held on July 7, 2014. Amendments to our amended and restated certificate of incorporation related to an increase in the authorized number of shares of our common stock and preferred stock and a proposed reverse stock split to maintain NASDAQ listing maintenance standards and other transactions contemplated by the Merger Agreement were not approved at this meeting. As a result of our not getting stockholder approval of a proposed reverse stock split at the July 7, 2014 annual stockholders’ meeting, we were unable to meet all of the listing requirements for the NASDAQ Exchange and our common stock began trading on the OTCQB market under the stock symbol MBVX. There is no impact on accounting for the Merger on July 8, 2014, as a result of not getting stockholder approval on all matters presented at the July 7, 2014 annual meeting.

The purchase price is based upon the fair value of MabVax Therapeutics Holdings (f.k.a. Telik, Inc.) common stock outstanding of 572,887 shares as of July 8, 2014, multiplied by the stock closing price at July 8, 2014 of \$11.20, or approximately \$6,416,000. The consideration transferred is based on the market price of MabVax Therapeutics Holdings since management has determined that this was the most reliable measure of fair value, taking into consideration a third party valuation we received for financial reporting purposes as outlined under the Financial Accounting Standards Board Accounting Standards Codification Topic 805: “Business Combination” in connection with the Merger.

The total estimated purchase price of the acquisition as of July 8, 2014 is as follows:

***Purchase Consideration:***

(In thousands)

Purchase Consideration		\$	6,416
Telik Assets:			
Cash and Cash Equivalents	\$	1,497	
Accounts Receivable		31	
Prepays and Other Current Assets		182	
			(1,710)
Telik Liabilities:			
Accrued Compensation		850	
Accrued Liabilities		111	
Accrued Contingent Termination Fee		591	
Warrant Liability		568	
			2,120
Goodwill		\$	<u>6,826</u>

**7. Redeemable Convertible Preferred Stock, Convertible Preferred Stock, Common Stock and Warrants**

***MabVax Therapeutics Series A and MabVax Therapeutics Series B preferred stock (Pre-Merger MabVax Therapeutics Issuances)***

In January 2014, holders of warrants to purchase shares of MabVax Therapeutics Series B redeemable convertible preferred stock exercised their rights to purchase 194,281 shares of MabVax Therapeutics Series B redeemable convertible preferred stock for proceeds of \$1,942.

In February 2014, the holders of MabVax Therapeutics Series A redeemable convertible preferred stock and MabVax Therapeutics Series B redeemable convertible preferred stock waived any rights to all prior accrued dividends they may have had a right to receive and amended the MabVax Therapeutics certificate of incorporation to eliminate their right to accrue dividends in the future as an inducement to buyers in the MabVax Therapeutics Series C-1 Preferred Stock Financing. The effect of this change reduced the liquidation preference for the MabVax Therapeutics Series A redeemable convertible preferred stock by \$2,187,762 and the MabVax Therapeutics Series B redeemable convertible preferred stock by \$486,938 as of February 12, 2014.

No dividends were ever declared by the MabVax Therapeutics Board of Directors since MabVax Therapeutics' inception on either of the MabVax Therapeutics Series A redeemable convertible preferred stock or the MabVax Therapeutics Series B redeemable convertible preferred stock.

#### ***Removal of Redemption Rights***

In March 2014, the majority of holders, or more than 60%, of the MabVax Therapeutics Series A redeemable convertible preferred stock and MabVax Therapeutics Series B redeemable convertible preferred stock agreed by letter commitment to MabVax Therapeutics to relinquish the MabVax Therapeutics Redemption Right, and MabVax Therapeutics reclassified the presentation on the consolidated balance sheets as permanent equity following the agreement.

#### ***Series C-1 preferred stock purchase agreement***

On February 12, 2014, MabVax Therapeutics entered into a Securities Purchase Agreement (the "MabVax Therapeutics Securities Purchase Agreement") and issued 3,697,702 shares of MabVax Therapeutics Series C-1 preferred stock, warrants to purchase 2,055,260 shares of MabVax Therapeutics common stock at \$3.62 a share (the "MabVax Therapeutics Series C Common Warrants") and warrants to purchase 1,848,851 shares of MabVax Therapeutics Series C-1 preferred stock at \$0.84 a share (the "MabVax Therapeutics Series C Preferred Warrants") for aggregate gross proceeds of \$3,100,000, less issuance costs of \$126,345 (the "MabVax Therapeutics Series C-1 Financing"). The MabVax Therapeutics Series C Common Warrants and Preferred Warrants were exercisable immediately. The MabVax Series C Common Warrants would have expired on February 13, 2022, and the MabVax Therapeutics Series C Preferred Warrants would have expired upon registration of the shares of MabVax Therapeutics common stock (or a successor entity) under the Securities Act. Because the warrants are immediately convertible at the option of the holder, MabVax Therapeutics recorded a deemed dividend of \$2,214,911 from the beneficial conversion feature associated with the issuance of the MabVax Series C-1 preferred stock and the MabVax Therapeutics Series C Common Stock Warrants and the MabVax Therapeutics Series C Preferred Stock Warrants.

In connection with the MabVax Therapeutics Series C-1 Financing, MabVax Therapeutics agreed to use its reasonable best efforts to raise at least an additional \$3,000,000 through the sale and issuance of shares of MabVax Therapeutics common stock initially intended to be at \$15.08 per share (the "Subsequent Capital Raise"). Substantially all of the investors in the MabVax Therapeutics Series C-1 Financing executed a financing commitment letter (such letters, the "Financing Commitment Letters") to purchase a pro rata number of shares of MabVax Therapeutics common stock at the purchase price of \$15.08 per share, representing in the aggregate at least \$750,000, subject to certain terms and conditions, including a condition that MabVax Therapeutics raise at least \$3,000,000 from new investors in the Subsequent Capital Raise. In addition, each such commitment letter provided that, in the event that less than \$3,000,000 was raised from new investors in the Subsequent Capital Raise and subject to certain terms and conditions, each investor party to such letter was required to purchase shares of MabVax Therapeutics preferred stock to be designated as MabVax Therapeutics Series C-2 convertible preferred stock at \$15.08 per share and in the aggregate amount of up to \$3,000,000 (the "Backstop Capital Raise").

On May 12, 2014, MabVax Therapeutics and certain investors amended the MabVax Therapeutics Securities Purchase Agreement to, among other things, (i) lower the price per share of the Subsequent Capital Raise from \$15.08 to \$9.93 per share, and (ii) provide that the price per share payable by investors as set forth in the Financing Commitment Letters would henceforth be the lower of (A) \$15.08 a share and (B) the lowest price paid in the Subsequent Capital Raise. The price per share of the Backstop Capital Raise was not changed as a result of the amendment. On July 7, 2014, prior to the Merger, MabVax Therapeutics raised over \$3.0 million from the sale of common stock and the Backstop Capital Raise was no longer in effect.

The MabVax Therapeutics Series C-1 preferred stock allowed the holders to require that MabVax Therapeutics redeem their shares of MabVax Therapeutics Series C-1 preferred stock, including any accrued but unpaid dividends, upon the occurrence of any of the following events (each, a “Triggering Event”): (i) the suspension of trading of common stock following registration of such shares, (ii) the failure to issue shares of MabVax Therapeutics common stock upon conversion of any MabVax Therapeutics Series C-1 preferred stock, (iii) the failure to authorize sufficient shares of MabVax Therapeutics common stock to permit the conversion of all outstanding shares of MabVax Therapeutics Series C-1 preferred stock and exercise of all MabVax Therapeutics Series C Common Warrants and MabVax Therapeutics Series C Warrants, (iv) failure to make certain required payments to the holders in excess of \$25,000, (v) a default on indebtedness in the aggregate amount of \$100,000, (vi) bankruptcy events, (vii) judgments requiring payments in excess of \$100,000, (viii) consummation of a change of control with an entity which did not have a class of securities registered for trading, (ix) failure of MabVax Therapeutics to initiate the process of becoming publicly traded (either through a merger into a public company or the filing of a registration statement) within 4 months of the closing of the MabVax Therapeutics Series C-1 Financing, (x) failure to complete such Merger within one year or such registration within 4 months of the closing of the MabVax Therapeutics Series C-1 Financing, (xi) issuance of common stock in violation of certain restrictions relating to employee equity, (xii) issuance of debt in violation of any agreement relating to the MabVax Therapeutics Series C-1 Financing, (xiii) failure to convert MabVax Therapeutics Series A preferred stock or MabVax Therapeutics Series B preferred stock on or prior to the date shares of MabVax Therapeutics common stock became publicly tradable, (xiv) any deviation of 20% or more from the annual budget approved by such holders, (xv) any deviation of 5% or more with respect to auditing and investors’ relations expenses, (xvi) failure to deliver the 2013 audited financials within 45 days of the closing of the MabVax Therapeutics Series C-1 Financing, (xvii) any deviation of any line item of the 2013 audited financials from those set forth in the 2013 unaudited financials delivered in connection with the MabVax Therapeutics Series C-1 Financing or (xviii) a breach of any representation, warranty, covenant or other term or condition of any agreement relating to the MabVax Therapeutics Series C-1 Financing. Certain Triggering Events had occurred as of May 9, 2014, but were subsequently waived by the holders of the MabVax Therapeutics Series C-1 preferred stock.

On July 8, 2014, the date of the Merger, all MabVax Therapeutics Series C-1 preferred stock was converted into shares of MabVax Therapeutics Holdings Series A-1 preferred stock, and the Triggering Events were removed. Because of the removal of the Triggering Events as of the Merger date, the MabVax Therapeutics Holdings Series A-1 convertible preferred stock is presented on the consolidated balance sheet as permanent equity as of December 31, 2014.

***Registration of Common Stock Issuable upon Conversion of Series A-1 Preferred Stock, and Conversions***

On October 14, 2014, the Company filed an Amendment No. 1 to a Registration Statement on Form S-1 (the “Form S-1”) that was initially filed on September 29, 2014, for the purpose of registering additional shares of MabVax Therapeutics Holdings common stock issuable upon conversion of outstanding shares of MabVax Therapeutics Holdings Series A-1 preferred stock. The Form S-1, as amended, to register 1,615,070 shares of common stock, was declared effective by the SEC at 4:00 p.m. Eastern Standard Time on November 12, 2014.

From November 13, 2014, to December 31, 2014, holders of Series A-1 preferred stock converted 1,169,452 shares into 693,335 shares of common stock.

***Exercise of MabVax Therapeutics Series C Preferred Warrants***

On July 7, 2014, MabVax Therapeutics received \$1.5 million in exchange for the exercise by holders of the MabVax Therapeutics Series C Preferred warrants to purchase 1,827,979 shares of MabVax Therapeutics Series C-1 preferred stock.

***MabVax Therapeutics Holdings Series B Redeemable Convertible Preferred Stock***

On May 12, 2014 (the “Closing Date”), MabVax Therapeutics Holdings entered into a securities purchase agreement (the “Series B Purchase Agreement”) with certain purchasers (the “Purchasers”) pursuant to which MabVax Therapeutics Holdings agreed to issue and sell to the Purchasers, subject to customary closing conditions, an aggregate of 1,250,000 shares of MabVax Therapeutics Series B redeemable convertible preferred stock and warrants (the “Series B Common Warrants”) to purchase up to an additional 78,125 shares of MabVax Therapeutics Holdings common stock, with an aggregate purchase price of \$2,500,000, or \$2.00 for each share of our Series B redeemable convertible preferred stock and related Series B Common Warrant (such transaction collectively, the “Series B Private Placement”). The closing of the Series B Private Placement took place on the Closing Date.

On May 8, 2014, MabVax Therapeutics Holdings filed a certificate of designation for the MabVax Therapeutics Holdings Series B preferred stock with the Secretary of State of the State of Delaware. The certificate of designations authorized 1,250,000 shares of Series B preferred stock. Holders of MabVax Therapeutics Series B redeemable convertible preferred stock (the "Holders") are entitled to cumulative dividends on each share held at a rate of 8% per annum on the Stated Value (as defined in the certificate of designations). Upon a liquidation event, the Holders are entitled to a liquidation preference per share, prior to any distribution of the Company's assets to the holders of its common stock, in an amount equal to the Stated Value plus accrued and unpaid dividends. After payment to the Holders of the full preferential amount, the Holders will, on a *pari passu* basis with the holders of the Company's common stock, participate in the distribution of any remaining assets of the Company, subject to certain limitations. Each Holder may elect to convert their Series B preferred stock into shares of the Company's common stock at the applicable conversion rate in effect at the time of such conversion. However, the Company shall not effect conversion of the Series B redeemable convertible preferred stock to the extent such conversion would result in the beneficial owner acquiring beneficial ownership of more than 4.99% of the Company's outstanding common stock post-conversion, including any shares of its common stock issuable upon exercise or conversion of other convertible securities held by such beneficial owner. The Company obtained stockholder approval for the securities being issued in the Series B Private Placement at the annual stockholder meeting held on July 7, 2014. The conversion rate is subject to full ratchet anti-dilution protection upon certain dilutive issuances of our common stock or convertible securities of the Company. Such conversion price will be subject to adjustment from and after the earlier of: (i) the date that some or all of the Registerable Securities (as defined below) have become registered pursuant to an effective registration statement and (ii) six months after the Closing Date at which time the conversion price of the Series B preferred stock shall equal the lower of (a) the initial conversion price and (b) 90% of the average of the 10 lowest weighted average prices of the Company's common stock during the 20 trading days immediately preceding applicable date of the conversion, of which the latter condition was reached on November 14, 2014. The Holders may also require the Company to redeem their shares of Series B redeemable convertible preferred stock prior to a change of control, as set forth in the certificate of designations. The certificate of designations further provides that the Holders are entitled to certain participation rights on issuances by the Company to holders of common stock in order to maintain their proportionate ownership, subject to certain customary exclusions, such as issuances pursuant to Company option plans, and in connection with the Merger.

The Series B Common Warrants became exercisable six months from the Closing Date, or November 12, 2014, expire five years from the Closing Date and may be exercised for cash or otherwise may be net-exercised. The Series B Common Warrants initially had a per share exercise price of \$26.64. On the 60th day following the earlier of (i) the date all of the shares underlying the Warrants become registered pursuant to an effective registration statement and (ii) six months following the Closing Date (in each case, the "Reset Date"), the exercise price shall be reset to equal the lower of (i) the current exercise price and (ii) 90% of the average of the 10 lowest weighted average prices of Common Stock during the 20 trading days immediately preceding the Reset Date. The price was reset to \$1.57 on January 11, 2015. The exercise price is subject to full ratchet anti-dilution adjustment for any issuances of common stock and convertible securities for common stock below the current conversion price, consistent with the terms of the Series B preferred stock.

In connection with the Series B Private Placement, the Company also entered into a Registration Rights Agreement with the Purchasers (the "Series B Registration Rights Agreement"). Pursuant to the Series B Registration Rights Agreement, the Company agreed to file a registration statement with the SEC covering resales of the Warrant Shares and the shares issuable upon conversion of the Series B preferred stock (together, the "Series B Registerable Securities") by the Purchasers no later than 60 days following the Closing Date, and to use its commercially reasonable best efforts to have such registration statement declared effective as soon as practicable. The Company bears all expenses of such registration of the resale of the Registerable Securities. On September 3, 2014, the Required Holders (as defined in the Series B preferred stock certificate of designations) temporarily waived the 60-day registration deadline for a five-day period.

As a result of the Series B Warrants' anti-dilution provision, the Series B Warrants are recorded as a current liability on our consolidated balance sheet. The outstanding warrant was valued at \$92,463 and \$567,885 as of December 31, 2014, and July 8, 2014 or the acquisition date, respectively. Our outstanding warrants are revalued on each balance sheet date, with changes in the fair value between reporting periods recorded in the consolidated statements of operations.

Warrants were valued using the Black-Scholes-Merton model. The warrant had only partial down round protection, as it has a price reset only on a down round financing, and not an increase in number of shares convertible with the warrant. The Company concluded that using the Black-Scholes-Merton model for the valuation as of December 31, 2014, is fairly accurate compared to a recent buyout offer. The fair value of warrants is estimated using the following assumptions, which, except for risk-free interest rate, are Level 3 inputs:

**Warrant liability valuation assumptions**

	As of December 31, 2014	As of July 8, 2014
Risk-free interest rate	1.75%	1.60%
Dividend yield	— %	— %
Expected volatility	86.67%	101.60%
Expected life of options, in years	4.36	4.90
Market price for common stock	\$ 1.82	\$ 11.60
Warrant exercise price, adjusted	\$ 1.80	\$ 26.64

At December 31, 2015 and 2014, financial instruments requiring fair value measurement totaled zero and \$92,463, respectively.

As a result of the Series B warrants' anti-dilution provision, the Series B warrants were recorded as a current liability in the amount of \$92,463 on our consolidated balance sheet as of December 31, 2014. On March 25, 2015, the Series B warrants were re-valued at \$72,656 prior to being exchanged into shares of common stock and Series D convertible preferred stock on a one for one basis and the warrant liability was eliminated and the Company recorded a gain of \$19,807 for the year ended December 31, 2015.

The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of December 31, 2014 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value:

	<b>Basis of Fair Value Measurement at December 31, 2014</b>			
	<b>December 31, 2014</b>	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Financial liabilities:				
Warrants	\$ 92,463	\$ —	\$ —	\$ 92,463
Total financial liabilities	<u>\$ 92,463</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 92,463</u>

The changes in the value of the warrant liability during the year ended December 31, 2015 were as follows:

Fair value – beginning of year	\$ 92,463
Change in fair value	(19,807)
Cancellation of warrants	(72,656)
Fair value – end of year	<u>\$ —</u>

The changes in the value of the warrant liability during the year ended December 31, 2014 were as follows:

Fair value - beginning of year	\$ —
Fair value on acquisition	567,885
Change in fair value	(475,422)
Fair value - end of year	<u>\$ 92,463</u>

There were no transfers between Level 1 and Level 2 measurements for the years ended December 31, 2015 and 2014.

### ***Dividends on Preferred Stock***

The Company immediately recognizes the changes in the redemption value on preferred stock as they occur and the carrying value of the security is adjusted to equal what the redemption amount would be as if redemption were to occur at the end of the reporting period based on the conditions that exist as of that date. The value adjustment made to the redemption value and preferred stock dividends on the Series A-1 and Series B Preferred Stock for the year ended December 31, 2015 and 2014, was an increase of \$93,234 and \$444,992, respectively.

### ***Conversion of Preferred Stock into Common Stock***

During quarter ended March 31, 2015, holders of Series A-1, Series B, and Series C preferred stock converted 64,019, 106,437, and 96,571 shares into 38,456, 276,883, and 120,714 shares of common stock, respectively; such conversions eliminated all outstanding Series A-1, Series B, and Series C preferred stock outstanding.

### ***Exchange of Series A-1 and Series B Preferred Stock and Warrants into Common Stock and Series D Preferred Stock***

On March 25, 2015, the Company entered into separate exchange agreements with certain holders of the Company's Series A-1 preferred stock and Merger warrants (the "Series A-1 Exchange Securities") and holders of the Company's Series B preferred stock and Series B warrants (the "Series B Exchange Securities" and, collectively with the Series A-1 Exchange Securities, the "Exchange Securities"), all previously issued by the Company. Pursuant to the exchange agreements, the holders exchanged the Exchange Securities and relinquished any and all other rights they may have had pursuant to the Exchange Securities, their respective governing agreements and certificates of designation, including any related registration rights, in exchange for an aggregate of 2,537,502 shares of the Company's common stock and an aggregate of 238,156 shares of the Company's newly designated Series D Convertible preferred stock (the "Series D preferred stock"), convertible into 23,815,600 shares of common stock. No cash was exchanged in the transaction. The Company recorded deemed dividends of \$9,017,512, \$8,655,998 and \$179,411 representing the excess fair value of the common stock issued over the original conversion terms of the Series A-1 and B preferred stock as part of the consideration for elimination of the Series A-1, Series B convertible preferred stock and Series A-1 warrant, respectively.

Additionally, for as long as a certain principal holder of Exchange Securities holds securities issued pursuant to the exchange agreements, subject to certain exceptions, the Company is restricted from issuing any shares of common stock or securities convertible into common stock, enter into any equity line of credit or issue any floating or variable priced equity linked instrument.

No commission or other payment was received by the Company in connection with the exchange agreements.

### ***MabVax Common Stock Financing***

On March 31, 2015, the Company consummated the first closing of the April 2015 Private Placement and sold \$4,714,726 of Units, net of \$281,023 in issuance costs, consisting of 6,661,000 shares of common stock and warrants to purchase 3,330,500 shares of common stock at \$1.50 a share. The Units were sold at a price of \$0.75 per Unit.

On April 10, 2015, the Company consummated the second and final closing of the April 2015 Private Placement and sold \$3,831,622 of Units, net of \$387,127 in issuance costs, of which \$2,500,000 of the Units consisted of Series E preferred stock and the balance of it consisting of 5,624,998 shares of common stock, together with warrants to all investors to purchase 4,479,167 shares of common stock at \$1.50 a share. Each Unit was sold at a purchase price of \$0.75 per Unit.

The Company paid commissions to broker-dealers in the aggregate amount of approximately \$574,000 in the April 2015 Private Placement.

OPKO was the lead investor in the April 2015 Private Placement, purchasing \$2,500,000 of Units consisting of Series E preferred stock.

As a condition to OPKO's participation in the April 2015 Private Placement, each of the other investors in the April 2015 Private Placement agreed to execute lockup agreements restricting the sale of 50% of the securities underlying the Units purchased by them for a period of six months and the remaining 50% prior to the expiration of one year following the final closing date of the April 2015 Private Placement.

On April 10, 2015, the Company agreed that \$3.5 million of the net proceeds of such closing would be paid into and held under the terms of an escrow agreement with Signature Bank, N.A pending the approval of a representative of OPKO or 10 weeks thereafter, unless released sooner or extended by the Company and OPKO. On June 22, 2015 the Company and OPKO extended the termination date of the escrow to 16 weeks from the final closing of the April 2015 Private Placement. In connection with the OPKO investment, Steven Rubin, Esq. was appointed advisor to the Company. The escrowed funds were to be returned to the applicable investors and the Company shall have no further obligation to issue Units to such investors in the event certain release conditions are not met. On June 30, 2015 the Company and OPKO entered into a letter agreement pursuant to which the Company granted the representative the right, but not the obligation, until June 30, 2016, to nominate and appoint up to two additional members of the Company's Board, or to approve the person(s) nominated by the Company pursuant to the agreement in consideration for the release of the escrowed funds. The nominees will be subject to the satisfaction of standard corporate governance practices and any applicable national securities exchange requirements. Upon signing the agreement, the escrowed funds were released to the Company.

The warrants are exercisable upon issuance and expire 30 months thereafter and may be exercised for cash or on a cashless basis. The warrants have a per share exercise price of \$1.50, subject to certain adjustments typical of warrants, namely stock splits, dividends and reverse-splits. The Company is prohibited from effecting the exercise of the warrants to the extent that, as a result of such exercise, the holder beneficially would own more than 4.99% in the aggregate, of the issued and outstanding shares of the Company's common stock calculated immediately after giving effect to the issuance of shares of common stock upon the exercise of the warrants.

In connection with the April 2015 Private Placement, the Company also entered into a registration rights agreements (the "Registration Rights Agreements") with the investors in the April 2015 Private Placement pursuant to which the Company has agreed to file a registration statement with the SEC covering resales of up to 25% of common stock issued under the Subscription Agreements and shares issuable upon conversion of the Series E preferred stock, in the event the investors elect to receive Series E preferred stock instead of common stock (together, the "Registrable Securities"), no later than 60 days following the final closing date of the April 2015 Private Placement, and to use its commercially reasonable best efforts to have such registration statement declared effective with 120 days after filing. The Company will bear all expenses of such registration of the resale of the Registrable Securities. Investors in the Private Placement also may be required under certain circumstances to agree to refrain from resales of a percentage of their securities upon request of an underwriter or placement agent in a future offering. The liquidated damages for failure to achieve effectiveness of the Registrable Securities is 1% a month 120 days after filing, and provided management has not used commercially reasonable best efforts to have the registration statement declared effective within that time frame.

On June 9, 2015 the Company and investors holding over 60% of the outstanding Registrable Securities (as such term is defined in the Registration Rights Agreements) entered into an amendment agreement to the Registration Rights Agreements in order to: (i) amend the definition of "Filing Date" for the initial registration statement such that such term shall be defined as "August 5, 2015" and (ii) waive any payments that may be due to the investors as a result of the Company not filing a registration statement on or before the Filing Date, as such term was originally defined. On August 4, 2015, the Company and investors holding over 70% of the outstanding Registrable Securities entered into a second amendment agreement to further extend the Filing Date to October 9, 2015.

On October 12, 2015, the Company and investors holding over 60% of the outstanding Registerable Securities (as such term is defined in the Registration Rights Agreements) entered into a third amendment agreement to the Registration Rights Agreements to suspend the Company's registration obligations under the Registration Rights Agreements and related subscription agreements during any period when the "Standstill" provision set forth in 5(u) of the subscription agreements is in effect.

On January 28, 2016, the Company filed a Registration Statement on Form S-1, registering 3,904,830 shares of common stock for resale representing 25% of shares issued in the April 2015 Private Placement, 3,071,500 shares of common stock and 833,333 shares of common stock which are issuable upon conversion of the Company's Series E Convertible Preferred Stock.

Except for certain issuances, for a period beginning on the closing date of the April 2015 Private Placement and ending on the date that is the earlier of (i) 24 months from the final closing date of the April 2015 Private Placement, (ii) the date the Company consummates a financing (excluding proceeds from the April 2015 Private Placement) in which the Company receives gross proceeds of at least \$10,000,000 and (iii) the date the common stock is listed for trading on a national securities exchange (such period until the earlier date, the “Price Protection Period”), in the event that the Company issues any shares of common stock or securities convertible into common stock at a price per share or conversion price or exercise price per share that is less than \$0.75, the Company shall issue to the investors in the April 2015 Private Placement such additional number of shares of common stock such that the investor shall own an aggregate total number of shares of common stock as if they had purchased the Units at the price of the lower price issuance. No adjustment in the warrants is required in connection with a lower price issuance.

The Company has also granted each investor prior to the expiration of 24 months following the final closing date of the April 2015 Private Placement, a right of participation in the Company’s financings.

In the event the Company conducts certain private or public offerings of its securities, each investor has agreed, if requested by the underwriter or placement agent so engaged by the Company in connection with such offering, to refrain from selling any securities of the Company for a period of up to 60 days.

Between April 13, 2015, and April 14, 2015, certain holders of warrants issued in the April 2015 Private Placement to purchase an aggregate of 1,849,999 shares of common stock exercised such warrants on a cashless basis for an aggregate issuance of 1,219,780 shares of common stock. As of December 31, 2015, there were 5,959,668 warrants outstanding to purchase common stock at \$1.50 a share.

On October 5, 2015, the Company closed a public offering of 2,500,000 shares of common stock and warrants to purchase 1,250,000 shares of common stock, at an offering price of \$1.10 per share. For every two shares of common stock sold, the Company issued one warrant to purchase one share of common stock. The Company received \$2,750,000 in gross proceeds, before underwriting discounts and commissions and offering expenses totaling approximately \$586,608, and without giving effect to the exercise of the underwriters’ over-allotment option. The Company intends to use the net proceeds from this offering to fund the HuMab-5B1 human antibody program through Phase I clinical development and for working capital and general corporate purposes.

The shares and warrants were separately issued and sold in equal proportions. The warrants are immediately exercisable, expire September 30, 2018, and have an exercise price of \$1.32 per share. The warrants will not be listed on any securities exchange or other trading market. As of December 31, 2015, there were warrants to purchase 1,250,000 shares of common stock outstanding. The Company granted the underwriters a 30-day option to purchase up to an additional 375,000 shares of common stock and up to an additional 187,500 warrants at the same price to cover over-allotments, if any.

Under the terms of the underwriting agreement entered into between the Company and the underwriter in the public offering, the Company, without the prior written consent of the underwriter, is prohibited, for a period of 90 days after execution of the underwriting agreement, from issuing any equity securities, subject to certain exceptions.

On October 12, 2015, the Company and investors holding over 60% of the outstanding Registerable Securities (as such term is defined in the Registration Rights Agreements) issued in the April 2015 Private Placement entered into a third amendment agreement to the Registration Rights Agreements to suspend the Company’s registration obligations under the Registration Rights Agreements and related subscription agreements during any period when the “Standstill” provision set forth in 5(u) of the related subscription agreements is in effect.

### **Series D Preferred Stock**

As of December 31, 2015, there were 191,491 shares of Series D preferred stock issued and outstanding which are convertible into an aggregate of 19,149,100 shares of common stock.

As contemplated by the exchange agreements governing the issuance of the Series D preferred stock and as approved by the Company's Board of Directors, the Company filed with the Secretary of State of the State of Delaware a Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (the "Series D Certificate of Designations"), on March 25, 2015. Pursuant to the Series D Certificate of Designations, the Company designated 1,000,000 shares of its blank check preferred stock as Series D preferred stock. Each share of Series D preferred stock has a stated value of \$0.01 per share. In the event of a liquidation, dissolution or winding up of the Company, each share of Series D preferred stock will be entitled to a per share preferential payment equal to the stated value. Each share of Series D preferred stock is convertible into 100 shares of common stock. The conversion ratio is subject to adjustment in the event of stock splits, stock dividends, combination of shares and similar recapitalization transactions. The Company is prohibited from effecting the conversion of the Series D preferred stock to the extent that, as a result of such conversion, the holder beneficially would own more than 4.99% (provided that certain investors elected to block their beneficial ownership initially at 2.49% in the exchange agreements), in the aggregate, of the issued and outstanding shares of the Company's common stock calculated immediately after giving effect to the issuance of shares of common stock upon the conversion of the Series D preferred stock. Each share of Series D preferred stock entitles the holder to vote on all matters voted on by holders of common stock. With respect to any such vote, each share of Series D preferred stock entitles the holder to cast such number of votes equal to the number of shares of common stock such shares of Series D preferred stock are convertible into at such time, but not in excess of the beneficial ownership limitations.

### **Series E Preferred Stock**

As of December 31, 2015, there were 33,333 shares of Series E preferred stock issued and outstanding, convertible into 3,333,300 shares of common stock.

On March 30, 2015, the Company filed with the Secretary of State of the State of Delaware a Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible preferred stock to designate 100,000 shares of its blank check preferred stock as Series E preferred stock.

The shares of Series E preferred stock are convertible into shares of common stock based on a conversion calculation equal to the stated value of such preferred share, plus all accrued and unpaid dividends, if any, on such share of Series E preferred stock, as of such date of determination, divided by the conversion price. The stated value of each share of Series E preferred stock is \$75 and the initial conversion price is \$0.75 per share, each subject to adjustment for stock splits, stock dividends, recapitalizations, combinations, subdivisions or other similar events. In addition, during the Price Protection Period, in the event the Company issues or sells, or is deemed to issue or sell, shares of common stock at a per share price that is less than the conversion price then in effect, the conversion price shall be reduced to such lower price, subject to certain exceptions. The Company is prohibited from effecting a conversion of the share of Series E preferred stock to the extent that, as a result of such conversion, such holder would beneficially own more than 4.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of shares of common stock upon conversion of the Series E preferred stock, which beneficial ownership limitation may be increased by the holder up to, but not exceeding, 9.99%. Each holder is entitled to vote on all matters submitted to stockholders of the Company, and shall have the number of votes equal to the number of shares of common stock issuable upon conversion of such holder's share of Series E preferred stock, but not in excess of beneficial ownership limitations. The shares of Series E preferred stock bear no interest.

### **Issuance of Common Stock under Common Stock Purchase Agreement**

In connection with a financing that took place in July 2014, or the July 2014 Financing Transaction, the Company assumed certain obligations as per the original agreement to issue additional shares to investors in the July 2014 Financing Transaction if a subsequent financing was at a price per share lower than the price per share in the July 2014 Financing Transaction. The Company therefore issued on March 31, 2015, an aggregate of 88,093 shares of common stock that were required to be issued in connection with the July 2014 Financing Transaction, as a result of the lower share price in the April 2015 Private Placement.

## **Grant of Restricted Shares**

### ***Rubin Grant***

On April 3, 2015, the Company entered into a consulting agreement with Steve Rubin pursuant to which he agreed to provide advisory services in connection with corporate strategy, licensing and business development estimated to be for a period of 12 months. In exchange for his services, the Company provided him with a one-time grant of 200,000 shares of the Company's restricted common stock, valued at \$2.30 a share. As the shares granted were fully vested upon grant and the Company has no legal recourse to recover the shares in the event of nonperformance, the Company recognized the grant date fair value of the shares as consulting expense upon grant during the second quarter of 2015.

### ***Ravetch Grant***

On April 4, 2015, the Board approved the issuance of an additional restricted stock award of 131,500 shares to Jeffrey Ravetch. This award is for future services covering at least a one-year period. The award was granted in addition to the prior award to Dr. Ravetch on April 2, 2015 of: (i) 34,250 restricted shares and (ii) options to purchase 34,250 shares of common stock with an exercise price of \$2.30 per share, for a total grant of 200,000 restricted shares and options. As the 131,500 shares granted were fully vested upon grant and the Company has no legal recourse to recover the shares in the event of nonperformance, the Company recognized the grant date fair value of the shares as consulting expense upon grant during the second quarter of 2015.

### ***Livingston Grant***

On April 4, 2015, the Board of Directors approved a restricted stock award by the Company of 1,000,000 shares of common stock, valued at \$2.30 a share, to be issued to Phil Livingston, Ph.D. for his continuing service to the Company. On May 13, 2015, the Compensation Committee of the Board clarified that the award is being granted in consideration for at least one year of Dr. Livingston's services. The committee further clarified that the vesting of the common stock shall be on the one-year anniversary of the Board of Directors' approval of the award, or April 4, 2016. The Company is expensing the grant date fair value of the award over the vesting period of one year.

### ***Consulting Agreement***

On April 5, 2015, the Company entered into a consulting agreement with The Del Mar Consulting Group, Inc. and Alex Partners, LLC, together, the "Investor Relations Consultants", pursuant to which such Investor Relations Consultants shall provide investor relations services to the Company in consideration for an immediate grant of 300,000 shares of the Company's restricted common stock and a monthly cash retainer of \$12,000 a month for ongoing services for a period of one year. The consultants also received an additional 200,000 shares of the Company's restricted common stock upon the Company's achieving a milestone based on its fully-diluted market capitalization. As the shares granted were fully vested upon grant and the Company has no legal recourse to recover the shares in the event of nonperformance, the Company recognized the grant date fair value of the 300,000 shares or \$690,000, as investor relations expense upon grant during the second quarter of 2015. The performance condition for the 200,000 shares became probable and the market capitalization metric was met during the second quarter; therefore, the Company recognized an additional \$460,000 of expense during the quarter ended June 30, 2015.

### ***Consultant Grants***

During 2015, the Board of Directors approved the issuance of restricted stock awards to two consultants totaling 120,000 shares with vesting terms ranging from one to three years, valued from \$1.77 to \$2.13 per share. The Company is expensing each of the grant date fair value of the awards over the performance period for the award, which will be re-measured at the end of each quarter until the performance is complete. For the year ended December 31, 2015, the Company expensed \$11,809 related to these grants. As of December 31, 2015, the expected future compensation expense related to these grants is \$70,991 based upon the Company's stock price on December 31, 2015.

## **8. Related Party Transactions**

In April 2015, the Company has granted a restricted stock award of 1,000,000 shares to Phil Livingston, Ph.D., an employee and Board member, for his continuing services to the Company. In addition, in April 2015, the Company has granted a restricted stock award of 131,500 shares for Jeffrey Ravetch, a Board member, for future consulting services.

In February 2014, MabVax Therapeutics issued approximately 44,000 shares of common stock to related parties in settlement of \$240,000 in related party liabilities for consulting services.

In connection with the Merger, MabVax Therapeutics Holdings (f.k.a. Telik, Inc.) signed separation agreements in May 2014 with nine employees and agreed to pay severances and health benefits upon closing of the Merger subject to certain provisions in the agreement. The total in severance and benefits costs paid subsequent to the Merger is approximately \$748,000. At December 31, 2015 and 2014, the accrued severance and benefits costs are approximately none and \$6,000, respectively.

## **9. Stock-based Compensation**

### ***Stock Incentive Plan***

In September 2008, the Company's stockholders approved the 2008 Stock Incentive Plan (the "2008 Plan") which became effective in September 2008 and under which 65,507 shares of the Company's common stock were initially reserved for issuance to employees, non-employee directors and consultants of the Company. In November 2012, the Company increased the authorized shares under the plan to 155,893. On February 14, 2013, the 2008 Plan terminated and no further grants of equity may be made thereunder.

In June 2014, MabVax Therapeutics Inc.'s stockholders approved the amended 2014 Stock Incentive Plan (the "2014 Plan") which became effective and was adopted by the Company in the Merger in July 2014. The 2014 Plan authorized the issuance of up to 351,443 shares, 152,017 of which are contingent upon the forfeiture, expiration or cancellation of the 2008 Reserved Shares.

The 2014 Plan provided for the grant of incentive stock options, non-incentive stock options, stock appreciation rights, restricted stock awards, and restricted stock unit awards to eligible recipients. The maximum term of options granted under the Stock Plan is ten years.

Employee option grants generally vest 25% on the first anniversary of the original vesting date, and the balance vests monthly over the following three years. The vesting schedules for grants to non-employee directors and consultants is determined by the Company's Compensation Committee. Stock options are generally not exercisable prior to the applicable vesting date, unless otherwise accelerated under the terms of the applicable stock plan agreement.

### ***Amendment of Equity Incentive Plan***

On March 31, 2015 the Company approved a Second Amended and Restated 2014 Employee, Director and Consultant Equity Incentive Plan (the "Plan"), effective as of and contingent upon the consummation of the initial closing of the sale of Units pursuant to the Subscription Agreement, to increase the number of shares reserved for issuance under the Plan from 158,073 to 8,360,789 shares of common stock. Additional changes to the Plan include:

- An "evergreen" provision to reserve additional shares for issuance under the Plan on an annual basis commencing on the first day of fiscal 2016 and ending on the second day of fiscal 2024, such that the number of shares that may be issued under the Plan shall be increased by an amount equal to the lesser of: (i) 8,000,000 or the equivalent of such number of shares after the administrator, in its sole discretion, has interpreted the effect of any stock split, stock dividend, combination, recapitalization or similar transaction in accordance with the Plan; (ii) the number of shares necessary such that the total shares reserved under the Plan equals (x) 15% of the number of outstanding shares of common stock on such date (assuming the conversion of all outstanding shares of Preferred Stock (as defined in the Plan) and other outstanding convertible securities and exercise of all outstanding warrants to purchase common stock) plus (y) 229,000; and (iii) an amount determined by the Board.
- Provision that no more than 3,000,000 shares may be granted to any participant in any fiscal year.
- Provisions to allow for performance based equity awards to be issued by the Company in accordance with Section 162(m) of the Internal Revenue Code.

**Stock-based Compensation**

Total estimated stock-based compensation expense, related to all of the Company's stock-based payment awards recognized under ASC 718, "Compensation—Stock Compensation" was comprised of the following:

	<b>Years Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
Research and development	\$ 929,633	\$ 163,019
General and administrative	3,534,062	441,957
Total share-based compensation expense	<u>\$ 4,463,695</u>	<u>\$ 604,976</u>

**Stock-based Award Activity**

The following table summarizes the Company's stock option activity for the years ended December 31, 2015 and 2014:

	Options Outstanding	Weighted Average Exercise Price
Outstanding at December 31, 2013	152,017	\$ 1.19
Granted	90,876	8.47
Exercised	—	—
Forfeited/cancelled/expired	—	—
Outstanding and expected to vest at December 31, 2014	242,893	\$ 3.92
Granted	3,015,850	2.23
Exercised	(2,779)	0.29
Forfeited/cancelled/expired	(12,923)	7.42
Outstanding and expected to vest at December 31, 2015	<u>3,243,041</u>	\$ 2.36
Vested and exercisable at December 31, 2015	<u>178,001</u>	\$ 3.59

The total unrecognized compensation cost related to unvested stock option grants as of December 31, 2015 was \$3,964,320 and the weighted average period over which these grants are expected to vest is 2.12 years. Due to limited activity in 2015, the Company has assumed a forfeiture rate of zero. The weighted average remaining contractual life of stock options outstanding at December 31, 2015 and 2014 is 9.13 years and 7.9 years, respectively.

Stock options granted to employees generally vest over a four-year period and vesting does not start until the one-year anniversary of the grant date. During the year ended December 31, 2014, the Company granted five new Board members appointed in connection with the Merger an aggregate of 55,580 in stock options, which were immediately vested on the grant date. There were no grants of stock options during the year ended December 31, 2015 with immediate vesting.

During 2015, the Company granted 3,015,850 options and 2,300,850 shares of restricted stock to its directors, officers, employees and consultants from the 2014 Plan. In addition, the Company granted 1,851,500 shares of restricted stock outside of the plan for consulting and investor relation services during the second quarter of 2015.

A summary of activity related to restricted stock grants under the Plan for the year December 31, 2015 is presented below:

	Shares	Weighted Average Grant-Date Fair Value
Non-vested at December 31, 2014	—	\$ —
Granted	2,300,850	2.28
Vested	—	—
Forfeited	—	—
Non-vested at December 31, 2015	<u>2,300,850</u>	\$ 2.28

As of December 31, 2015, unamortized compensation expense related to restricted stock grants amounted to \$3,843,264, which is expected to be recognized over a weighted average period of 2.27 years.

**Valuation Assumptions**

The Company used the Black-Scholes-Merton option valuation model, or the Black-Scholes model, to determine the stock-based compensation expense recognized under ASC 718. The Company’s expected stock-price volatility assumption was based solely on the weighted average of the historical and implied volatility of comparable companies whose share prices are publicly available. The expected term of stock options granted was based on the simplified method in accordance with Staff Accounting Bulletin No. 110, or SAB 110, as the Company’s historical share option exercise experience did not provide a reasonable basis for estimation. The risk-free interest rate was based on the U.S. Treasury yield for a period consistent with the expected term of the stock award in effect at the time of the grant.

	Years Ended December 31,	
	2015	2014
Risk-free interest rate	0.9 to 1.8%	0.1 to 2 %
Dividend yield	0%	0%
Expected volatility	81 to 87%	84 to 100%
Expected life of options, in years	5.5 and 6.0	5 and 6.25
Weighted average grant date fair value	\$ 1.56	\$ 4.73

Because the Company had a net operating loss carryforward as of December 31, 2015, no tax benefits for the tax deductions related to stock-based compensation expense were recognized in the Company’s consolidated statements of operations. Additionally, there were 2,779 stock options exercised during the year ended December 31, 2015, and there were no stock option exercises in the corresponding period of 2014.

**Management Bonus Plan**

On April 2, 2015, the Compensation Committee of the Board of Directors approved the 2015 Management Bonus Plan (the “Management Plan”) outlining maximum target bonuses of the base salaries of certain of the Company’s executive officers. Under the terms of the Management Plan, the Company’s Chief Executive Officer shall receive a maximum target bonus of up to 50% of his annual base salary, the Chief Financial Officer shall receive a maximum target bonus of up to 35% of his annual base salary and the Company’s Vice President shall receive a maximum target bonus of up to 25% of his annual base salary. During the year ended December 31, 2015, the Company accrued and expensed \$323,363 related to the Management Plan.

On April 4, 2015, the Board approved the following Non-Employee Director Policy (the “Incumbent Director Policy”) with respect to incumbent non-employee members of the Board in the event that they are replaced before their term expires:

- A one-time issuance of 20,000 restricted shares of common stock;
- The vesting of all options and restricted stock grants held on such date; and
- The payment of all earned but unpaid cash compensation for their services on the Board and its committees, as of such date.

On April 4, 2015, in connection with his resignation from the Board, Michael Wick received a one-time restricted stock grant of 20,000 shares under the Incumbent Director Policy.

**Common Stock Reserved for Future Issuance**

Common stock reserved for future issuance consists of the following at December 31, 2015:

Common stock reserved for conversion of preferred stock and warrants	29,692,068
Common stock options outstanding	3,243,041
Authorized for future grant or issuance under the Stock Plan	2,970,012
Unvested restricted stock	2,300,850
<b>Total</b>	<b><u>38,205,971</u></b>

**10. Net Loss per Share**

The Company calculates basic and diluted net loss per share using the weighted average number of shares of common stock outstanding during the period.

When the Company is in a net loss position, it excludes from the calculation of diluted net loss per share all potentially dilutive stock options, preferred stock and warrants, and the diluted net loss per share is the same as the basic net loss per share for such periods. If the Company was to be in a net income position, the weighted average number of shares used to calculate the diluted net income per share would include the potential dilutive effect of in-the-money securities, as determined using the treasury stock method.

The table below presents the potentially dilutive securities that would have been included in the calculation of diluted net loss per share if they were not antidilutive for the periods presented.

	<b>Years Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
Stock options	3,243,041	44,615
MabVax Series A redeemable convertible preferred stock	—	137,607
MabVax Series B redeemable convertible preferred stock	—	156,247
MabVax Series C-1 redeemable convertible preferred stock	—	412,444
Series B redeemable convertible preferred stock	—	102,895
Series A-1 preferred stock	—	742,658
Series C preferred stock	—	47,023
Series D preferred stock	19,149,100	—
Series E preferred stock	3,333,300	—
Unvested restricted stock	2,300,850	—
Warrants to purchase common stock	7,209,668	—
<b>Total</b>	<b><u>35,235,959</u></b>	<b><u>1,643,489</u></b>

## **11. Contracts and Agreements**

### ***Life Technologies Licensing Agreement***

On September 24, 2015, the Company entered into a licensing agreement with Life Technologies Corporation (“Life Technologies”), a subsidiary of Thermo Fisher Scientific. Under the agreement, MabVax agreed to license certain cell lines from Life Technologies to be used in the production of recombinant proteins for the Company’s clinical trials. The amount of the contract is for \$450,000 and was fully expensed during the year ended December 31, 2015. The Company paid \$225,000 during the year ended December 31, 2015, related to this contract.

### ***Rockefeller University Collaboration***

In July 2015, the Company entered into a research collaboration agreement with Rockefeller University’s Laboratory of Molecular Genetics and Immunology. The Company provided antibody material to Rockefeller University, which is exploring the mechanism of action of constant region (Fc) variants of the HuMab-5B1 in the role of tumor clearance. The Company will supply additional research materials as requested by the university, which is evaluating ways to optimize the function.

### ***NCI Neuroblastoma Vaccine Grant***

In July 2012, the NCI awarded the Company a SBIR Program grant to support the Company’s program to manufacture the clinical material and develop an Investigational New Drug Application for a vaccine to prevent the recurrence of Neuroblastoma (the “NCI Neuroblastoma Vaccine Grant”). The project period for Phase I of the grant ended in December 2012 and the Company received a one-year extension on the project. The Company records revenue associated with the NIH Grants as the related costs and expenses are incurred. For the year ended December 31, 2014, the Company recorded \$32,355 of revenue associated with the NCI Neuroblastoma Vaccine Grant.

### ***NCI PET Imaging Agent Grant***

In September 2013, the NCI awarded the Company a SBIR Program Contract to support the Company’s program to develop a PET imaging agent for pancreatic cancer using a fragment of the Company’s HuMab-5B1 antibody (the “NCI PET Imaging Agent Grant”). The project period for Phase I of the grant award of approximately \$250,000 covered a nine-month period which commenced in September 2013 and ended in June 2014.

On August 25, 2014, the Company was awarded a \$1.5 million contract for the Phase II portion of the NCI PET Imaging Agent Grant. The contract is intended to support a major portion of the preclinical work being conducted by the Company, together with its collaboration partner, MSK, to develop a novel Positron Emission Tomography (“PET”) imaging agent for detection and assessment of pancreatic cancer. The total contract amount for Phase I and Phase II of approximately \$1,749,000 supports research work through June 2016.

The Company records revenue associated with the NCI PET Imaging Agent Grant as the related costs and expenses are incurred. For the years ended December 31, 2015 and 2014, the Company recorded \$1,141,451 and \$271,820 of revenue associated with the NCI PET Imaging Agent Grant, respectively.

### ***Juno Therapeutics Option Agreement***

On August 29, 2014, MabVax Therapeutics entered into an Option Agreement (the “Option Agreement”) with Juno Therapeutics, Inc. (“Juno”). Pursuant to the Option Agreement, MabVax Therapeutics granted Juno the option to obtain an exclusive, world-wide, royalty-bearing license (the “License”) authorizing Juno to develop, make, have made, use, import, have imported, sell, have sold, offer for sale and otherwise exploit certain patents MabVax Therapeutics developed with respect to fully human antibodies with binding specificity against human GD2 or sialyl Lewis A antigens (the “Patents”) and certain MabVax Therapeutics controlled biologic materials. Juno may exercise its option to purchase the License until the earlier of June 30, 2016 or 90 days from the date MSK completes its research with respect to the Patents in accordance with the terms of agreements by and between MSK and MabVax Therapeutics.

During the years ended December 31, 2015 and 2014, no revenues had been earned under the Option Agreement; however, the Option Agreement remains valid and active.

The Option Agreement may be terminated by either party (i) upon material breach of the other party if the breach is not cured within 30 days, or (ii) with 60 days' prior written notice in the event the other party becomes the subject of a voluntary or involuntary petition in bankruptcy. Juno may terminate the Option Agreement at any time upon 30 days' prior written notice. MabVax Therapeutics may terminate the Option Agreement if Juno, or any Juno employee or affiliate, is a party to any action or proceeding in which Juno, or any Juno employee or affiliate, opposes the Patents or otherwise seeks a determination that any of the Patents are invalid or unenforceable if Juno, or as applicable, its employee and/or affiliate, fails to discontinue its involvement in such an action within 10 days of receiving notice from MabVax Therapeutics.

As consideration for the grant of the exclusive option to purchase the License, Juno has agreed to pay MabVax Therapeutics a one-time up-front option fee in the low five figures. Should the option be exercised, MabVax Therapeutics would expect to negotiate with Juno to pay amounts that include MabVax Therapeutics license fees, milestone payments, and royalty-based compensation in connection with entering into a License. The terms of the License including the financial terms are expected to be agreed upon at a future date.

## **12. Commitments and contingencies**

### ***Litigation***

On May 30, 2014, a class action lawsuit was commenced in Santa Clara County Superior Court, State of California, on behalf of Cadillac Partners and others similarly situated, naming as defendants, MabVax Therapeutics, the Company and the Company's directors, Hudson Bay Capital Management LP, Bio IP Ventures LLC, Hudson Bay Master Fund Ltd., and Hudson Bay IP Opportunities Master Fund LP, together the "Parties". The suit alleged the defendants breached certain fiduciary duties, or aided and abetted a breach of fiduciary duties, in connection with the Company's Merger with MabVax Therapeutics. In support of their purported claims, the plaintiff alleged, among other things, that the Company's Board has historically failed to fulfill its fiduciary duty to its stockholders, and claiming with respect to the Series B Private Placement and the Merger, that such transactions involved an inadequate sales process and included preclusive deal protection devices, and that the Company's Board of Directors would receive personal benefits not available to its public stockholders as a result of the Merger. The plaintiff sought to enjoin the Merger and obtain damages as well as attorneys' and expert fees and costs.

On June 29, 2014, the parties entered into a Stipulation and Settlement (the "Settlement"), pursuant to which the Company agreed to file with the SEC certain supplemental disclosures in connection with the Merger. The Settlement was subject to certain confirmatory discovery to be undertaken by the plaintiff and to the Parties' agreement on the payment of the plaintiff's attorneys' fees and expenses.

On July 16, 2014, the Company and all other parties to the litigation entered into an agreement which, if consummated, would settle the litigation (the "Proposed Settlement"). Among many other terms, under the Proposed Settlement the Company and all defendants will receive a broad release of any and all claims pertaining to the Series B Private Placement, the Merger, the prior disclosure and a wide variety of other matters. The Proposed Settlement also calls for the parties to ask the court to, among other things, enter orders enjoining other stockholders from bringing similar actions, certifying the putative settlement class, and approving the Proposed Settlement as a fair, final, and binding resolution of the litigation. Under the Proposed Settlement, the Company and the other defendants have expressly denied the allegations of the complaint and denied engaging in any other misconduct, nor will any of them make any payment or in any respect amend the negotiated terms of the since-consummated Series B Private Placement and Merger. Finally, under the Proposed Settlement, the Company and the other defendants have not agreed to pay any legal fees, or reimburse any expenses, allegedly incurred by the plaintiffs who filed the complaint; instead, the Company expects that counsel for those plaintiffs will present any such disputed claim for legal fees and expenses to the court for resolution.

On April 20, 2015, the Parties made an application for an Order for Notice and Scheduling of Hearing of Settlement in accordance with a Stipulation of Settlement dated as of April 20, 2015 (the "Action"), which sets forth the terms and conditions for settlement and which provides for dismissal of the Action with prejudice. The Order after Hearing on June 12, 2015, provided preliminary approval of the settlement that was agreed to by the Parties, in which the Company provided supplemental disclosures in the definitive proxy filed with the SEC on June 30, 2014. Notice of the action as a class action was sent to class members in July 2015.

On September 18, 2015, an Order and Final Judgment was entered by the Superior Court of the State of California, approving the settlement that was agreed upon by both parties and closing the case. The Company anticipates that there will be no additional future expenses incurred in this action by the Company after the December 31, 2015 balance sheet date which would not be offset by insurance.

### **Operating Leases**

In connection with the Merger, the Company recorded a \$590,504 contingent lease termination fee, related to the termination of the master lease and sublease of the Porter Drive Facility by MabVax Therapeutics Holdings (f.k.a. Telik, Inc.), which is payable to ARE-San Francisco No. 24 ("ARE") if the Company receives \$15 million or more in additional financing in the aggregate, but otherwise forgiven.

On September 2, 2015, the Company entered into a lease (the "Lease") with AGP Sorrento Business Complex, L.P., for certain premises of office and laboratory space in buildings located at 11535 Sorrento Valley Rd., San Diego, California, to serve as the Company's corporate offices and laboratories (the "New Premises"). Due to the fact that certain tenant improvements needed to be made to the New Premises before the Company could take occupancy, the term of the Lease did not commence until the New Premises were ready for occupancy, on February 4, 2016. The Lease terminates six years after such term commencement date, unless earlier terminated in accordance with the Lease. Pursuant to the terms of the Lease, the monthly base rent will be \$35,631, subject to annual increases as set forth in the Lease.

The Company has an option to extend the Lease term for a single, five-year period. If the Lease term is extended for the optional five-year period, the monthly base rent will be adjusted based on fair market rental value. In addition to rent, the Company agreed to pay a portion of the taxes and utility, maintenance and other operating costs paid or accrued in connection with the ownership and operation of the property.

The Company previously leased its corporate office and laboratory space under an operating lease that, as amended on August 1, 2010, expired on July 31, 2015. The lease contained an option to cancel at various dates prior to the termination date by paying a cancellation penalty. The Company has provided a refundable security deposit of \$11,017 to secure its obligations under the lease, which was included in other long-term assets in the accompanying consolidated financial statements. We recognize rent expense on a straight-line basis over the term the lease. Rent expense of \$122,236 and \$115,118 was recognized in the years ended December 31, 2015 and 2014, respectively.

Minimum future annual operating lease obligations are as follows as of December 31, 2015:

2016	\$ 391,941
2017	439,330
2018	452,510
2019	466,085
2020	480,068
Thereafter	535,776
Total	\$ 2,765,710

### **Restructuring Plan upon Closing of the Merger**

In connection with the Merger, the Company signed separation agreements in May 2014 with nine employees and agreed to pay severances and health benefits upon closing of the Merger subject to certain provisions in the agreements. As of December 31, 2015 and 2014, zero and approximately \$6,000 in severance and benefits costs remained.

### **13. Income Taxes**

During the years ended December 31, 2015 and 2014, the Company did not record a provision or benefit for current or deferred income taxes in the consolidated statement of operations due to its cumulative net losses.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets are as follows as of December 31, 2015 and 2014:

	<u>2015</u>	<u>2014</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 14,502,000	\$ 9,478,000
Tax credits	4,803,000	4,128,000
Accrued expenses and other	<u>1,861,300</u>	<u>225,000</u>
Total deferred tax assets	21,166,300	13,831,000
Less valuation allowance	<u>(21,166,300)</u>	<u>(13,831,000)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

The Company has evaluated the available evidence supporting the realization of its gross deferred tax assets, including the amount and timing of future taxable income, and has determined that it is more likely than not that the deferred tax assets will not be realized. Due to such uncertainties surrounding the realization of the Company's deferred tax assets, the Company maintains a valuation allowance of \$21,166,300 against its deferred tax assets as of December 31, 2015. Realization of the deferred tax assets will be primarily dependent upon the Company's ability to generate sufficient taxable income prior to the expiration of its net operating losses.

During the year ended December 31, 2014, MabVax Therapeutics, Inc. merged with Telik, Inc. in a tax-free reorganization. As a result of the merger, all components of Telik's deferred tax assets are now included as deferred tax assets of MabVax Therapeutics, Inc. These pre-merger deferred tax assets are net operating loss carryforwards of \$1,588,000, research and development credit carryforwards of \$4,457,000, in total equaling \$6,045,000. The current year change in these assets has been reflected in the provision for income taxes.

As of December 31, 2015, the Company had net operating loss carryforwards of approximately \$36,375,000 and \$36,616,000 for federal and state income tax purposes, respectively. These may be used to offset future taxable income and will begin to expire in varying amounts in 2028 to 2035. The Company also has research and development credits of approximately \$297,000 and \$6,827,000 for federal and state income tax purposes, respectively. The federal credits may be used to offset future taxable income and will begin to expire at various dates beginning in 2030 through 2035. The state credits may be used to offset future taxable income, and such credits carry forward indefinitely.

The Company is subject to taxation in the U.S. and California jurisdictions. Currently, no historical years are under examination. The Company's tax years ending December 31, 2015 and 2014 are subject to examination by the U.S. and state taxing authorities due to the carryforward of unutilized net operating losses and research and development credits.

Utilization of the Company's net operating loss carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to an "ownership change" that may have occurred, or that could occur in the future, as defined and required by Section 382 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions. These ownership changes may limit the amount of net operating loss carryforwards and research and development credit carryforwards, and other tax attributes that can be utilized annually to offset future taxable income and tax, respectively. Any limitation may result in the expiration of a portion of the net operating loss carryforwards or research and development credit carryforwards before utilization. The net operating loss carryforwards and research and development credit carryforwards inherited as a result of the merger with Telik, Inc. have been severely limited under these rules and will likely not be realized.

In general, an "ownership change" results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders or public groups. The Company intends to complete a study in the future to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company's formation, and will complete such study before the use of any of the aforementioned attributes.

The provision for income taxes differs from the amount computed by applying the U.S. federal statutory tax rate (34% in 2015 and 2014) to income taxes as follows:

	<u>2015</u>	<u>2014</u>
Tax benefit computed at 34%	\$ (6,155,300)	\$ (2,692,100)
State tax provision, net of federal tax benefit	(1,551,444)	(462,800)
Change in valuation allowance	7,335,300	3,146,000
Other	371,444	8,900
Tax provision (benefit)	<u>\$ —</u>	<u>\$ —</u>

The Company has adopted ASC 740-10-25. This interpretation clarifies the criteria for recognizing income tax benefits under ASC 740, "Accounting for Income Taxes", and requires additional disclosures about uncertain tax positions. Under ASC 740-10-25 the financial statement recognition of the benefit for a tax position is dependent upon the benefit being more likely than not to be sustainable upon audit by the applicable taxing authority. If this threshold is met, the tax benefit is then measured and recognized at the largest amount that is greater than 50 percent likely of being realized upon ultimate settlement.

#### 14. Subsequent Events

On January 15, 2016, the Company and Oxford Finance LLC, as collateral agent and lender (the “Lender” or “Collateral Agent”) entered into a Loan and Security Agreement (the “Loan Agreement”) providing for senior secured term loans to the Company in an aggregate principal amount of up to \$10,000,000, subject to the terms and conditions set forth in the Loan Agreement. On January 15, 2016, the Company received an initial loan of \$5,000,000 (“Term A Loan”) under the Loan Agreement, before fees and issuance costs of approximately \$381,000.

Under the Loan Agreement, if the Company achieves (a) positive interim data on the Phase 1a HuMab-5B1 antibody trial in pancreatic cancer and (b) uplisting of its common stock onto the NASDAQ Stock Market or New York Stock Exchange (the “Term B Event”) then until the earliest to occur of 60 days from the Term B Event or September 30, 2016, and provided there has been no event of default, the Company may request a second tranche in the amount of \$5,000,000 under the Loan Agreement (“Term B Loan” and together with Term Loan A the “Term Loans”).

Interest on the Term Loans accrues at a rate equal to the greater of (i) 11.50% and (ii) the sum of (a) the thirty (30) day U.S. LIBOR rate reported in *The Wall Street Journal* on the last Business Day of the month that immediately precedes the month in which the interest will accrue, plus (b) 11.29%. Interest is payable monthly in arrears. The Term Loans mature on February 1, 2020. Upon the occurrence of an Event of Default, the interest rate under the Term Loans shall be equal to 5% plus the Interest Rate then in effect.

The Term Loans are secured by a security interest in all of the assets of the Company and its current and future subsidiaries, excluding intellectual property but including proceeds of intellectual property.

The Company may prepay all but not less than all of the Term loans advanced under the Loan Agreement, provided that the Company provides written notice to the Collateral Agent at least 30 days prior to such prepayment, and pays the lender an amount equal to the outstanding principal of the Term Loans, plus accrued and unpaid interest through the prepayment date, the Final Payment and the prepayment fee equal to (i) 3% of the outstanding balance, if the loan is prepaid within 18 months of the funding date, (ii) 2% of the outstanding balance, if the loan is prepaid 18 months after through and including the second anniversary of the funding date and (iii) 1% of the outstanding balance if the loan is prepaid after the second anniversary of the funding date and prior to the maturity date of the loan (the “Prepayment Fee”) and all other obligations that are due and payable under the Loan Agreement including any applicable expenses of the lender. The Final Payment is an amount equal to the original principal of the Term Loan multiplied by 3%.

The Loan Agreement contains customary representations and covenants that, subject to exceptions, restrict the Company’s ability to: pay dividends (other than dividends payable solely in capital stock) or redeem or repurchase any capital stock, make investments, incur additional liens, engage in mergers, acquisitions, and transact with affiliates, undergo a change in control, add or change business locations and engage in businesses that are not related to existing businesses.

The Company also issued the Lender five-year warrants to purchase an aggregate of 1,666,668 shares of the Company’s common stock at \$0.75 per share.

In connection with the execution of the Loan Agreement, the Company entered into an amendment of Sections 8(a) and 8(b) of certain Exchange Agreements with the Company dated March 25, 2015 held by a certain holder of the Company’s Series D Preferred Stock. The Amendment requires the Company to obtain consent of the Holder for certain future equity or debt issuances, and modifies the termination date for this requirement to be the earlier to occur of: (a) April 1, 2017; (b) the date on which the Company has raised \$10 million in equity financing; (c) the date on which the Company has closed one or more licensing agreements with corporate partners pursuant to which the Company is entitled to receive in total a minimum of \$10,000,000 in initial licensing or equity investments under such agreements; and (d) the date on which shares of the Company’s common stock are listed on a national securities exchange. The Company issued 100,000 shares of common stock to the Holder in connection with the Amendment.

**LETTER AGREEMENT**

January [ ], 2016

MabVax Therapeutics Holdings, Inc.  
11588 Sorrento Valley Rd., Suite 20  
San Diego, CA 92121  
Phone: (858) 259-9405  
Attn: J. David Hansen, President and Chief Executive Officer

Dear Mr. Hansen,

This Letter Agreement supersedes and replaces in its entirety that certain Letter Agreement by and between MabVax Therapeutics Holdings, Inc. and Southern Biotech, Inc. dated January 6, 2016.

MabVax Therapeutics Holdings, Inc. (the "Company") and Southern Biotech, Inc. ("Southern Bio") hereby agree (this "Letter Agreement") that:

Those certain rights under Sections 8a and 8b of each of that certain Exchange Agreement, dated March 25, 2015, between the Company and Southern Bio with respect to the exchange of the Company's Series A-1 Preferred Stock and Series A-1 Warrants held by Southern Bio for shares of the Company's common stock and Series D Convertible Preferred Stock (such agreement, the "A Exchange Agreement"), and the Exchange Agreement, dated March 25, 2015, between the Company and Southern Bio with respect to the exchange of the Company's Series B Preferred Stock and Series B Warrants held by Southern Bio for shares of the Company's common stock and Series D Convertible Preferred Stock (such agreement, the "B Exchange Agreement" and, collectively including both the A and B Exchange Agreements, referred to as the "Exchange Agreement Rights") are hereby replaced, clarified and modified in their entirety as follows:

8a. Limitation on Issuances and Financings.

- (i) For a period beginning on the date of this letter agreement and ending on the first to occur of (a) April 1, 2017; (b) the date on which the Company has entered into agreement(s) for an equity raise that totals at least \$10 million and has closed the financing; (c) the date on which the Company has closed one or more licensing agreements with corporate partners pursuant to which the Company is entitled to receive in total a minimum of \$10,000,000 in initial licensing or equity investments under such agreements; and (d) the date on which shares of the Company's common stock (the "Common Stock") are listed on any of The New York Stock Exchange, Inc., the NYSE MKT LLC, The NASDAQ Global Select Market, The NASDAQ Global Market, The NASDAQ Capital Market or any similar national exchange (the "Prohibited Period"), the Company shall not, without the prior consent of Southern Bio, issue any Common Stock or securities convertible into or exercisable for shares of Common Stock (or modify any of the foregoing which may be outstanding) to any person or entity or incur any financing debt, other than with respect to an Excepted Issuance.
  - (ii) For purposes hereof, "Excepted Issuance" shall be defined as
    - a. The issuance of shares of Common Stock or options to purchase Common Stock issued to directors, officers or employees of the Company of up to 7,631,021 shares of Common Stock or Convertible Securities convertible into that number of shares of Common Stock during the Prohibited Period (as adjusted for stock splits, combinations and similar transactions) under the Second Amended and Restated MabVax Therapeutics Holdings, Inc. 2014 Employee, Director and Consultant Equity Incentive Plan; and
    - b. The issuance of warrants in connection with the Financing contemplated with Oxford Finance LLC or in connection with any debt financing or debt refinancing under clause (c) below.
    - c. Any debt financing involving Oxford Finance LLC or any of its affiliates in its or any such affiliate's capacity as a lender, agent, arranger or otherwise, and any debt refinancing of all or any portion of any of the foregoing.
-

- (iii) In addition to the restrictions set forth in (i) above, during the Prohibited Period, the Company will not, without the prior consent of Southern Bio, enter into any Equity or debt financing, other than (a) lease financing arrangements for equipment being used by the Company or (b) any Excepted Issuance.
- (iv) In addition to the restrictions set forth in (i) above, during the Prohibited Period, the Company will not, without the prior consent of Southern Bio, sell any development product assets currently held by the Company.
- (v) In addition to the restrictions set forth in (i) above, during the Prohibited Period, the Company will provide Barry Honig with five (5) days' notice prior to the consummation of any financing and secure his consent for such financing, other than in connection with any Excepted Issuance.

8b. No Assignment.

The rights in Section 8a above are specific to Southern Bio, and may only be exercised by the managing partner/president of Southern Bio, which is Barry Honig. Such rights shall not be assigned or transferred to or assumed by any other party or individual, voluntarily or by operation of law, and any such purported assignment, transfer or assumption shall be void and of no force or effect. Any transfer or purported transfer of the Exchange Agreement shall immediately terminate all rights under Section 8a above. Further, Southern Bio acknowledges and agrees that no rights pursuant to sections 8a or 8b of the Exchange Agreements were transferred or assigned to or assumed by any other party or individual, prior to the date of this Letter Agreement.

As conditions precedent to the effectiveness of this Letter Agreement Southern Bio shall have provided its consent to Oxford Finance LLC's proposed debt financing of \$10 million and associated transactions (the "Financing") in a separate letter to Oxford Finance LLC that contains language acceptable to Oxford Finance LLC to proceed with closing of the Financing with the Company, and such Financing shall have been consummated.

Southern Bio represents, warrants and covenants that the execution, delivery and performance of the Loan and Security Agreement by and between the Company and Oxford Finance LLC (the "LSA") and all other Loan Documents (as defined in the LSA) and the transactions contemplated thereby does not violate or result in a breach of any agreement, instrument or document among the Company and Southern Bio or any of its affiliates.

This Letter Agreement shall be governed by the laws of the state of New York, without giving effect to any conflict of laws provision, and may not be amended other than through a written agreement executed by the Company and Southern Bio.

**Southern Biotech, Inc.**

By: \_\_\_\_\_  
Name: Barry Honig  
Title: President

**MabVax Therapeutics Holdings, Inc.**

By: \_\_\_\_\_  
Name: J. David Hansen  
Title: President and Chief Executive Officer

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the registration statements on Form S-8 (Nos. 333-44826, 333-58020, 333-118614, 333-135396, 333-161132, 333-174355 and 333-203200) and Form S-3 (No. 333-176121), of MabVax Therapeutics Holdings, Inc., of our report dated March 14, 2016, related to our audit of the consolidated financial statements of MabVax Therapeutics Holdings, Inc., as of December 31, 2015 and 2014 and for the years then ended, which report included an explanatory paragraph relating to MabVax Therapeutics, Inc.'s ability to continue as a going concern, included in this Annual Report on Form 10-K.

/s/ CohnReznick LLP

San Diego, California  
March 14, 2016

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**  
**PURSUANT TO SECTION 302 OF**  
**THE SARBANES-OXLEY ACT OF 2002**

I, J. David Hansen, certify that:

- 1) I have reviewed this Annual Report on Form 10-K of MabVax Therapeutics Holdings, Inc.;
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 14, 2016

/s/ J. David Hansen

J. David Hansen

President and Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER****PURSUANT TO SECTION 302 OF****THE SARBANES-OXLEY ACT OF 2002**

I, Gregory P. Hanson, certify that:

- 1) I have reviewed this Annual Report on Form 10-K of MabVax Therapeutics Holdings, Inc.;
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 14, 2016

/s/ Gregory P. Hanson  
Gregory P. Hanson  
Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**  
**PURSUANT TO 18 U.S.C. Sec.1350,**  
**AS ADOPTED PURSUANT TO**  
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of MabVax Therapeutics Holdings, Inc. (the Company) on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, J. David Hansen, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15 (d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 14, 2016

/s/ J. David Hansen  
J. David Hansen  
President and Chief Executive Officer  
(Principal Executive Officer)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to MabVax Therapeutics Holdings, Inc. and will be furnished to the Securities and Exchange Commission or its staff upon request.

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**  
**PURSUANT TO 18 U.S.C. Sec.1350,**  
**AS ADOPTED PURSUANT TO**  
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of MabVax Therapeutics Holdings, Inc. (the Company) on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Gregory P. Hanson, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15 (d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 14, 2016

/s/ Gregory P. Hanson  
Gregory P. Hanson  
Chief Financial Officer  
(Principal Financial Officer)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to MabVax Therapeutics Holdings, Inc. and will be furnished to the Securities and Exchange Commission or its staff upon request.