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

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014
or

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

For the transaction period from _____ to _____

Commission file number: 000-53127

Lion Biotechnologies, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Nevada	**75-3254381**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
21900 Burbank Blvd, Third Floor, Woodland Hills	**91367**
(Address of Principal Executive Offices)	(Zip Code)

(818) 992-3126
(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class	**Name Of Each Exchange On Which Registered**
Common Stock, $0.000041666 **Par Value per Share**	**The Nasdaq Global Market**

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

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

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 website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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 (§229.405) 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, accelerated filer or non-accelerated filer (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 ☐	Accelerated filer ☒
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates on June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $87,400,000. Shares of common stock held by directors and executive officers and any ten percent or greater stockholders and their respective affiliates have been excluded from this calculation, because such stockholders may be deemed to be "affiliates" of the Registrant. This is not necessarily determinative of affiliate status of other purposes. As of March 16, 2015, there were 44,082,138 shares of the registrant's common stock outstanding.

Documents Incorporated By Reference

Portions of registrant's proxy statement relating to registrant's 2015 annual meeting of stockholders have been incorporated by reference in Part III of this annual report on Form 10-K.

EXPLANATORY NOTE

The registrant was previously a "smaller reporting company" under applicable Securities and Exchange Commission Rules and Regulations that determined it no longer qualified as such as of its June 30, 2014 determination date, at which time the registrant met the definition of an "accelerated filer." In accordance with Item 10(f)(2)(i) of Regulation S-K, the registrant is permitted to use the scaled disclosure requirements applicable to smaller reporting companies in this Annual Report on Form 10-K. The registrant will be transitioning to the disclosure requirements applicable to accelerated filers beginning with the registrant's Quarterly Report on Form 10-Q for the quarterly period ending March 31, 2015.

TABLE OF CONTENTS

"SAFE HARBOR" STATEMENT

Some of the information contained in this Annual Report may include forward-looking statements that reflect our current views with respect to our research and development activities, business strategy, business plan, financial performance and other future events. These statements include forward-looking statements both with respect to us, specifically, and the biotechnology sector, in general. Statements that include the words "expect," "intend," "plan," "believe," "project," "estimate," "may," "should," "anticipate," "will" and similar statements of a future or forward-looking nature identify forward-looking statements for purposes of the federal securities laws or otherwise.

All forward-looking statements involve inherent risks and uncertainties, and there are or will be important factors that could cause actual results to differ materially from those indicated in these statements. We believe that these factors include, but are not limited to, those factors set forth in the sections entitled "Business," "Risk Factors," "Legal Proceedings," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Controls and Procedures" in this Annual Report, all of which you should review carefully. Please consider our forward-looking statements in light of those risks as you read this Annual Report. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law.

If one or more of these or other risks or uncertainties materializes, or if our underlying assumptions prove to be incorrect, actual results may vary materially from what we anticipate. All subsequent written and oral forward-looking statements attributable to us or individuals acting on our behalf are expressly qualified in their entirety by this Statement.

PART I

Item 1. Business

References in this Annual Report to "we," "us," "our" or the "company" refer to this company, now known as Lion Biotechnologies, Inc. We are a Nevada corporation that, until September 26, 2013, was known as Genesis Biopharma, Inc.

All references to the number of shares issued or outstanding in this Annual Report, and all per share and other similar data, reflect a 1-for-100 reverse stock split that we effected on September 26, 2013.

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of novel cancer immunotherapy products designed to harness the power of a patient's own immune system to eradicate cancer cells. Our lead program is an adoptive cell therapy utilizing tumor-infiltrating lymphocytes (TIL), which are T cells derived from patients' tumors, for the treatment of metastatic melanoma. TIL therapy is being developed in collaboration with Steven Rosenberg, M.D., Ph.D., Chief of Surgery Branch at the National Cancer Institute (NCI). Dr. Rosenberg is a recognized pioneer in immuno-oncology and adoptive cell therapy.

A patient's immune system, particularly their TIL, plays an important role in identifying and killing cancer cells. TIL consist of a heterogeneous population of T cells that can recognize a wide variety of cancer-specific mutations and can overcome tumor escape mechanisms. TIL therapy involves growing a patient's TIL in special culture conditions outside the patient's body, or ex vivo, and then infusing the T cells back into the patient in combination with interleukin-2 (IL-2). By taking TIL away from the immune-suppressive tumor microenvironment in the patient, the T cells can rapidly proliferate. Billions of TIL, when infused back into the patient, are more able to search out and eradicate the tumor.

We have a Cooperative Research and Development Agreement (CRADA) with the U.S. Department of Health and Human Services, as represented by the NCI, through which we are funding the research and development of TIL-based product candidates for the treatment of advanced solid tumors. Pursuant to the CRADA, we fund NCI clinical trials with TIL therapy that are being conducted in collaboration with Dr. Rosenberg. In a 101-patient, Phase 2 clinical trial conducted at the NCI, about half of the patients with relapsed/refractory metastatic melanoma treated with TIL therapy achieved an objective response. An objective response occurs when there is a complete remission or a partial remission of the tumor. A complete remission requires a complete disappearance of all detectable evidence of disease, and a partial remission typically requires at least approximately 50% regression of measurable disease without new sites of disease. As of November 2014, 14 out of the 101 patients had experienced a complete remission and continue to remain in remission. Severe and life threatening toxicities occurred mostly in the first week after cell infusion and generally resolved within a few weeks. We are also funding an NCI-sponsored, Phase 2 clinical trial of a TIL therapy utilizing enriched tumor-reactive T cells to treat patients with metastatic melanoma. In addition to melanoma, we expect to fund multiple NCI-sponsored clinical trials involving TIL therapy to treat a variety of solid tumors, including, cervical, head and neck, bladder, breast, and lung cancers. Dr. Rosenberg has filed or intends to file investigational new drug applications (INDs) with the FDA in order to conduct these trials. Depending on the availability of funding, our evaluation of commercial viability of some of these product candidates and other factors, our goal is to submit separate INDs to conduct our own clinical trials relating to some or all of these product candidates. The CRADA provides us with an option to negotiate commercialization licenses from the NIH for additional intellectual property relating to certain TIL-based product candidates developed by the NCI under the CRADA.

We have a worldwide, exclusive patent license from the National Institutes of Health (NIH) for intellectual property to develop, manufacture and commercialize TIL therapy for the treatment of melanoma, and a worldwide, non-exclusive license to this intellectual property for the treatment of ovarian cancer, breast cancer, and colorectal cancer. We also have an exclusive license from the NIH for intellectual property relating to a TIL-based therapy utilizing enriched tumor reactive T cells patients with metastatic melanoma.

In January 2015 our IND for a company-sponsored, Phase 2 clinical trial designed to establish the feasibility of our lead product canidate, LN-144, and assess its overall safety in patients with metastatic melanoma was allowed by the U.S. Food and Drug Administration (FDA). We expect to initiate this trial later this year. The trial's primary objective is to determine the safety and feasibility of the administration of TIL therapy. Our company-sponsored, Phase 2 trial will use a protocol that is nearly identical to one which is currently being used at the NCI to treat patients. However, we believe we have streamlined and improved the NCI's manufacturing process of TIL production for our LN-144 product candidate. Assuming that the trial results meet our expectations, we plan to initiate a pivotal trial for regulatory approval for LN-144 in 2016. If the data from this pivotal trial are compelling, we intend to discuss with the FDA the filing of a Biologics License Application (BLA) for approval of LN-144 as a therapy for refractory metastatic melanoma.

We also intend to apply for an orphan drug designation for LN-144 in the United States and Europe to treat metastatic melanoma. This designation may provide seven years of market exclusivity in the United States, subject to certain limited exceptions. However, the orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review or approval process.

We are pursuing relapsed/refractory metastatic melanoma as our first target indication because of the promising initial NCI results and the commercial opportunity inherent in the significant unmet need of this patient population. Melanoma is a common type of skin cancer, accounting for approximately 76,000 patients diagnosed and 9,700 deaths each year in the United States according to the NCI. About 4% of patients with melanoma have metastatic disease. Patients with relapsed/refractory metastatic melanoma following treatment under the current standards of care have a particularly dire prognosis with very few curative treatment options.

In addition to the research and development being conducted under the CRADA, in 2014 we established our own significant internal research and development capabilities in Tampa, Florida, near the H. Lee Moffitt Cancer & Research Institute (Moffitt) on the campus of the University of South Florida, to explore the next-generation of TIL technology and new product candidates, as well as generate new intellectual property.

Company History

We filed our original Articles of Incorporation with the Secretary of State of Nevada on September 17, 2007. Until March 2010, we were an inactive company known as Freight Management Corp. On March 15, 2010, we changed our name to Genesis Biopharma, Inc., and in 2011 we commenced our current business. In May 2013 we completed a restructuring of our outstanding debt and equity securities (the “Restructuring”) and raised $1.25 million through the sale of our common stock. As part of the Restructuring, we converted $7.2 million of senior secured promissory notes, $1.7 million of bridge promissory notes, and $0.3 million in other outstanding debt into shares of common stock at a conversion price of $1.00 per share. In connection with, and shortly after the Restructuring, we replaced our Chief Executive Officer and most of our directors. On July 24, 2013, we acquired Lion Biotechnologies, Inc., a Delaware corporation. On September 26, 2013, we amended and restated our Articles of Incorporation to, among other things, change our name to Lion Biotechnologies, Inc., effect a 1-for-100 reverse stock split (pro-rata reduction of outstanding shares) of our common stock, increase (after the reverse stock split) the number of our authorized number of shares of common stock to 150,000,000 shares, and authorize the issuance of 50,000,000 shares of “blank check” preferred stock, $0.001 par value per share.

Our principal executive offices are located at 21900 Burbank Boulevard, 3rd Floor, Woodland Hills, California 91367, and our telephone number at that address is (818) 992-3126. Our website is located at www.lionbio.com. Information on our website is not, and should not be considered, part of this Annual Report.

Recent Developments

On December 22, 2014 we closed an underwritten offering of 6,000,000 shares of our common stock, including shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares, at a price of $5.75 per share. The net proceeds to us from the offering were approximately $32.2 million.

On January 22, 2015, we expanded our CRADA with the NCI to include research and development on four additional solid tumor indications. As amended, in addition to metastatic melanoma, the CRADA now also includes the development of TIL therapy for the treatment of patients with bladder, lung, triple-negative breast, and HPV-associated cancers.

On January 30, 2015, our IND application to the FDA seeking authorization to initiate a company-sponsored, multicenter Phase 2 study of LN-144 for the treatment of refractory metastatic melanoma was allowed.

On February 9, 2015, the NIH granted us an exclusive, worldwide license to treat metastatic melanoma with TIL therapy.

On February 10, 2015, we entered into an exclusive patent license agreement with the NIH under which we received an exclusive, worldwide license to the NIH's rights in and to two patent-pending technologies related to methods for improving TIL therapy.

On February 16, 2015, we appointed Ryan D. Maynard as a new member of our Board of Directors and as the Chair of our Board's Audit Committee. Mr. Maynard currently is the Executive Vice President and Chief Financial Officer of Rigel Pharmaceuticals, Inc., a clinical-stage drug development public company.

On February 26, 2015, our stock commenced trading on the Nasdaq Global Market. Prior thereto, our common stock was quoted on the OTCQB Marketplace.

On March 3, 2015 we closed an underwritten public offering of 9,200,000 shares of our common stock, including shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares, at a price of $8.00 per share (the "Public Offering"). The net proceeds to us from the Public Offering were approximately $68.2 million.

Strategy

Our goal is to be a leader in the development and commercialization of cell-based immunotherapies to treat solid tumors. We are developing a portfolio of TIL-based product candidates with the potential to meaningfully improve survival and quality of life for cancer patients. Key elements of our strategy include:

- Expedite clinical development, regulatory approval, and commercialization of our lead product candidate

Based on results from NCI-sponsored clinical trials, we plan to advance our lead product candidate, LN-144, for the treatment of patients with refractory metastatic melanoma. We filed an IND with the FDA in December 2014 to initiate a company-sponsored Phase 2 single-arm, multicenter clinical trial of LN-144 in patients with refractory metastatic melanoma. We anticipate patient enrollment to begin mid2015.

If data from this company-sponsored Phase 2 trial are consistent with previous results from the NCI, we will initiate a multicenter, registration trial in 2016. Assuming the results from the registration trial are positive, we will discuss with the FDA the filing of a BLA for approval of LN-144 as a treatment for patients with refractory metastatic melanoma. The FDA may grant accelerated approval for product candidates for serious conditions that fill an unmet medical need based on a surrogate or intermediate clinical endpoint, including tumor shrinkage, because such shrinkage is considered reasonably likely to predict a real clinical benefit of longer life. We believe our accelerated approval strategy can be warranted given the limited options for patients with refractory metastatic melanoma. However, even if the FDA grants accelerated approval, confirmatory trials may still be required.

- Continue collaboration with the NCI to develop adoptive cell therapy technologies

Our CRADA with the NCI offers us the opportunity to identify technologies for development based on human proof-of-concept data, which significantly reduces the risk in our product portfolio. In collaboration with the NCI, we are exploring the treatment of additional solid tumor indications, including cervical, head and neck, lung, bladder, and breast cancers. We currently intend to file one or more INDs relating to TIL therapy for the treatment of a cancer other than melanoma in late 2015. These INDs will be based on human proof-of-concept results generated by the NCI under the CRADA. Our CRADA with the NCI expires in 2016 but may be extended for an additional five years. We intend to foster and, where mutually beneficial, expand our relationship with the NCI to further identify future product candidates, including products based on additional novel immunotherapy technology. Our goal is to exclusively license and develop TIL-based technologies to treat a variety of solid cancers based on data from NCI-sponsored clinical trials that we are funding under the CRADA.

· Establish commercialization and marketing capabilities of current and future pipeline products

If we receive regulatory approval for our lead product candidate, we plan to have our own specialty sales and marketing organization to commercialize LN-144. We expect to initially focus on the top 50 referral centers in the United States that have experience treating metastatic melanoma patients with interleukin-2 (IL-2). We are in the process of developing a commercial strategy for markets outside the United States, where we may partner with third parties to commercialize and market approved product candidates.

We currently plan to use contract manufacturing organizations (CMOs) to supply our TIL-based products. CMOs limit the amount of upfront capital investment; however, we may establish our own manufacturing facilities in the future for better margins and rapid implementation of innovative changes. We intend to carefully manage our fixed cost structure, maximize optionality, and reduce the long-term cost of manufacturing our products.

Immune system

The immune system recognizes danger signals and responds to threats at a cellular level. The most significant components of the cellular aspect of the adaptive immune response are T cells (or T lymphocytes), so called because they generally mature in the thymus. T cells can be distinguished from other white blood cells by T cell receptors present on their cell surface. These receptors contribute to tumor surveillance by helping T cells recognize infected cells as well as cancerous cells. T cells are involved in both sensing and killing infected or cancerous cells, as well as coordinating the activation of other cells in an immune response.

Although the immune system is designed to identify foreign or abnormal proteins expressed on tumor cells, this process is often defective in cancer patients. The defective process sometimes occurs when the cancer cells closely resemble healthy cells and go unnoticed or if tumors lose their protein expression. Additionally, cancer cells employ a number of mechanisms to escape immune detection to suppress the effect of the immune response. Some tumors also encourage the production of regulatory T cells that prevent cytotoxic T cells from attacking the cancer.

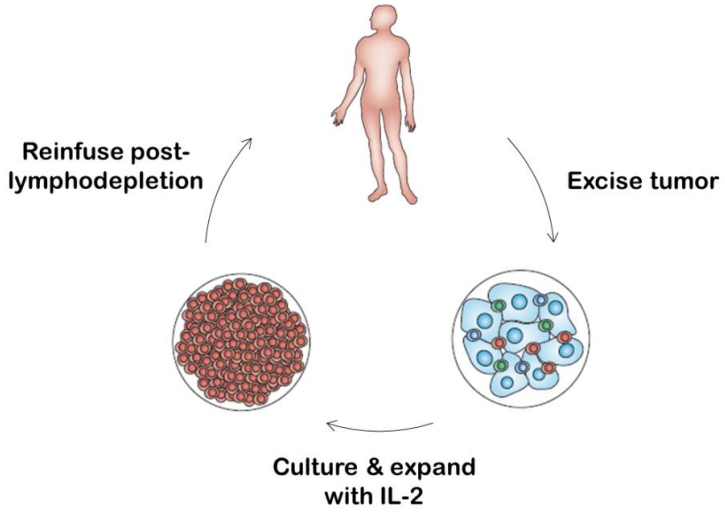
Cancer immunotherapy

Despite the progress that has been made over the past several decades, effective treatment of cancer, especially solid tumors continues to be challenging. Some reasons solid tumors are so difficult to treat are because: in many solid tumors, multiple genes (as many as 100’s of genes) are mutated, solid tumors are heterogeneous (i.e. different cells in the tumor have distinct genetic lesions), it is not always clear which particular mutations are critical, and tumors can adapt and find a way to evade treatments that target a single mutation. In addition, the tumor can suppress the patient’s natural immune response. When T cells with cancer-specific receptors are absent, present in low numbers, of poor quality or rendered inactive by suppressive mechanisms employed by tumor tissue, the cancer can grow and spread to various organs. In addition, standard of care treatments can be deleterious to T cells' ability to kill cancer.

We believe adoptive cell therapy with the use of human cells as therapeutic entities to reengage the immune system will be the next significant advancement in the treatment of cancer. These cellular therapies may avoid the long-term side effects associated with current treatments and have the potential to be effective regardless of the type of previous treatments patients have experienced. We believe TIL therapy in particular has the potential to treat solid tumors by overcoming the limits of a patient’s immunosurveillance by increasing the effectiveness and number of a patient's cancer-specific T cells.

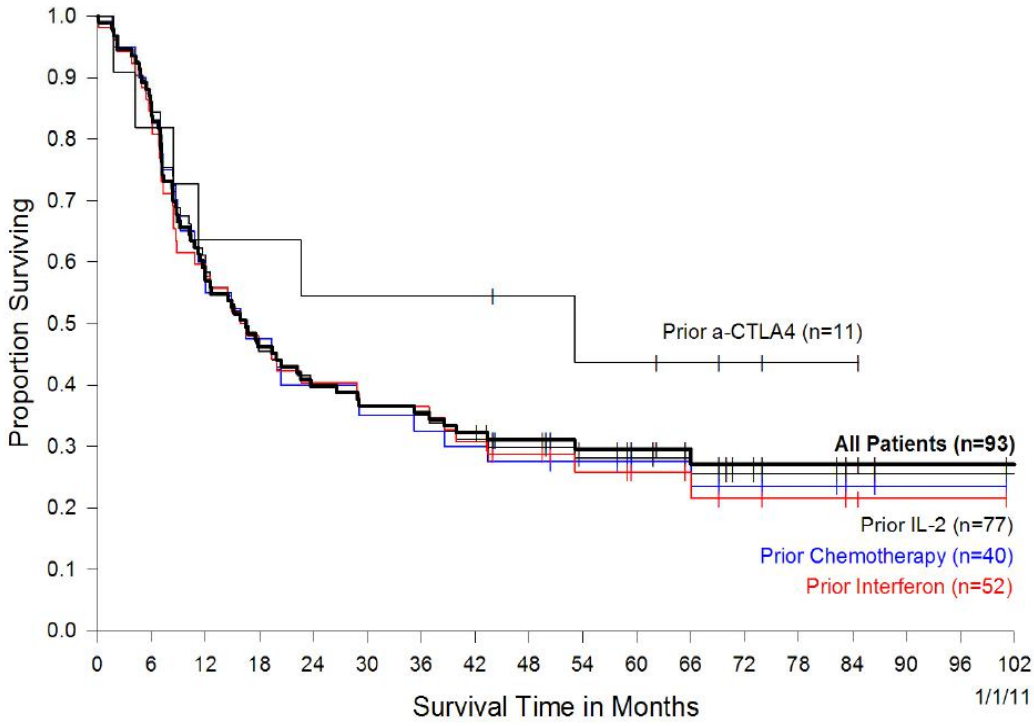
Tumor-infiltrating lymphocytes

Adoptive cell therapy with TIL involves (1) harvesting T cells from a patient's tumor, (2) culturing and expanding the number of TIL, and (3) infusing the functional TIL back into the patient followed by treatment with IL-2. TIL are a heterogeneous population of T cells that can recognize and kill cancer cells. Currently, the TIL manufacturing process that we are developing takes approximately four to five weeks from receipt of the patient's tumor to infusion of the TIL back into the patient. We intend to treat patients with a single infusion of TIL after they receive a short chemotherapy lymphodepletion regimen, which is intended to improve the survival and proliferative capacity of the newly infused T cells. After infusion, the TIL can proliferate inside a patient and potentially infiltrate the tumor microenvironment to eliminate large numbers of cancer cells. TIL can overcome several mechanisms of tumor escape to which endogenous T cells may be susceptible.



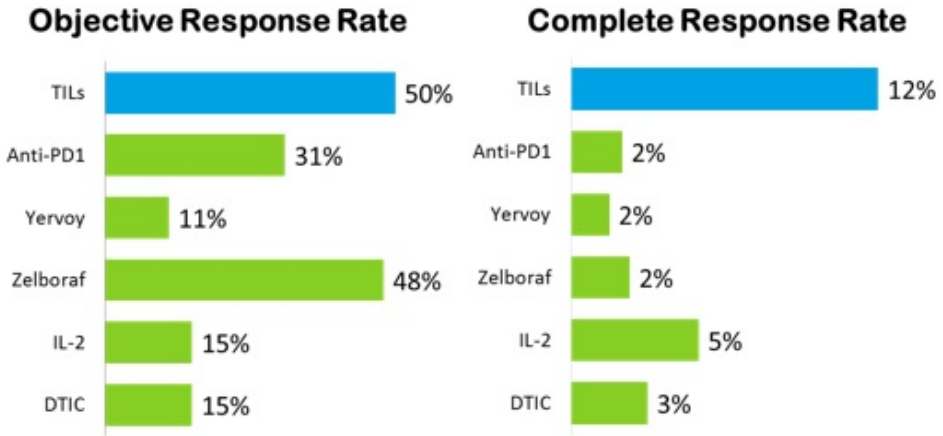
To date, hundreds of metastatic melanoma patients have already been treated with TIL therapy at different hospitals in the US, Europe, Canada, and Israel. Clinical responses have been relatively consistent: almost half of the melanoma patients treated with TIL have an objective response (i.e. tumor regression of 50% or more), and about one in ten patients have a complete response with no evidence of disease remaining after only one administration (see table below showing clinical data from four major centers). Many patients respond to TIL therapy despite experiencing tumor progression after previously being treated with other therapies. The following table shows the reported response rates at the following four institutions for stage IV metastatic melanoma patients refractory to other treatments:

In a Phase 2 trial conducted at the NCI, 93 patients with metastatic melanoma were treated with TIL therapy (after a lymphodepletion regimen of either chemotherapy alone or with radiation) followed by IL-2. As shown in the below graph, 20 of the 93 patients (22%) achieved a complete tumor regression, and 19 have ongoing complete regressions beyond six years as of April 2014. The graph below shows the long term survival of this 93 patient NCI study showing more than 25% long term survivors over 8 years.



Results from different clinical trials suggest that TIL therapy compares very favorably to other treatments already approved to treat metastatic melanoma. For comparison, the objective response rate for ipilimumab is only 11% with a complete response rate of 2%. The objective response rates for nivolumab and pembrolizumab are 32% and 24%, respectively, with complete responses in 3% and 1% of patients, respectively.

TIL therapy in patients with metastatic melanoma have durable responses with high complete response rates relative to CTLA-4 antibodies, such as ipilimumab (Yervoy), BRAF inhibitors, such as vemurafenib (Zelboraf), PD-1/PD-L1 antibodies, such as nivolumab (Opdivo) or lambrolizumab (Keytruda), interleukin 2 (IL-2), and anti-cancer chemotherapy drugs such as dacarbazine (DTIC). The following chart summarizes the response rates relative to other treatment options.



(The data summary above compares various treatments used for melanoma at various stages and is a summary overview based on various published results. Some of these products may have higher or lower response rates in other studies. These comparisons are not based on head-to-head randomized trials rather historical data only. The patients selected in these trials vary from 1st line to 2nd or 3rd line and, therefore, the foregoing chart should be used for illustrative purposes only, and not as a direct comparison.)

Product pipeline

We are developing a portfolio of TIL-based products for the treatment of solid tumors. Our lead pipeline candidate, LN-144, is an adoptive cell therapy using TIL to treat patients with refractory metastatic melanoma. In addition to LN-144, we intend to develop additional TIL-based pipeline products to treat a variety solid tumors, as well as next-generation TIL therapies that are more potent and less costly to manufacture. Under our CRADA, we are collaborating with the NCI on the development of TIL therapies for a variety of solid tumor indications, including cervical, head and neck, bladder, breast, and lung cancers. In addition, at our research and development facility in Tampa, Florida, we are also developing and evaluating a variety of technologies that can improve the growth and potency of TIL. Depending on the data developed from these efforts, we expect to expand our product development efforts to develop products for one or more of these other indications.

LN-144

We are developing LN-144 to treat metastatic melanoma. Melanoma is a common type of skin cancer, accounting for approximately 76,000 patients diagnosed and 9,700 deaths each year in the United States according to the NCI. Patients with relapsed/refractory metastatic melanoma following treatment under the current standards of care have a particularly dire prognosis with very few curative treatment options.

First-line therapy for metastatic melanoma patients usually consists of treatment with ipilimumab, a CTLA-4 monoclonal antibody. Approximately 11% of metastatic melanoma patients have an objective response when treated with ipilimumab. For patients who relapse or are refractory to ipilimumab, the current standard of care for second-line therapy is either nivolumab or pembrolizumab, which are PD-1 monoclonal antibodies. About 32% of patients treated with nivolumab and 24% of patients treated with pembrolizumab achieve an objective response. While nivolumab and pembrolizumab are currently used as second-line therapies, the National Comprehensive Cancer Network (NCCN) has recommended that both PD-1 antibodies be used as first-line treatment. Patients who do not respond to the current second-line therapies have very few treatment options and typically have a very poor prognosis.

Clinical Experience

In a Phase 2 clinical trial conducted at the NCI, 101 refractory metastatic melanoma patients were randomized to receive either TIL therapy after non-myeloablative lymphodepleting chemotherapy or TIL therapy after both non-myeloablative lymphodepleting chemotherapy and total body irradiation. About 54% of the patients in the trial achieved an objective response. There was no statistical difference in objective response between patients in either arm. As of November 2014, fourteen patients had experienced a complete remission and continue to remain in remission.

Safety

Overall, toxicities or adverse events during TIL therapy have almost entirely been associated with the either the lymphodepletion regimen or the high-dose IL-2 therapy given after TIL infusion. Few adverse events have been documented following the TIL infusion itself, with Grade 3 or higher events rarely found. Severe and life threatening toxicities due to TIL therapy occur mostly in the first week after cell infusion but generally resolve within a few weeks. To date, some patients have experienced vitiligo and uveitis, but there has been no other evidence of off-target effects associated with TIL therapy.

Early toxicities related specifically to the infusion of TIL (those which are seen immediately following the cell infusion and prior to IL-2 administration) are generally mild and include fevers, chills, headache, and malaise. Toxicities which occur following administration of IL-2 but are thought to be related to the cells include immune mediated events such as vitiligo, transient uveitis, hearing loss, and vestibular dysfunction. The use of the non-myeloablative lymphodepletion regimen prior to cell administration increases the toxicity of this treatment as profound myelosuppression occurs in all patients.

The standard approach to the administration of high-dose IL-2 in all studies is to continue dosing until patients can no longer tolerate treatment. The most commonly seen grade 4 events are pulmonary and renal impairment, and mental status changes. These toxicities may sometimes require intubation for protection of the patient's airway. Although these patients require significant supportive measures during this period, all toxicities are reversible and the overwhelming majority of patients have suffered no long term sequelae following this treatment regimen. However, fatal complications are possible and it is therefore only appropriate to carry out this experimental treatment in the context of life threatening metastatic cancer.

Development strategy

In February 2015, the FDA allowed an IND to initiate our company-sponsored Phase 2, open-label, single-arm multicenter clinical trial to treat about 20 patients with refractory metastatic melanoma. Patients with refractory disease are those who have not responded to other, non-TIL treatments. We anticipate patient enrollment to begin the middle of 2015. We currently expect that the Phase 2 trial will be conducted at five sites. The primary endpoints will be safety and tolerability; secondary endpoints will include feasibility and overall response rate. If results are consistent with prior results at the NCI, we intend to initiate a larger trial for regulatory approval. The design of this larger trial has yet to be confirmed and will depend on discussions with the FDA and additional clinical data. We intend to initiate the larger, registration trial in 2016. Assuming the results demonstrate a clinical benefit, we will file a BLA with the FDA for regulatory approval.

In addition to our company-sponsored and NCI-sponsored clinical trials, we are collaborating with Moffitt to evaluate TIL therapy in combination with ipilimumab or nivolumab in patients with metastatic melanoma.

Additional TIL-based Product Candidates

In collaboration with the NCI, we are developing TIL therapy for a variety of solid tumor indications, including cervical, head and neck, bladder, breast, and lung cancers. Under the CRADA, we are funding a clinical trial involving TIL therapy to treat cervical cancer. As of June 2014, three out of nine patients with cervical cancer demonstrated an objective response after being treated with TIL therapy; two of which had complete responses and one had a partial response. As part of the CRADA, we are also funding a trial to treat patients with lung cancer; only two patients have been treated so far. Depending on results from the clinical trials conducted at the NCI, we will pursue the development and regulatory approval for the additional indications. We anticipate filing of one or more IND applications with the FDA to treat one or more of the cancers other than melanoma with TIL therapy by the end of 2015.

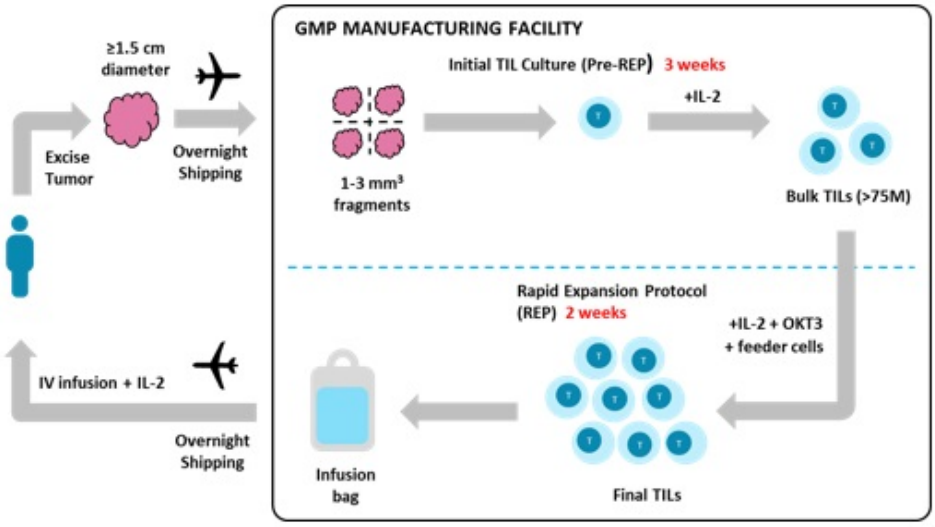
Enriched TIL

Pursuant to the CRADA, we are also supporting a Phase 2 clinical trial at the NCI to evaluate TIL enriched for CD137 (aka4-1BB) expression to treat patients with metastatic melanoma. The next-generation TIL technology supports more potent and efficient TIL production by selecting for TIL that express various inhibitory receptors, including 4-1BB, PD-1, TIM-3 and/or LAG-3. TIL that express these proteins are associated with higher tumor reactivity, so potentially fewer of the enriched cells are needed to be therapeutically effective. The technology has potential to substantially reduce the time and cost of manufacturing.

Process development/manufacturing

Our manufacturing and processing of TIL-based product candidates is based on an improved version of the NCI's original manufacturing and processing of TIL. The NCI has successfully produced TIL from tumors in more than 90% of metastatic melanoma patients. For LN-144, we will use a very similar manufacturing process that is being used in ongoing NCI clinical trials. We believe we have streamlined and improved the NCI's original process.

Because it is critical to rapidly treat patients with highly aggressive cancers, we are implementing in our company-sponsored Phase 2 clinical trial, a manufacturing process for LN-144 that takes approximately four to five weeks from receipt of the patient's tumor to infusion of the TIL back to the patient. The processing of LN-144 begins with the collection of the patient's tumor, which is then sent to a central processing facility, where the T cells are isolated. These cells are stimulated to proliferate, then propagated in cell culture flasks until sufficient cells are available for infusion back into the patient. The TIL is then washed at the cell processing site and shipped back to the clinical center where they can be administered to the patient. In preparation for administration of the TIL, the patient undergoes a short chemotherapy lymphodepletion regimen, which is intended to improve the survival and proliferative capacity of the newly infused T cells. The following diagram illustrates our proposed TIL manufacturing process.



We have entered into a Manufacturing Services Agreement with Lonza Walkersville, Inc. (Lonza) pursuant to which Lonza has agreed to manufacture, package, ship and handle quality assurance and quality control of our TIL. We expect Lonza to process and manufacture LN-144 for our clinical trials in patients with refractory metastatic melanoma. Cell processing activities are conducted at Lonza under current good manufacturing processes, or cGMP, using qualified equipment and materials. We believe all materials and components utilized in the production of the final TIL product are readily available from qualified suppliers. We expect to rely on Lonza to meet anticipated clinical trial demands. In the future, we may rely on Lonza or other third parties, or develop our own manufacturing capabilities for the manufacturing and processing of TIL-based product candidates for our clinical trials. To meet projected needs for commercial sale quantities, we may develop our own commercial manufacturing facility to supply and process products. Developing our own manufacturing capabilities may require more costs than we anticipate or result in significant delays. If we are unable to develop our own manufacturing capabilities, we will rely on contract manufacturers, including both current and alternate suppliers, to ensure sufficient capacity is available for commercial purposes prior to the filing of a BLA.

Commercialization plan

We currently have no sales, marketing or commercial product distribution capabilities and have no experience as a company in marketing products. We intend to build our own commercialization capabilities over time.

In the U.S., there are approximately 76,000 patients diagnosed with melanoma each year. About 4% of patients with melanoma have metastatic disease. If LN-144 is approved, we expect to commercialize the product in the U.S. with a focused specialty sales force targeting the top 50 hospitals and clinics that have experience in treating patients with IL-2. We believe we can address physicians who treat metastatic melanoma with a direct specialty sales force.

Outside the US, we have not yet defined our regulatory and commercial strategy for LN-144. Our commercial strategy for markets outside the US may include the use of strategic partners, distributors, a contract sales force or the establishment of our own commercial structure. We plan to further evaluate these alternatives as we approach approval for one of our product candidates.

As additional product candidates advance through our pipeline, our commercial plans may change. Clinical data, size of the development programs, size of the target market, size of a commercial infrastructure, and manufacturing needs may all influence our U.S., Europe, and rest-of-world strategies.

Intellectual property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We plan also to rely on regulatory protection afforded through orphan drug designations, data exclusivity, market exclusivity and patent term extensions where available. To achieve this objective, a strategic focus for us has been to identify and license key patents that provide protection and serve as an optimal platform to enhance our intellectual property and technology base.

We have conducted extensive freedom-to-operate (FTO) analyses of the current patent landscape with respect to our lead product candidate, and based on these analyses, we believe that we have the FTO for TIL therapy. However, the area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties.

We are working to develop the next-generation of TIL technologies. Based on our current development plans, our goal is to file our first patent applications directed to these technologies by the end of 2015.

NIH license agreement 2011. Pursuant to a patent license agreement with the NIH, dated October 5, 2011 (the "NIH License Agreement"), we received a non-exclusive, worldwide license to certain intellectual property, including intellectual property related to TIL-based product candidates for the treatment of melanoma, ovarian, breast, and colorectal cancers. The terms of this license require us to pay the NIH minimum annual royalties in the amount of $20,000 and to make performance-based payments upon successful completion of clinical and regulatory benchmarks relating to the licensed products. The aggregate potential benchmark payments are $36.3 million, of which aggregate payments of $31.5 million are due only after marketing approval of the first TIL-based product candidates in the United States, Europe, or Asia. The first benchmark payment of $300,000 will be due upon the completion of our first company-sponsored human clinical study of a licensed product in the United States. We must also pay the NIH royalties on net sales of products covered by the license at rates in the mid-single digits. To the extent we enter into a sublicensing agreement relating to a licensed product, we are required to pay the NIH a percentage of all consideration received from a sublicensee, which percentage will decrease based on the stage of development of the licensed product at the time of the sublicense. Any such sublicense payments shall be made in lieu of, and not in addition to, benchmark payments. The license will expire upon expiration of the last patent contained in the licensed patent rights, unless terminated earlier. The NIH may terminate or modify the NIH license in the event of a material breach, including if we do not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. We may terminate the license, or any portion thereof, at our sole discretion at any time upon 60 days written notice to the NIH. In addition, the NIH has the right to require us to sublicense the rights to the product candidates covered by this license upon certain conditions, including if we are not reasonably satisfying required health and safety needs or if we are not satisfying requirements for public use as specified by federal regulations.

The following is a list of the unexpired and pending patents that we have licensed from the NIH under the NIH License Agreement:

Exclusive License

Pat./Pub. No.	Title	Country	Status
20120244133	Methods of growing TILs in gas-permeable containers	US	Pending
8383099	Adoptive cell therapy with young T cells	US	Issued
20140030806	Adoptive cell therapy with young T cells	US	Pending

Nonexclusive License

Pat./Pub. No.	Title	Country	Status
8034334	Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy	US	Issued
1545204	Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy	EP	Pending
2497552	Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy	CA	Issued
2003265948	Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy	AU	Granted
8287857	Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy	US	Issued

The NCI patents first begin to expire in 2023, with the last of these patents, which broadly claims culturing and administering TIL, expiring in 2029.

In February 2015, through a second license that was limited to metastatic melanoma, the NIH License Agreement was amended to grant us the exclusive, worldwide rights to certain intellectual property related to TIL-based product candidates for the treatment of metastatic melanoma. In consideration for the exclusive rights granted under the amendment to the NIH License Agreement, we agreed to pay the NIH a non-refundable upfront licensing fee within 60 days after the effective date of the amendment, to pay customary royalties based on a percentage of net sales (which percentage is in the mid-single digits), a percentage of revenues from sublicensing arrangements, and lump sum benchmark payments upon the successful completion of our first Phase 2 clinical study, the successful completion of our first Phase 3 clinical study, the receipt of the first FDA approval or foreign equivalent for a licensed product or process resulting from the licensed technologies, the first commercial sale of a licensed product or process in the United States, and the first commercial sale of a licensed product or process in any foreign country. The following two patent applications have been licensed to us under the 2015 patent license agreement with the NIH:

1. U.S. Provisional Patent Application No. 61/771,247 filed March 1, 2013 entitled “Methods Of Producing Enriched Populations Of Tumor-Reactive T Cells From Tumor”

2. PCT Patent Application No. PCT/US2013/038799, filed April 30, 2013, entitled “Methods Of Producing Enriched Populations Of Tumor-Reactive T Cells From Tumor” (published as WO 2014/133567)

The foregoing two patent applications relate to our TIL-based product candidates that are enriched tumor reactive T cells that express activation markers, such as CD137 (or 4-1BB) or PD-1.

Moffit License In July 2014, we entered into an exclusive license agreement with the H. Lee Moffitt Cancer Center and Research Institute, Inc. (Moffitt) under which we received an exclusive, worldwide license to Moffitt’s rights in and to two provisional patent-pending technologies (filed under “Compositions and Methods for Improving Tumor-Infiltrating Lymphocytes for Adoptive Cell Therapy”) related to methods for improving TIL for adoptive cell therapy. The license covers the application of this technology to metastatic melanoma and other tumor types, including triple-negative breast cancer, non-small cell lung cancer and other tumors that historically have been difficult to treat. Pursuant to the Moffitt License Agreement, we agreed to pay an upfront licensing fee, payable within 30 days of the effective date of the Moffitt License Agreement, and a patent issuance fee payable upon the issuance of the first U.S. patent covering the subject technology. In addition, we have agreed to pay milestone license fees upon completion of specified milestones, customary royalties based on a specified percentage of net sales (which percentage is in the low single digits) and sublicensing payments, as applicable, and annual minimum royalties beginning with the first sale of products based on the licensed technologies, which minimum royalties will be credited against the percentage royalty payments otherwise payable in that year. We will also be responsible for all costs associated with the preparation, filing, maintenance and prosecution of the patent applications and patents covered by the Moffitt License Agreement related to the treatment of any cancers in the United States, Europe and Japan and in other countries selected that we and Moffitt agreed to.

Enriched TIL license agreement 2015 Pursuant to an exclusive patent license agreement with the NIH, dated February 10, 2015, we were granted an exclusive, worldwide license to two patent-pending technologies related to TIL-based product candidates that are enriched for tumor-reactive T cells that express activation markers, including CD137 (or 4-1BB) and PD-1. In consideration for the rights granted under this exclusive patent license agreement, we agreed to pay the NIH a non-refundable upfront licensing fee within 60 days after the effective date of the agreement, and to pay customary royalties based on a percentage of net sales (which percentage is in the mid-single digits), a percentage of revenues from sublicensing arrangements, and lump sum benchmark payments upon the successful completion of our first Phase 2 clinical study, the successful completion of our first Phase 3 clinical study, the receipt of the first FDA approval or foreign equivalent for a licensed product or process resulting from the licensed technologies, the first commercial sale of a licensed product or process in the United States, and the first commercial sale of a licensed product or process in any foreign country.

The exclusive license will terminate upon expiration of the last patent contained in the licensed patent rights, unless terminated earlier. None of the applications included in the NIH licensed patent rights have issued yet. The NIH may terminate or modify the NIH license in the event of a material breach, including if we do not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. We may terminate the license, or any portion thereof, at our sole discretion at any time upon 60 days written notice to the NIH. In addition, the NIH has the right to require us to sublicense the rights to the product candidates covered by this license upon certain conditions, including if we are not reasonably satisfying required health and safety needs or if we are not satisfying requirements for public use as specified by federal regulations.

Moffitt license agreement

In July 2014, we entered into an exclusive license agreement with the H. Lee Moffitt Cancer Center and Research Institute, Inc. (Moffitt) under which we received an exclusive, worldwide license to Moffitt's rights in and to two provisional patent-pending technologies (filed under "Compositions and Methods for Improving Tumor-Infiltrating Lymphocytes for Adoptive Cell Therapy") related to methods for improving TIL for adoptive cell therapy. The license covers the application of this technology to metastatic melanoma and other tumor types, including triple-negative breast cancer, non-small cell lung cancer and other tumors that historically have been difficult to treat. Pursuant to the Moffitt License Agreement, we agreed to pay an upfront licensing fee, payable within 30 days of the effective date of the Moffitt License Agreement, and a patent issuance fee payable upon the issuance of the first U.S. patent covering the subject technology. In addition, we have agreed to pay milestone license fees upon completion of specified milestones, customary royalties based on a specified percentage of net sales (which percentage is in the low single digits) and sublicensing payments, as applicable, and annual minimum royalties beginning with the first sale of products based on the licensed technologies, which minimum royalties will be credited against the percentage royalty payments otherwise payable in that year. We will also be responsible for all costs associated with the preparation, filing, maintenance and prosecution of the patent applications and patents covered by the Moffitt License Agreement related to the treatment of any cancers in the United States, Europe and Japan and in other countries selected that we and Moffitt agreed to.

CRADA. In August 2011, we entered into the CRADA with the NCI, for the research and development of improved methods for the generation and selection of autologous TIL, for developing approaches for large-scale production of TIL, and to conduct clinical trials using these improved methods of generating TIL for the treatment of metastatic melanoma. On January 22, 2015, we amended the CRADA to include four new indications. Accordingly, as amended, in addition to metastatic melanoma, the CRADA now also includes the development of TIL therapy for the treatment of patients with bladder, lung, triple-negative breast, and HPV-associated cancer.

The principal goal of the CRADA is to develop and evaluate effective adoptive cell transfer-based immunotherapies using TIL for the treatment of patients with metastatic melanoma, bladder, lung, triple-negative breast, and HPV-associated cancers. In particular, the CRADA relates to the in vitro development of improved methods for the large scale generation and selection of TIL with anti-tumor reactivity from patients, the development of large scale TIL generation in accord with Good Manufacturing Practice (GMP) procedures, and the development of clinical trials using these improved methods of large scale TIL generation. These activities are conducted through a research plan that we jointly developed with the NCI.

Each party to the CRADA individually owns all inventions, data and materials produced solely by its employees in the course of performing the activities under the CRADA. The parties jointly own any inventions and materials that are jointly produced by employees of both parties in the course of performing activities under the CRADA. Subject to certain conditions, this collaboration provides us with the first option to negotiate commercialization licenses from the NIH to intellectual property relating to TIL-based product candidates conceived or first reduced to practice in performance of the CRADA research plan. This includes the right to negotiate a license to intellectual property related to TIL-based product candidates that are being tested in multiple clinical trials that we are funding under the CRADA. We may exercise this right by providing written notice after either (1) we receive notice that a patent application covering an invention has been filed, or (2) the date on which we file a patent application for an invention. We then have ten months to negotiate the license with the NIH. These time periods may be extended by the U.S. Public Health Service upon good cause. Pursuant to the terms of the CRADA, we are currently required to make quarterly payments of $500,000 to the NCI for support of research activities. To the extent we license patent rights relating to a TIL-based product candidate, we will be responsible for all patent-related expenses and fees, past and future, relating to the TIL-based product candidate. In addition, we will be required to supply certain test articles, including TIL, grown and processed under cGMP conditions, suitable for use in clinical trials, where we hold the IND for such clinical trial. The CRADA has a five-year term expiring on August 5, 2016. The CRADA may be terminated at any time by mutual written consent. We or NCI may unilaterally terminate the CRADA for any reason or for no reason at any time by providing written notice at least 60 days before the desired termination date.

Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. With respect to both licensed and company-owned intellectual property, 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 commercial products and methods of manufacturing the same. We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Competition

The biotechnology and pharmaceutical industries put significant resources in developing novel and proprietary therapies for the treatment of cancer. We compete with many different sources in the space of immunotherapy, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions, as well as companies developing novel targeted therapies for cancer. Universities and public and private research institutions in the U.S. and Europe are also potential competitors. For example, a Phase 3 study comparing TIL to standard ipilimumab in patients with metastatic melanoma is currently being conducted in Europe by the Netherlands Cancer Institute, the Copenhagen County Herlev University Hospital, and the University of Manchester. While these universities and public and private research institutions primarily have educational objectives, they may develop proprietary technologies that lead to other FDA approved therapies or that secure patent protection that we may need for the development of our technologies and products. We anticipate that we will face intense and increasing competition as new drugs and therapies enter the market and advanced technologies become available.

Due to their promising clinical therapeutic effect in clinical exploratory trials, we anticipate substantial direct competition from other organizations developing advanced T-cell therapies. In particular, we expect to compete with therapies with genetically engineered T cells rendered reactive against tumor-associated antigens prior to their administration to patients. Genetically engineered T cells are being pursued by several companies, including Adaptimmune, Celgene (in collaboration with bluebird bio), Kite Pharma, Juno Therapeutics, Novartis and others.

While other types of cancer immunotherapies may potentially be used in combination with TIL, such as checkpoint blockers, to enhance efficacy, we also expect substantial direct competition from other types of immunotherapies. We face competition from immunotherapy treatments offered by companies such as Amgen, AstraZeneca, Bristol-Myers, Merck, and Roche. Immunotherapy is also being pursued by several biotechnology companies as well as by large-cap pharmaceutical companies. We cannot predict whether other types of immunotherapies may be enhanced and show greater efficacy and may have direct and substantial competition from such immunotherapies in the future.

Many potential competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance and may render our treatments obsolete or non-competitive. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Government regulations

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulation;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is begun;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;

- preparation of and submission to the FDA of a Biologics License Application, or BLA, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practices, or cGMP, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigations to assess compliance with Good Clinical Practices; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States, which must be updated annually when significant changes are made.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

When a trial using genetically engineered cells is conducted at, or sponsored by, institutions receiving NIH funding for recombinant DNA research, prior to the submission of an IND to the FDA, a protocol and related documentation is submitted to and the study is registered with the NIH Office of Biotechnology Activities, or OBA, pursuant to the NIH Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines. Compliance with the NIH Guidelines is mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA, and many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. The NIH is responsible for convening the Recombinant DNA Advisory Committee, or RAC, a federal advisory committee, that discusses protocols that raise novel or particularly important scientific, safety, or ethical considerations at one of its quarterly public meetings. The OBA will notify the FDA of the RAC's decision regarding the necessity for full public review of a protocol. RAC proceedings and reports are posted to the OBA web site and may be accessed by the public. If the FDA allows the IND to proceed, but the RAC decides that full public review of the protocol is warranted, the FDA will request at the completion of its IND review that sponsors delay initiation of the protocol until after completion of the RAC review process.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices, or cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent Institutional Review Board, or IRB, for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase I— The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase II— The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase II clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase III clinical trials.

- Phase III— The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

- Phase IV— In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase IV studies may be made a condition to approval of the BLA.

Phase I, Phase II and Phase III testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. The submission of a BLA requires payment of a substantial User Fee to FDA, and the sponsor of an approved BLA is also subject to annual product and establishment user fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

Once a BLA has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may request additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. For a fast track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. A fast track designated product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the Food and Drug Administration Safety and Innovation Act, or FDASIA, which was enacted and signed into law in 2012, established the new breakthrough therapy designation. A sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors may request the FDA to designate a breakthrough therapy at the time of or any time after the submission of an IND, but ideally before an end-of-phase II meeting with FDA. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough designation also allows the sponsor to file sections of the BLA for review on a rolling basis. .

Fast Track designation, priority review and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identify of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug many not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. We plan to seek orphan drug designation for some or all of our product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may, among other things, halt our clinical trials, require us to recall a product from distribution, or withdraw approval of the BLA.

We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our product candidates, and expect to rely in the future on third parties for the production of commercial quantities. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

Other Healthcare Laws and Compliance Requirements

Our sales, promotion, medical education and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services, other divisions of the Department of Health and Human Services and state and local governments. Our promotional and scientific/educational programs must comply with the federal Anti-Kickback Statute, the Foreign Corrupt Practices Act, the False Claims Act, the Veterans Health Care Act, physician payment transparency laws, privacy laws, security laws, and additional state laws similar to the foregoing.

The federal Anti-Kickback Statute prohibits, among other things, the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state health care programs as well as private payors.

The False Claims Act, or FCA, imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. Actions under the FCA may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposed new reporting requirements on drug manufacturers for payments or other transfers of value made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Certain states also mandate implementation of commercial compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians and other healthcare professionals.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s privacy and security standards directly applicable to “business associates,” defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Coverage and Reimbursement

Sales of pharmaceutical products depend significantly on the availability of third-party coverage and reimbursement. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. Although we currently believe that third-party payors will provide coverage and reimbursement for our product candidates, if approved, these third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of our products. The product candidates that we develop may not be considered cost-effective. It is time consuming and expensive for us to seek coverage and reimbursement from third-party payors. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have 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 payors 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. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, which will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

In the EU, member states require both regulatory clearances by the national competent authority and a favorable ethics committee opinion prior to the commencement of a clinical trial. Under the EU regulatory systems, marketing authorization applications may be submitted under either a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all EU member states. It is compulsory for medicines produced by certain biotechnological processes. Because our products are produced in that way, we would be subject to the centralized process. Under the centralized procedure, pharmaceutical companies submit a single marketing authorization application to the EMA. Once granted by the European Commission, a centralized marketing authorization is valid in all EU member states, as well as the EEA countries Iceland, Liechtenstein and Norway. By law, a company can only start to market a medicine once it has received a marketing authorization.

Employees

As of December 31, 2014, we had 14 employees, all of whom are full-time, 8 of whom hold Ph.D. or M.D. degrees, 9 of whom were engaged in research and development activities and 5 of whom were engaged in business development, finance, information systems, facilities, human resources or administrative support. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Available Information

We maintain a website at www.lbio.com and make available there, free of charge, our periodic reports filed with the Securities and Exchange Commission ("SEC"), as soon as is reasonably practicable after filing. The public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website at http:/www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers such as us that file electronically with the SEC.

Executive Officers of the Registrant

The following table sets forth the name, age and position of individuals who hold positions as executive officers of our company. There are no family relationships between any director or executive officer and any other director or executive officer of our company. Executive officers are elected by the Board of Directors and serve at the discretion of the Board.

Name	Age	Position
Elma Hawkins, Ph.D.	58	Chief Executive Officer, President and Director
Michael Handelman	55	Chief Financial Officer
Laszlo Radvanyi, Ph.D.	54	Chief Scientific Officer
James Bender, Ph.D.	65	Vice President--Manufacturing

Elma Hawkins, Ph.D. Dr. Hawkins was appointed as our Chief Executive Officer effective January 1, 2015. From August 21, 2014 until her appointment on January 1, 2015, Dr. Hawkins was our President and Chief Operating Officer. Between August 21, 2014 and February 2014, Dr. Hawkins served as our Head of Clinical Development under a consulting agreement. Since 2006 Dr. Hawkins has been an independent consultant to various biotechnology companies and financial institutions. Dr. Hawkins started her career at Warner-Lambert/Parke-Davis in Clinical Research. Later she joined the Center for the Study of Drug Development at Tufts Medical School. Following that, she held various positions at BioSurface Technology and Genzyme Corporation, and at Antigenics, most recently as that company's Vice Chairman. Later, she was President and CEO of Advanced Viral Research. She also serves on the Health Care Advisory Board for the Partnership for New York City. Dr. Hawkins has BSc in Mathematics and Chemistry, BSc (Hons) in Chemistry, MSc in Organic Chemistry, a PhD in Organic Chemistry and an MBA with specialization in entrepreneurship.

Michael Handelman. Mr. Handelman has served as our Chief Financial Officer and Secretary since February 2011. He also was on our Board of Directors from February 2011 until the Restructuring in May 2013. Mr. Handelman served as the Chief Financial Officer and as a financial management consultant of Oxis International, Inc., a public company engaged in the research, development and commercialization of nutraceutical products, from August 2009 until October 2011. From November 2004 to July 2009, Mr. Handelman served as Chief Financial Officer and Chief Operating Officer of TechnoConcepts, Inc., formerly a public company engaged in designing, developing, manufacturing and marketing wireless communications semiconductors, or microchips. Prior thereto, Mr. Handelman served from October 2002 to October 2004 as Chief Financial Officer of Interglobal Waste Management, Inc., a manufacturing company, and from July 1996 to July 1999 as Vice President and Chief Financial Officer of Janex International, Inc., a children's toy manufacturer. Mr. Handelman was also the Chief Financial Officer from 1993 to 1996 of the Los Angeles Kings, a National Hockey League franchise. Mr. Handelman is a certified public accountant and holds a degree in accounting from the City University of New York.

James Bender, Ph.D. Dr. Bender joined us as our Vice President – Manufacturing on January 6, 2014. From September 2008 to December 2013 and has served as Vice President of Clinical Development and then as Vice President – Product Development and Manufacturing at ImmunoCellular Therapeutics, Ltd., a publicly-held clinical-stage biotechnology company focused on developing immune-based therapies to treat cancer. From 2002 through 2008, Dr. Bender held various positions at IDM Pharma, most recently as director of product development where he led that company's efforts relating to the clinical development of a cancer vaccine for the treatment of lung cancer. Prior to that, he held various positions at Nexell Therapeutics relating to the development of therapeutic stem cell and cancer vaccine products. Prior to that, Dr. Bender spent ten years with Baxter Healthcare Corporation, eight years with the University of New Mexico School of Medicine and five years with St. Joseph's Hospital in Albuquerque, New Mexico. He has over 75 scientific publications, is an inventor of 11 U.S. patents and holds a Ph.D. degree in immunology from the University of New Mexico and an M.P.H. in laboratory management from the University of Michigan.

Laszlo Radvanyi, Ph.D. Dr. Radvanyi became our Chief Scientific Officer in June 2014. Dr. Radvanyi was a member of our Scientific & Medical Advisory Board from June 2011 until his appointment as our Chief Scientific Officer. Dr. Radvanyi currently is an Adjunct Professor at the Moffitt Cancer Center. From January 2005 through June 2104, Dr. Radvanyi had a dual appointment professorship in the Departments of Breast Medical Oncology and Melanoma Medical Oncology at the University of Texas, M.D. Anderson Cancer Center where he conducted clinical studies on tumor infiltrating lymphocytes therapy in metastatic melanoma. Prior thereto, Dr. Radvanyi served from October 2000 until January 2005 as a research scientist at the Immunology Group at Sanofi-Pasteur in Toronto. Dr. Radvanyi currently serves on the scientific advisory board of Aethlon Medical, Inc. Dr. Radvanyi received his Ph.D. in clinical biochemistry from the University of Toronto and completed post-doctoral fellowships at Scripps Research Institute and Harvard Medical School.

Item 1A. Risk Factors

The risks described below may not be the only ones relating to our company. Additional risks that we currently believe are immaterial may also impair our business operations. Our business, financial conditions and future prospects and the trading price of our Common Stock could be harmed as a result of any of these risks. Investors should also refer to the other information contained or incorporated by reference in this Annual Report on Form 10-K, including our financial statements and related notes, and our other filings from time to time with the Securities and Exchange Commission.

Risks Related To Our Business

We have a history of operating losses; we expect to continue to incur losses and we may never be profitable.

We are a clinical-stage biopharmaceutical company. We have no products approved for commercial sale and have not generated any revenue. As of December 31, 2014, we had an accumulated deficit of $76.8 million. In addition, during the fiscal year ended December 31, 2014, we incurred a net loss of $12.2 million. Since our inception we have not generated any revenues. We do not expect to generate any meaningful product sales or royalty revenues for the foreseeable future, if ever. We expect to incur significant additional operating losses in the future as we expand development and clinical trial efforts.

Our ability to achieve long-term profitability is dependent upon obtaining regulatory approvals for our products and successfully commercializing our products alone or with third parties. However, our operations may not be profitable even if any of our products under development are successfully developed and produced and thereafter commercialized.

Our research and development efforts are to a large extent dependent upon the CRADA.

Although we opened our own research and development laboratory in 2014, we have limited internal research and development capabilities. As a result, we conduct a large portion of our research and development under the CRADA we entered into with the NCI. Under the CRADA, the NCI currently engaged in research and development related to the development of improved methods of large scale TIL generation for the ACT treatment of patients with metastatic melanoma, bladder, lung, triple-negative breast, and HPV-associated cancers. We are obligated to make annual payments of $2,000,000 under the CRADA. In addition, although the CRADA has a five year term, either party to the CRADA has the right to terminate the CRADA upon 60 days' notice to the other party. As a result, no assurance can be given that the NCI will not terminate the CRADA in the future and that the CRADA will, therefore, remain in effect until we complete our desired research thereunder.

We expect to use the results of the NCI's clinical trials to support the filing with the FDA of investigational new drug applications, or INDs, to conduct more advanced clinical trials of LN-144 and additional product candidates. However, we have limited control over the nature or timing of the NCI's clinical trials and limited visibility into their day-to-day activities. The research we are funding constitutes only a small portion of the NCI's overall research. Other research being conducted by Dr. Rosenberg may at times receive higher priority than research on our programs. These factors could adversely affect the timing of our IND filings and our ability to conduct future planned clinical trials.

Under the CRADA, we have an option to negotiate commercialization licenses from the NIH to intellectual property relating to TIL-based product candidates developed in the course of the CRADA research plan. However, we would have to negotiate with the NIH for such a license. There can be no assurance that we would be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. Further, to the extent we would like to negotiate a license to a patent filed before the CRADA was entered into, another party may object to the NIH granting us a license during a 30-day public notification period, and the NIH may decide not to grant us the license.

We have limited experience in operating our current business, which makes it difficult to evaluate our business plan and our prospects.

Until March 2010, we were an inactive company known as Freight Management Corp. In 2010 and 2011, we pursued the development of drugs for the treatment of cancer based on the anti-CD55+ antibodies. However, test results from the studies performed for us as part of the anti-CD55+ antibody program failed to meet the pre-clinical development endpoints, and in 2011 we terminated these efforts. In 2011 we entered in our current line of business and entered into the NIH License Agreement, the CRADA and the manufacturing services agreement with Lonza Walkersville, Inc. As a result, we have only a limited operating history in our current line of business on which a decision to invest in our company can be based. The future of our company currently is dependent upon our ability to implement our new business plan, as that business plan may be modified from time to time by our new management. While we believe that we have a sound business plan and research and development strategy, we have only a limited operating history against which we can test our plans and assumptions, and investors therefore cannot evaluate the likelihood of our success.

We face the problems, expenses, difficulties, complications and delays normally associated with a small, new biotechnology company, many of which are beyond our control. Accordingly, our prospects should be considered in light of the risks, expenses and difficulties frequently encountered in the establishment of a new business developing new technologies in an industry that characterized by a number of market entrants and intense competition. Because of our size and limited resources, we may not possess the ability to successfully overcome many of the risks and uncertainties frequently encountered by early stage companies involved in the new and rapidly evolving field of biotechnology in general, and in cancer treatment in particular. If our research and development efforts are successful, we may also face the risks associated with the shift from development to commercialization of new products based on innovative technologies. There can be no assurance that we will be successful in developing our new business.

We may encounter substantial delays in our clinical trials, or may not be able to conduct our trials on the timelines we expect.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. We expect to initiate our first company sponsored clinical trial later in 2015 and intend to file with the FDA several new INDs for product candidates in the next two years. However, we cannot be sure that we will be able to submit INDs at this rate, and we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design;
- the FDA may not allow us to use the clinical trial data from a research institution to support an IND if we cannot demonstrate the comparability of our product candidates with the product candidate used by the relevant research institution in its clinical studies;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies;
- delays in recruiting suitable patients to participate in our clinical studies;
- failure by our CROs, other third parties, or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's current good clinical practices, or cGCPs, requirements, or applicable regulatory guidelines in other countries;
- patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs;

- transfer of manufacturing processes from the NCI to Lonza or other larger-scale facilities operated by a contract manufacturing organization, or CMO, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and

- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

The deviations in our proposed new products from existing products may require us to perform additional testing, which will increase the cost, and extend the time for obtaining approval.

Our TIL based therapy is based on the ACT technology that we licensed from the NIH and that is presently available as a physician-sponsored investigational therapy for the treatment of Stage IV metastatic melanoma in the U.S. at the National Cancer Institute, MD Anderson Cancer Center, and the H. Lee Moffitt Cancer & Research Institute. The current method of treatment is very labor intensive and expensive, which has limited its widespread application. We developing new processes that we anticipate will enable more efficient manufacturing of our products. We may have difficulty demonstrating that the new products produced from our new processes are identical to the existing products. The FDA may require additional clinical testing before permitting a larger clinical trial with the new processes, and also the new product may not be as efficacious in the new clinical trials. Cellular products are not considered as well characterized products because there are hundreds of markers present on these cells, and even small changes in manufacturing processes could alter the cell types. It is unclear at this time which of those markers are critical for success of these cells to combat cancer, so our ability to predict the outcomes with newer manufacturing processes is limited. The changes that we may make to the existing manufacturing process may require additional testing, which may increase costs and timelines associated with these developments.

In addition to developing a TIL based therapy on existing ACT technology, we are currently evaluating the desirability of conducting clinical trials of our products in combination with other existing drugs for the treatment of metastatic melanoma. These combination therapies will require additional testing and clinical trials will require additional FDA regulatory approval and will increase our future cost of expenses.

We will need additional financing in order to complete the development and commercialization of our various product candidates.

Our research and development and our operating costs have been substantial and are expected to increase. We expect to continue to spend substantial amounts to continue the clinical development of LN-144 and our other product candidates. As of December 30, 2014, we had $44.9 million in cash. The net proceeds that we received in March 2015 from the Public Offering were approximately $68.2 million, after deducting the underwriting discounts and commissions and estimated offering expenses. We believe that the cash available to us after the recent public offering will be sufficient to fund our operations for at least the next 24 months. However, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may require additional capital for the further development and commercialization of our product candidates and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Our license and collaboration agreements may also be terminated if we are unable to meet the payment obligations under the agreements. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

We will have to hire additional executive officers and employees to operate our business.

We currently have only 14 full-time employees, of whom five are executive officers and 9 are engaged in research of development. The loss of the services of any of executive officers or research personnel could delay our product development programs and our research and development efforts. In order to develop our business in accordance with our business plan, we will have to hire additional qualified personnel, including in the areas of manufacturing, clinical trials management, regulatory affairs, and business development. Having received the net proceeds of the Public Offering, we now have sufficient funds to hire what we believe are the necessary employees to support our planned operations, and have commenced our search for additional key employees. However, competition for qualified employees among companies in the biotechnology and biopharmaceutical industry is intense, and no assurance can be given that we will be able attract, hire, retain and motivate the highly skilled employees that we need. If we are unable to hire new skilled personnel, including management, our ability to properly develop our products and to implement our business plan will be adversely affected, which will result in a reduction in the value of our shares of common stock.

We are subject to extensive regulation, which can be costly, time consuming and can subject us to unanticipated delays; even if we obtain regulatory approval for some of our products, those products may still face regulatory difficulties.

All of our potential products, cell processing and manufacturing activities, are subject to comprehensive regulation by the FDA in the United States and by comparable authorities in other countries. The process of obtaining FDA and other required regulatory approvals, including foreign approvals, is expensive and often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. In addition, regulatory agencies may lack experience with our technologies and products, which may lengthen the regulatory review process, increase our development costs and delay or prevent their commercialization.

No adoptive cell therapy using tumor infiltrating lymphocytes has been approved for marketing in the U.S. by the U.S. Food and Drug Administration (FDA). Consequently, there is no precedent for the successful commercialization of products based on our technologies. In addition, we have had only limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain timely FDA approvals, if at all. We have not yet sought FDA approval for any adoptive cell therapy product. We will not be able to commercialize any of our potential products until we obtain FDA approval, and so any delay in obtaining, or inability to obtain, FDA approval would harm our business.

If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be fined, forced to remove a product from the market and experience other adverse consequences including delay, which could materially harm our financial results. Additionally, we may not be able to obtain the labeling claims necessary or desirable for the promotion of our products. We may also be required to undertake post-marketing trials. In addition, if we or others identify side effects after any of our adoptive cell therapies are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our products may be required.

It may take longer and cost more to complete our clinical trials than we project, or we may not be able to complete them at all.

For budgeting and planning purposes, we have projected the date for the commencement, continuation and completion of our various clinical trials. However, a number of factors, including scheduling conflicts with participating clinicians and clinical institutions, and difficulties in identifying and enrolling patients who meet trial eligibility criteria, may cause significant delays. We may not commence or complete clinical trials involving any of our products as projected or may not conduct them successfully.

Our goal is to initiate our own company-sponsored, Phase 2 clinical trial to establish the feasibility of our lead product, LN-144, and to assess its overall safety in patients with metastatic melanoma by mid-2015. However, we have not enrolled any patients yet, and we cannot guarantee that the trial will commence as scheduled. In addition, we currently also plan to initiate a Phase 3 clinical trial in 2016 in second line metastatic melanoma (those refractory to existing treatments) patients. However, because we have not yet obtained the FDA's approval for our proposed Phase 3 trial, the timing and scope of that Phase 3 trial are still uncertain (including uncertainties as to whether it will be a pivotal trial, how many patients we will have to treat, and what kind of patients those will be). Depending on the FDA's requirements, the Phase 3 trial could differ substantially from our plans and could cost more, and take longer than we anticipate.

We expect to rely on medical institutions, academic institutions or clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our products. We will have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. If we fail to commence or complete, or experience delays in, any of our planned clinical trials, our stock price and our ability to conduct our business as currently planned could be harmed.

We currently anticipate that we will have to rely on our manufacturing partner, Lonza Walkersville, Inc., to manufacture our adoptive cell therapy products for clinical trials. If Lonza fails to commence or complete, or experiences delays in, manufacturing our adoptive cell therapy products, our planned clinical trials will be delayed, which will adversely affect our stock price and our ability to conduct our business as currently planned.

We may not be able to license new TIL technology from the NIH as we plan to do.

An important element of our intellectual property portfolio is to license additional rights and technologies from the NIH. Our inability to be able to license the rights and technologies that we currently have identified, or that we may in the future identify, could have a material adverse impact on our ability to complete the development of our current products or to develop additional products. We are currently in discussions with the NIH to obtain a license from the NIH for NIH patents and other TIL-related intellectual properties and for other cancer indications. No assurance can be given that we will be successful in licensing these rights or technologies from the NIH. Failure to obtain these additional rights and licenses would detrimentally affect our planned development of additional product candidates and could increase the cost, and extend the timelines associated with our development of such other products.

We will be unable to commercialize our products if our trials are not successful.

Our research and development programs are at an early stage. We must demonstrate our products' safety and efficacy in humans through extensive clinical testing. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of our products, including but not limited to the following:

- safety and efficacy results in various human clinical trials reported in scientific and medical literature may not be indicative of results we obtain in our clinical trials;
- after reviewing test results, we or our collaborators may abandon projects that we might previously have believed to be promising;
- we, our collaborators or regulators, may suspend or terminate clinical trials if the participating subjects or patients are being exposed to unacceptable health risks; and
- the effects our potential products have may not be the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

Clinical testing is very expensive, can take many years, and the outcome is uncertain. It can take as much as 24 months or more before we learn the results from any clinical trial using our adoptive cell therapy with TIL. The data collected from our clinical trials may not be sufficient to support approval by the FDA of our TIL-based product candidates for the treatment of solid tumors. The clinical trials for our products under development may not be completed on schedule and the FDA may not ultimately approve any of our product candidates for commercial sale. If we fail to adequately demonstrate the safety and efficacy of any product candidate under development, we may not receive regulatory approval for those products, which would prevent us from generating revenues or achieving profitability.

We are required to pay substantial royalties under our license agreements with the NIH, and we must meet certain milestones to maintain our license rights.

Under our license agreements with the NIH for our adoptive cell therapy technologies, we are currently required to pay substantial royalties to that institution based on our revenues from sales of our products utilizing the licensed technologies, and these royalty payments could adversely affect the overall profitability for us of any products that we may seek to commercialize. In order to maintain our license rights under the NIH license agreements, we will need to meet certain specified milestones, subject to certain cure provisions, in the development of our product candidates. There is no assurance that we will be successful in meeting all of the milestones in the future on a timely basis or at all.

Because LN-144 represents, and our other potential product candidates will represent novel approaches to the treatment of disease, there are many uncertainties regarding the development, the market acceptance, third-party reimbursement coverage and the commercial potential of our product candidates.

There is no assurance that the approaches offered by LN-144 or our other potential product candidates will gain broad acceptance among doctors or patients or that governmental agencies or third-party medical insurers will be willing to provide reimbursement coverage for proposed product candidates. Moreover, we do not have verifiable internal marketing data regarding the potential size of the commercial market for our product candidates, nor have we obtained independent marketing surveys to verify the potential size of the commercial markets for our current product candidates or any future product candidates. Since our current product candidates and any future product candidates will represent new approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these product candidates. Accordingly, we may spend large amounts of money trying to obtain approval for product candidates that have an uncertain commercial market. The market for any products that we successfully develop will also depend on the cost of the product. We do not yet have sufficient information to reliably estimate what it will cost to commercially manufacture our current product candidates, and the actual cost to manufacture these products could materially and adversely affect the commercial viability of these products. If we do not successfully develop and commercialize products based upon our approach, we will not become profitable, which would materially and adversely affect the value of our common stock.

No assurance can be given that we will be able to develop a new, more efficient manufacturing process upon which our business plan to commercialize TIL-based products is dependent.

Pursuant to the CRADA, and in cooperation with Lonza Walkersville and potentially other manufacturers, we are trying to develop improved methods for the generating and selecting autologous TILs, and to develop methods for large-scale production of autologous TILs that are in accord with current Good Manufacturing Practices ("cGMP") procedures. Developing a new, scaled-up, pharmaceutical manufacturing process that can more efficiently, and in a more automated manner measure, produce and control the physical and/or chemical attributes of our products in a cGMP facility is subject to many uncertainties and difficulties. We have never manufactured our adoptive cell therapy product candidate on any scale, commercial or otherwise, nor has Lonza Walkersville, Inc., our main manufacturing provider. As a result, we cannot give any assurance that we will be able to establish a manufacturing process that can produce our products at a cost or in quantities necessary to make them commercially viable. Moreover, our third-party manufacturers will have to continually adhere to current cGMP regulations enforced by the FDA through its facilities inspection program. If the facilities of these manufacturers cannot pass a pre-approval plant inspection, the FDA premarket approval of our products will not be granted. In complying with cGMP and foreign regulatory requirements, we and any of our third-party manufacturers will be obligated to expend time, money and effort in production, record-keeping and quality control to assure that our products meet applicable specifications and other requirements. If we or any of our third-party manufacturers fail to comply with these requirements, we may be subject to regulatory action. No assurance can be given that we will be able to develop such a manufacturing process, or that our partners will thereafter be able to establish and operate such a production facility.

We cannot prevent other companies from licensing most of the same intellectual properties that we have licensed or from otherwise duplicating our business model and operations.

The intellectual properties that we are using to develop TIL-based cancer therapy products were licensed to us by the NIH. However, only a few of the issued or pending patents that the NIH licensed to us are exclusive, and those are exclusive only with respect to melanoma. Otherwise, the License Agreement is non-exclusive, and any other party could obtain a license for some or all of the non-exclusive licensed intellectual properties that we currently use. No assurance can be given that the NIH has not previously licensed, or that the NIH hereafter will not license to other biotechnology companies some or all of the non-exclusive technologies available to us under the NIH License Agreement. In addition, a certain pending U.S. patent application in the NIH License Agreement is not owned solely by the NIH. No assurance can be given that NIH's co-owner of the certain pending U.S. patent application in the License Agreement has not previously licensed, or that the co-owner thereafter will not license, to other biotechnology companies some or all of the technologies available to us. Co-ownership of these intellectual properties will create issues with respect to our ability to enforce the intellectual property rights in courts, and will create issues with respect to the accountability of one entity with respect to the other.

Since the NCI, MD Anderson Cancer Center, and the H. Lee Moffitt Cancer & Research Institute and others already use the ACT technology in therapy for the treatment of Stage IV metastatic melanoma, their methods and data are also available to third parties, who may want to enter into our line of business and compete against us. We currently do not own any exclusive rights that could be used to prevent third parties from duplicating our business plan or from otherwise directly competing against us. While additional technologies that may be developed under our CRADA may be licensed to us on an exclusive basis, no assurance can be given that our existing exclusive rights and these new rights will be sufficient to prevent others from duplicating our business plan or from providing substantially similar products.

If we are unable to protect our proprietary rights, we may not be able to compete effectively or operate profitably.

Our success is dependent in part on maintaining and enforcing the patents and other proprietary rights that we have licensed and may develop, and on our ability to avoid infringing the proprietary rights of others. All of our intellectual property rights are licensed from another entity, and as such the preparation and prosecution of these patents and patent applications was not performed by us or under our control. Furthermore, patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and, consequently, patent positions in our industry may not be as strong as in other more well-established fields. The patent positions of biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date.

For example, there have been significant changes in U.S. patent laws, as well significant changes in interpretation of U.S. patent law. These changes may materially affect our patents, as well as the ability of our Licensors or us to obtain patents. Changes in patent laws, as well as in the interpretation patent law in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims in our intellectual property that may be allowed or enforceable. In addition, the U.S. Supreme Court has recently issued opinions that greatly impact the law regarding patent eligible subject matter. As a consequence, one or all claims of issued patents in our intellectual property may be deemed invalid during litigation or in a proceeding before the United States Patent and Trademark Office, and pending applications in our intellectual property may be deemed unpatentable, due to the application of this new law. Accordingly, the United States Patent and Trademark Office may not issue patents from the patent applications licensed to us. If issued, the patents may not give us an advantage over competitors with similar technology.

The issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be given to the patents we have licensed from the NIH or from Moffitt if either the NIH, Moffitt or we attempt to enforce the patents and/or if they are challenged in court or in other proceedings, such as oppositions, which may be brought in foreign jurisdictions to challenge the validity of a patent. A third party may challenge the validity or enforceability of a patent after its issuance by the Patent Office. It is possible that a competitor may successfully challenge our patents or that a challenge will result in limiting their coverage. Moreover, the cost of litigation to uphold the validity of patents and to prevent infringement can be substantial. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to us. Moreover, it is possible that competitors may infringe our patents or successfully avoid them through design innovation. To stop these activities we may need to file a lawsuit. These lawsuits are expensive and would consume time and other resources, even if we were successful in stopping the violation of our patent rights. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of our patents were upheld, a court would refuse to stop the other party on the ground that its activities are not covered by, that is, do not infringe, our patents.

Should third parties file patent applications, or be issued patents claiming technology also used or claimed by our licensor(s) or by us in any future patent application, we may be required to participate in interference proceedings in the United States Patent and Trademark Office to determine priority of invention for those patents or patent applications that are subject to the first-to-invent law in the United States, or may be required to participate in derivation proceedings in the United States Patent and Trademark Office for those patents or patent applications that are subject to the first-inventor-to-file law in the United States. We may be required to participate in such interference or derivation proceedings involving our issued patents and pending applications. We may be required to cease using the technology or to license rights from prevailing third parties as a result of an unfavorable outcome in an interference proceeding or derivation proceeding. A prevailing party in that case may not offer us a license on commercially acceptable terms.

We face significant competition from other biotechnology and pharmaceutical companies and from non-profit institutions.

Competition in the field of cancer therapy is intense and is accentuated by the rapid pace of technological development. Research and discoveries by others may result in breakthroughs which may render our products obsolete even before they generate any revenue. There are products currently under development by others that could compete with the products that we are developing. Many of our potential competitors have substantially greater research and development capabilities and manufacturing, marketing, financial and managerial resources than we do. Our competitors may:

- develop safer or more effective immunotherapeutics and other therapeutic products;
- reach the market more rapidly, reducing the potential sales of our products; or
- establish superior proprietary positions.

Potential competitors in the market for treating metastatic melanoma will be companies such as Bristol-Myers Squibb, Roche/Genentech, Merck, Amgen, Pfizer, and GlaxoSmithKline, which already have products on the market or in development. Other companies, such as Novartis, Celgene, Kite Pharmaceuticals, Juno Therapeutics, and Adaptimmune, which are focused on genetically T cell technologies to treat cancer, may also be competitors. All of these companies, and most of our other current and potential competitors have substantially greater research and development capabilities and financial, scientific, regulatory, manufacturing, marketing, sales, human resources, and experience than we do. Many of our competitors have several therapeutic products that have already been developed, approved and successfully commercialized, or are in the process of obtaining regulatory approval for their therapeutic products in the United States and internationally.

Universities and public and private research institutions in the U.S. and Europe are also potential competitors. For example, a Phase 3 study comparing TIL to standard ipilimumab in patients with metastatic melanoma is currently being conducted in Europe by the Netherlands Cancer Institute, the Copenhagen County Herlev University Hospital, and the University of Manchester. While these universities and public and private research institutions primarily have educational objectives, they may develop proprietary technologies that lead to other FDA approved therapies or that secure patent protection that we may need for the development of our technologies and products.

We will be dependent on third party vendors to design, build, maintain and support our manufacturing and cell processing facilities and our information technology infrastructure and systems.

As a result of our strategy to out-source most of our research and development and all of our manufacturing, we rely very heavily on third parties to perform for us, or assist us with a variety of important functions, including research and development, manufacturing and clinical trials management. We also license all of our technology from others and, at this time, do not own any intellectual properties or technologies. We intend to rely upon Lonza Walkersville, Inc. or other third party contract manufacturers to produce large quantities of materials needed for clinical trials and product commercialization. Third party manufacturers may not be able to meet our needs with respect to timing, quantity or quality. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical testing may be delayed, thereby delaying the submission of products for regulatory approval or the market introduction and subsequent sales of our products. Any such delay may lower our revenues and potential profitability.

We intend to rely heavily on third party vendors to design, build, maintain and support our information technology infrastructure and systems, and supply us with data center and bandwidth services. Any inability to design or delay in implementing such information technology infrastructure and systems that are compliant with 21 CFR §11, the FDA's guidelines on electronic records, and other regulations, or a disruption in network access or other services provided by these third party vendors, could significantly harm our business. Any financial or other difficulties our third-party vendors face may have negative effects on our business, the nature and extent of which we cannot predict. We will exercise little control over these third party vendors, which increases our vulnerability to any problems associated with the services they provide. We will need to license technology, software, and databases from third parties to facilitate certain aspects of the development of our information technology infrastructure and systems. Any errors, failures, interruptions or delays experienced in connection with these third party technologies and information services could negatively impact our business and could expose us to liabilities to third parties.

If any third party collaborator breaches or terminates its agreement with us, or fails to conduct its activities in a timely manner, the commercialization of our products under development could be slowed down or blocked completely. It is possible that our collaborators will change their strategic focus, pursue alternative technologies or develop alternative products, either on their own or in collaboration with others, as a means for developing treatments for the diseases targeted by our collaborative programs. The effectiveness of our collaborators in marketing our products will also affect our revenues and earnings.

We intend to continue to enter into additional third party collaborative agreements in the future. However, we may not be able to successfully negotiate any additional collaborative arrangements. If established, these relationships may not be scientifically or commercially successful.

The use of our technologies could potentially conflict with the rights of others.

Our potential competitors or others may have or acquire patent rights that they could enforce against us. If they do so, then we may be required to alter our products, pay licensing fees or cease activities. If our products conflict with patent rights of others, third parties could bring legal actions against us or our collaborators, licensees, suppliers or customers, claiming damages and seeking to enjoin manufacturing and marketing of the affected products. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected products. We may not prevail in any legal action and a required license under the patent may not be available on acceptable terms or at all.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial. Some of our competitors may be better able to sustain the costs of complex patent litigation because they have substantially greater resources. If there is litigation against us, we may not be able to continue our operations.

Should third parties file patent applications, or be issued patents claiming technology also used or claimed by us, we may be required to participate in interference proceedings in the United States Patent and Trademark Office to determine priority of invention. We may be required to participate in interference proceedings involving our issued patents and pending applications. We may be required to cease using the technology or to license rights from prevailing third parties as a result of an unfavorable outcome in an interference proceeding. A prevailing party in that case may not offer us a license on commercially acceptable terms.

We are exposed to potential product liability claims, and insurance against these claims may not be available to us at a reasonable rate in the future.

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We do not have clinical trial insurance coverage, but we intend to obtain such liability coverage in the future. However, such insurance coverage may not be available to us at an acceptable cost, if at all. We may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. Regardless of merit or eventual outcome, liability claims may result in decreased demand for a product, injury to our reputation, withdrawal of clinical trial volunteers and loss of revenues. Thus, whether or not we are insured, a liability claim or product recall may result in losses that could be material.

We have received a subpoena in the SEC investigation now known as "In the Matter of Certain Stock Promotions," the consequences of which are unknown.

As disclosed in Item 3. Litigation, below, on April 23, 2014 we received a subpoena from the SEC that stated that the staff of the SEC is conducting an investigation now known as *"In the Matter of Certain Stock Promotions*," and that the subpoena was issued as part of the foregoing investigation. The SEC's subpoena and accompanying letter did not indicate whether we are, or are not, under investigation. We have cooperated with the SEC and have completed our production of documents in response to the subpoena. To date, the SEC has not requested any further action from us. Nevertheless, the SEC may in the future require us to produce additional documents or other materials.

In general, the subpoena required us to give the SEC certain documents regarding, and communications between anyone at this company and certain listed persons and entities (which include investor-relations firms and persons associated with the investor-relations firms), and articles regarding this company posted on certain equity research or other financial websites. Although the SEC has not publicly disclosed the goals and targets of its investigation, we believe that the SEC is investigating improper conduct by investor relations firms relative to the payment of bloggers and other authors for promotional articles written about public companies. A number of articles have been written about us that may be available on the internet and elsewhere. Investors considering an investment in our securities should review this Annual Report and the other documents that we filed with the SEC rather than relying on internet blogs or other similar articles and publications.

We are unaware of the scope or timing of the SEC's investigation. As a result, we do not know how the SEC investigation is proceeding, when the investigation will be concluded, or if we will become involved to a greater extent than merely responding to the April 2014 subpoena. If we receive additional subpoenas or other requests for documents from the SEC, complying with any such future requests could distract the time and attention of our officers and directors or divert our resources away from ongoing research and development programs. Furthermore, it is possible that we currently are, or may hereafter become a target of the SEC's investigation. Any such investigation could result in significant legal expenses, the diversion of management's attention from our business, damage to our business and reputation, and could subject us to a wide range of remedies, including an SEC enforcement action.

Risks Related to Our Securities

Our stock may be traded in low volumes, so you may be unable to sell your shares at or near the quoted bid prices if you need to sell your shares.

As a small company, the shares of our common stock may trade infrequently and in low volumes, meaning that the number of persons interested in purchasing our common shares at or near bid prices at any given time may be relatively small. This situation may be attributable to a number of factors, including the fact that we are a small early stage company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community who can generate or influence sales volume. As a consequence, there may be periods when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give you any assurance that a broader or more active public trading market for our common shares will develop or be sustained. Due to these conditions, we can give you no assurance that you will be able to sell your shares at or near bid prices if you need money or otherwise desire to liquidate your shares. As a result, investors could lose all or part of their investment.

Our existing directors and executive officers hold a substantial amount of our common stock and may be able to prevent other stockholders from influencing significant corporate decisions.

As of December 31, 2014, our officers and directors beneficially owned over 27% of our outstanding common stock. These stockholders, if they act together, may be able to direct, or materially affect the outcome of matters presented to our stockholders, including the election of our directors and other corporate actions such as:

- our merger with or into another company;
- a sale of substantially all of our assets; and
- amendments to our articles of incorporation.

The decisions of these stockholders may conflict with our interests or those of our other stockholders.

The market price of our stock may be adversely affected by market volatility.

The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;
- developments with respect to patents or proprietary rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed such estimates;
- conditions and trends in the pharmaceutical and other industries;
- general economic, political and market conditions and other factors; and
- the occurrence of any of the risks described in this Annual Report.

You may experience future dilution as a result of future equity offerings or other equity issuances.

We will have to raise additional capital in the future. To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock.

Future sales of our common stock may depress our stock price.

As of March 12, 2015, we had over 44 million shares of our common stock outstanding. However, we have registered 13,931,426 additional shares of our common stock that could be issued under outstanding common stock purchase warrants and under outstanding shares of convertible preferred stock. If a significant number of the registered shares underlying the warrants or shares of convertible preferred stock are issued and sold on the market, the prevailing trading price could be adversely affected. In addition, we may currently expect to file a registration statement to register the future public resale of up to 9,602,743 shares of our common stock held by Ayer Capital Management LP and Bristol Investment Fund Ltd., two of our larger shareholders. In connection with the Public Offering, Ayer Capital Management LP and Bristol Investment Fund Ltd. agreed not to sell any of their shares until May 3, 2015. The sudden release of any of these additional freely trading shares onto the market, or the perception that such shares will or could come onto the market, could have an adverse effect on the trading price of our stock. In addition to the shares that are, or may be registered for re-sale, an additional 3,819,801 shares of restricted stock are currently eligible for public resale under Rule 144. The sale of these Rule 144 shares may also adversely affect prevailing market prices for our common stock.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results. As a result, we could become subject to sanctions or investigations by regulatory authorities and/or stockholder litigation, which could harm our business and have an adverse effect on our stock price.

As a public reporting company, we are subject to various regulatory requirements, including the Sarbanes-Oxley Act of 2002, which requires our management to assess and report on our internal controls over financial reporting. As a small company with few employees, we have not had sufficient personnel to properly conduct all of internal control procedures and activities that require segregation of powers and responsibilities. As a result, as of December 31, 2014, we did not maintain effective internal control over our financial reporting systems. While we are attempting to remedy this material weakness, we may not be able to fully comply with the internal control requirements of the Sarbanes-Oxley Act of 2002, and future material weaknesses in our internal controls may arise. Material weaknesses in our internal controls could result in a loss of investor confidence in our financial reports, have an adverse effect on our stock price, and subject us to sanctions or investigation by regulatory authorities or stockholder litigation.

Our board could issue "blank check" preferred stock without stockholder approval with the effect of diluting existing stockholders and impairing their voting rights.

Our articles of incorporation authorize the issuance of up to 50,000,000 shares of "blank check" preferred stock (of which only 17,000 have been designated as the Series A Convertible Preferred Stock) with designations, rights and preferences as may be determined from time to time by our board of directors. Our board is empowered, without stockholder approval, to issue one or more series of preferred stock with dividend, liquidation, conversion, voting or other rights which could dilute the interest of, or impair the voting power of, our common stockholders. The issuance of a series of preferred stock could be used as a method of discouraging, delaying or preventing a change in control. For example, it would be possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change in control of our company.

We do not anticipate paying cash dividends for the foreseeable future, and therefore investors should not buy our stock if they wish to receive cash dividends.

We have never declared or paid any cash dividends or distributions on our common stock. We currently intend to retain our future earnings to support operations and to finance expansion and, therefore, we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of August 1, 2013, our new corporate offices are located at 21900 Burbank Blvd, Third Floor, Woodland Hills, California 91367. We currently lease these offices under a six-month lease for a monthly rental of $3,400.

In July 2014, we entered into a five -year lease with the University of South Florida Research Foundation for an approximately 5,100 square foot facility located at 3802 Spectrum Boulevard Tampa, Florida 33612. The new facility is part of the University of South Florida research park and is used as our research and development facilities. Our monthly base rent for this facility is $10,443 for the first year, which amount will increase by 3% annually. We have the option to extend the lease term of this facility for an additional five year period on the same terms and conditions, except that the base rent for the renewal term will be increased in accordance with the applicable consumer price index.

We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

SEC *Subpoena*

On April 23, 2014, we received a subpoena from the SEC that stated that the staff of the SEC is conducting an investigation *In the Matter of Galena Biopharma, Inc. File No. HO 12356* (*now known as* "*In the Matter of Certain Stock Promotions*") and that the subpoena was issued to us as part of the foregoing investigation. The SEC's subpoena and accompanying letter do not indicate whether we are, or are not, under investigation. We have fully cooperated with the SEC and as of November 2014, we had completed our production of documents in response to the subpoena. To date, the SEC has not requested any further action from the Company.

The subpoena required us to give the SEC, among other materials, all communications between anyone at our company and certain persons and entities (which include investor-relations firms and persons associated with the investor-relations firms), all documents related to the listed persons and entities, all articles regarding us posted on certain equity research or other financial websites, and documents and communications related to individuals who post or have posted articles regarding us on equity research or other financial websites.

Other

Other than the foregoing SEC subpoena, there are no other pending legal proceedings to which we are a party or of which our property is the subject. However, from time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not Applicable.

PART II

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

On February 26, 2015, our common stock was listed for trading on the Nasdaq Global Market under the symbol "LBIO". From October 23, 2013 until February 26, 2015, our common stock was quoted on the OTC QB market of the OTC Markets. Prior to October 23, 2013, our common stock was quoted on the OTC Pink Limited market and on the OTC Bulletin Board.

The following table shows the high and low prices of our common shares on the OTC QB market of the OTC Markets, the OTC Pink Limited market and the OTC Bulletin Board. The following quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions. *The prices in the following table have been adjusted to reflect a 1-for-100 reverse stock split that we effected on September 26, 2013.*

Fiscal Year Ended December 31, 2013	**High**	**Low**
First Quarter	$ 20.00	$ 3.00
Second Quarter	$ 7.00	$ 1.00
Third Quarter	$ 16.00	$ 1.65
Fourth Quarter	$ 18.00	$ 3.41

Fiscal Year Ended December 31, 2014	**High**	**Low**
First Quarter	$ 10.00	$ 4.75
Second Quarter	$ 11.25	$ 5.50
Third Quarter	$ 8.50	$ 6.07
Fourth Quarter	$ 8.40	$ 4.97

Stockholders

As of December 31, 2014, there were approximately 123 holders of record of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of individual stockholders represented by these holders of record. In addition, we had 3 holders of record who owned shares of our Series A Convertible Preferred Stock. The transfer agent for our Common Stock is Corporate Stock Transfer, Inc., located at 3200 Cherry Creek South Drive, Suite 430, Denver, Colorado 80209.

Dividends

We have not paid any dividends on our Common Stock to date and do not anticipate that we will pay dividends in the foreseeable future. Any payment of cash dividends on our Common Stock in the future will be dependent upon the amount of funds legally available, our earnings, if any, our financial condition, our anticipated capital requirements and other factors that the Board of Directors may think are relevant. However, we currently intend for the foreseeable future to follow a policy of retaining all of our earnings, if any, to finance the development and expansion of our business and, therefore, do not expect to pay any dividends on our Common Stock in the foreseeable future.

Under the terms of the Series A Convertible Preferred Stock, we may not declare, pay or set aside any dividends on shares of any class or series of capital stock (other than dividends on shares of common stock payable in shares of common stock) unless the holders of the Series A Convertible Preferred Stock first receive, or simultaneously receive, an equal dividend on each outstanding share of Series A Convertible Preferred Stock.

Equity Compensation Plan Information

See Part III, Item 12, “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters,” of this Annual Report for information regarding securities authorized for issuance under our equity compensation plans, which information is incorporated herein by reference.

Recent Sales of Unregistered Securities

During the fiscal quarter ended December 31, 2014, four accredited investors who held warrants that we sold to them in the November 2013 Private Placement, exercised warrants to purchase 88,000 shares of common stock at an exercise price of $2.50 per share ($220,000 in the aggregate). These shares were issued pursuant to an exemption available under Section 4(2) of the Securities Act of 1933, as amended. No commissions were paid with respect to these warrants exercises.

During the fiscal quarter ended December 31, 2014, the Company granted 22,500 shares of restricted stock to 2 of its employees. These shares were issued pursuant to an exemption available under Section 4(2) of the Securities Act of 1933, as amended, and no commissions were paid with respect to these grants.

Repurchase of Shares

We did not repurchase any shares during the fourth quarter of the fiscal year covered by this report.

Item 6. Selected Financial Data

	Years Ended December 31,				
	2014	**2013**	**2012**	**2011**	**2010**
Net revenue	$ —	$ —	$ —	$ —	$ —
Operating expenses:					
Research and development	$ 2,704,597	$ 1,329,000	$ 1,656,000	$ 1,756,000	$—
Selling, general, and administrative [1]	9,335,772	4,655,000	6,476,000	19,303,000	815,413
Cost of Lion transaction - related party	—	16,656,250	—	—	—
Other income (loss)	5,660	(2,740,597)	4,824,927	(4,475,782)	—)
Net loss [1]	12,034,709	25,381,000	3,307,619	25,694,100	1,607,988)
Net loss per share	(0.48)	(3.47)	(0.04)	(0.34)	(0.02)

	As of December 31,				
	2014	**2013**	**2012**	**2011**	**2010**
Total assets	$ 46,506,847	$ 19,873,649	$ 29,413	$ 568,430	$ 1,460,952
Total debt	1,661,760	2,269,932	11,348,889	13,349,348	822,867
Derivative liabilities	—	—	—	7,937,793	792,575
Total stockholders' equity	44,845,087	17,603,717	(11,319,476)	(12,780,918)	638,085

See "Management's Discussion and Analysis of Financial Condition and Results of Operations" below, and the consolidated financial statements and accompanying notes and previously filed Annual Reports on Form 10-K for further information regarding our consolidated results and financial position for periods reported herein and for known factors that will impact comparability of future results.

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

The following discussion and analysis of our results of operations and financial condition should be read in conjunction with our financial statements and the notes to those financial statements that are included elsewhere in this report. Our discussion includes forward-looking statements based upon current expectations that involve risks and uncertainties, such as our plans, objectives, expectations and intentions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of a number of factors, including those set forth under the "Business" section and elsewhere in this report. We use words such as "anticipate," "estimate," "plan," "project," "continuing," "ongoing," "expect," "believe," "intend," "may," "will," "should," "could," and similar expressions to identify forward-looking statements. All forward-looking statements included in this report are based on information available to us on the date hereof and, except as required by law, we assume no obligation to update any such forward-looking statements.

Background on the Company and Recent Events Affecting our Financial Condition and Operations

On October 5, 2011 we licensed certain rights to the adoptive cell therapy from the NIH and to a manufacturing process for a TIL-based therapy (initially for Stage IV metastatic melanoma). In order to develop the adoptive cell immunotherapies we licensed from the NIH, effective August 5, 2011, we signed a Cooperative Research and Development Agreement ("CRADA") with the NIH and the NCI. Since the initial NIH license, we have amended the initial license and entered into an additional license for additional technologies. In addition, we have amended the CRADA to increase the scope of the research and development conducted thereunder. Under the terms of the CRADA, we now are required to provide $2,000,000 per year (in quarterly installments of $500,000) to support research activities thereunder.

Since we entered into the License Agreement, we have not made any sales that would have required us to make royalty payments to the NIH, nor were there any benchmarks or milestones achieved that would have required us to make lump sum benchmark royalty payments under the NIH license agreement.

In May 2013 we completed a restructuring of our unregistered debt and equity securities (the "Restructuring") and raised $1.25 million. Creditors holding (i) an aggregate of approximately $7.2 million (including accrued interest and penalties) of the senior secured notes, (ii) an aggregate of approximately $1.7 million (including accrued interest and penalties) of bridge promissory notes, and (iii) an aggregate of approximately $0.3 million of other outstanding debt converted these debts into shares of common stock at a conversion price of $1.00 per share. In connection with the Restructuring, we also sold a total of 3,605,069 shares of common stock for $1,250,000. The effect of the Restructuring and related stock sales and transactions was to extinguish all outstanding secured and unsecured promissory notes (representing liabilities of approximately $8,373,000 in the aggregate) and to raise a total of $1,350,000 of cash from the sale of the securities.

On July 24, 2013, we acquired Lion Biotechnologies, Inc., a privately owned Delaware corporation ("Lion Delaware"), through a merger with our newly formed Delaware subsidiary (the "Lion Merger"). In the Lion Merger, Lion Biotechnologies' stockholders received, in exchange for all of their issued and outstanding shares of common stock, an aggregate of 2,690,000 shares of our common stock with a fair value of $6,700,000 (of these shares, 1,340,000 were issued at the closing of the merger, and an additional 1,350,000 shares of common stock were issued later in 2013 upon the achievement of certain milestones related to our financial performance and position). The acquisition was done to acquire access to technical and managerial resources to build our current and future products, which we believed would enhance or future operations and enable us to obtain additional funding.

In November 2013, in order to fund our operating expenses, including our expected research and development expenses, we raised a total of $23.3 million in a private placement (the "Private Placement") from the sale of 3,145,300 shares of our common stock, 17,000 shares of a new series of preferred stock designated as "Series A Convertible Preferred Stock," and warrants to purchase an aggregate of 11,645,300 shares of common stock. The amount of net proceeds that is available to us from the Private Placement, after placement agent fees, legal fees and other expenses, approximately $21.8 million.

In late 2014 we established our own research and development laboratory at the University of South Florida Research Foundation in Tampa, Florida. We currently employ 9 researchers, scientists and other personnel at that facility.

On December 22, 2014, we sold 6,000,000 shares in an underwritten offering. The net proceeds of that offering, after deducting underwriting discounts and commissions and offering expenses payable by us, were $32.2 million.

On March 3, 2015, we sold 9,200,000 shares of our common stock in an underwritten public offering. The net proceeds to us from the offering were $68.2 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

Results of Operations for the Year Ended December 31, 2014 Compared to the Year Ended December 31, 2013

Revenues

As a development stage company that is currently engaged in the development of therapeutics to fight cancer, we have not yet generated any revenues from our biopharmaceutical business or otherwise since our formation. We currently do not anticipate that we will generate any revenues during 2014 from the sale or licensing of any products.

Costs and expenses

Operating Expenses. Operating expenses include compensation for our employees who are dedicated to research and development, general and administrative activities, legal fees, audit and tax fees, consultants and professional services, and general corporate expenses. Our operating expenses were $9,335,772 and $4,655,000 for the fiscal years ended December 31, 2014 ("fiscal 2014") and 2013 ("fiscal 2013"), respectively. Our operating expenses in fiscal 2014 increased compared to fiscal 2013 as we ramped up our operations, established a new laboratory in Tampa, Florida, and hired additional employees. During most of fiscal 2013 we were engaged in the Restructuring and in raising capital to fund our future operations. We raised $23.3 million in the Private Placement in November 2013, which funds we invested in 2014 in the expansion of our operations. Operating expenses also increased in fiscal 2014 because of a $1,046,000 increase in stock based compensation (stock based compensation was $3,796,000 and $2,750,000 in fiscal 2014 and 2013, respectively). Our operating expenses in fiscal 2014 also increased compared to fiscal 2013 due to increased legal fees related to patent and licensing issues and in connection with responding to the SEC's subpoena in the "*In the Matter of Certain Stock Promotions*" investigation being conducted by the SEC (see, "Item 3. Legal Proceedings", above). Since the Private Placement, we have engaged additional employees and consultants, which will also increase the amount of cash compensation we will pay in 2015 and thereafter.

Cost of Lion Transaction. In July 2013, we entered into an Agreement and Plan of Merger (the "Lion Agreement") with Lion Biotechnologies, Inc., a privately held Delaware corporation. Under the Lion Agreement, Lion Biotechnologies, Inc.'s stockholders received, in exchange for all of their issued and outstanding shares of common stock, an aggregate of 1,340,000 shares of our common stock with a fair value of $6,700,000. Under the Lion Agreement, we also were obligated to issue an additional 1,350,000 shares of common stock upon the achievement of certain milestones related to our financial performance and position). These other milestones were achieved in the fourth quarter of fiscal 2013 and, as a result, we issued all 1,350,000 shares (having a fair value of $9,956,250) in fiscal 2013. The value of the shares issued under the Lion Agreement was recognized and recorded as an expense in 2013. The purpose of the Lion Agreement was to acquire access to technical and managerial resources to build our current and future products, which we believed would enhance or future operations and enable us to obtain additional funding. The technical resources that we acquired included access to next generation T-cell technologies (including term sheets for such technologies), access to cancer vaccine technologies that Lion Biotechnologies, Inc. was evaluating at Harvard University, NIH, Baylor University and other institutions, and other proprietary technologies and ideas on novel T-cell manufacturing technologies that that company was designing.

Research and Development. Research and development costs were $2,704,597 in fiscal 2014 compared to $1,329,367 for the year ended December 31, 2013. Research and development expenses in both fiscal 2014 and fiscal 2013 included $1,000,000 paid and accrued under the CRADA with the NIH and fees paid to the NIH under the NIH License Agreement. In fiscal 2014 we expanded our research and development activities by engaging Lonza to commence setting up a centralized TIL manufacturing center, through a clinical trial grant agreement with Moffitt Cancer Center to expand an ongoing Phase 1 study of TIL combined with ipilimumab in patients with metastatic melanoma, and through our own research and development activities conducted at our Tampa laboratory. We intend to engage in significant research and development activities in the future, which activities are expected to substantially increase our annual research and development expenses.

Other income (expense)

Interest (expense) income. Interest income represents the income on the funds held during fiscal 2014 in our various bank accounts. Most of the funds we held in fiscal 2014 were the net proceeds from the November 2013 Private Placement. Interest expense of $444,000 in fiscal 2013 represents the amount of interest that accrued in fiscal 2013 on the various promissory notes we issued to fund our operations, including the $5,000,000 of 7% Tranche A Senior Unsecured Convertible Notes and Tranche B Senior Unsecured Convertible Notes we issued in 2011 and the $1,231,000 of 12% secured promissory notes we issued in 2012. As described above, in May 2013 we effected the Restructuring, in which substantially all of our then outstanding indebtedness was converted into shares of our common stock. Because we converted all of our interest-bearing obligations in the 2013 Restructuring, we did not accrue any interest expense in fiscal 2014.

Cost of Exchange Transaction (Restructuring). In May 2013 we effected the Restructuring in which we converted outstanding indebtedness into shares of our common stock, exchanged outstanding warrants into additional shares of common stock, and issued shares of our common stock at discounted prices. We recorded a non-cash expense of $2,296,000 in fiscal 2013 as a result of the Restructuring. No such expenses were incurred in 2014.

Net Loss

We had a net loss of $12,040,369 and $25,381,000 in fiscal 2014 and fiscal 2013, respectively. Our net loss for fiscal 2014 decreased as compared to fiscal 2013 primarily as a result of non-cash cost of the transaction with Lion Biotechnologies, Inc., a Delaware corporation, under the Lion Agreement ($16,656,000). Excluding the effects of the expense realized due to the Lion Agreement transaction, our net loss in fiscal 2014 would have increased by $3,499,000 compared to fiscal 2013, primarily because of increased operating expenses and increased research and development expenses.

As a development stage company, we do not expect to generate any revenues during 2015, and we expect to continue to incur net losses.

Liquidity and Capital Resources

As a result of the $32,240,172 of net proceeds that we received on December 22, 2014 in the underwritten offering of 6,000,000 shares of our common stock, as of December 31, 2014 we had cash or cash equivalents of $44,909,000. As of December 31, 2014, we had $43,313,000 of working capital and a current ratio of 28 to 1. On March 3, 2015, we received an additional $68,238,500 of net proceeds from our public offering completed at that time.

During 2015, we expect to further ramp up our operations, which will increase the amount of cash we will use in our operations. Our budget for 2015 includes significantly increased spending for both the development of our LN-144 lead product candidate and on research and development for non-melanoma indications and other TIL enhancements. In addition, we anticipate that we will have higher payroll expenses as we increase our professional staff, as well as higher ongoing payments under the CRADA. Our budget anticipates that we will spend approximately 20 million this year, although that amount may change materially. Based on the funds we had available on December 31, 2014 and the additional net proceeds we received in the March 3, 2015 public offering, we believe that we have sufficient capital to fund our anticipated operating expenses for at least 24 months.

As of December 31, 2014, our long-term obligations consisted of $1,000,000 per year, which amount increased to $2,000,000 per year as a result of the January 2015 amendment to the CRADA, and the benchmark payments we are required to make to the NIH based on the development and commercial release of licensed products using the technology underlying the NIH License Agreement. If we achieve all benchmarks for metastatic melanoma, our current primary focus, up to the product's first commercial sale in the United States, the total amount of all such benchmark payments payable under the NIH License Agreement will be $9,490,000 for the melanoma indication. Other than the two foregoing contractual obligations to the NCI and the NIH, we had no long-term debt obligations, no capital lease obligations, no material purchase obligations or other similar long-term liabilities. In addition, we have no financial guarantees, debt or lease agreements or other arrangements that could trigger a requirement for an early payment or that could change the value of our assets, and we do not engage in trading activities involving non-exchange traded contracts.

Inflation and changing prices have had no effect on our continuing operations over our two most recent fiscal years.

Recent Accounting Pronouncements

On June 10, 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2014-10 (ASU 2014-10), Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation. ASU 2014-10 eliminates the requirement to present inception-to-date information about income statement line items, cash flows, and equity transactions, and clarifies how entities should disclose the risks and uncertainties related to their activities. ASU 2014-10 also eliminates an exception provided to development stage entities in Consolidations (ASC Topic 810) for determining whether an entity is a variable interest entity on the basis of the amount of investment equity that is at risk. The presentation and disclosure requirements in Topic 915 are no longer required for interim and annual reporting periods beginning after December 15, 2014. The revised consolidation standards will take effect in annual periods beginning after December 15, 2015, however, early adoption is permitted. The Company adopted the provisions of ASU 2014-10 starting with its quarterly report on Form 10-Q for the six months ended June 30, 2014.

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers. ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current U.S. GAAP and replace it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. The ASU also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for reporting periods beginning after December 15, 2016, and early adoption is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. Management is currently assessing the impact the adoption of ASU 2014-09 and has not determined the effect of the standard on our ongoing financial reporting.

In April 2014, the FASB issued Accounting Standards Update No. (ASU) 2014-08, Presentation of Financial Statements (Topic 205) and Property, Plant and Equipment (Topic 360). ASU 2014-08 amends the requirements for reporting discontinued operations and requires additional disclosures about discontinued operations. Under the new guidance, only disposals representing a strategic shift in operations or that have a major effect on the Company's operations and financial results should be presented as discontinued operations. This new accounting guidance is effective for annual periods beginning after December 15, 2014. The Company is currently evaluating the impact of adopting ASU 2014-08 on the Company's results of operations or financial condition.

In August 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, which provides guidance on determining when and how to disclose going-concern uncertainties in the financial statements. The new standard 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. An entity must provide certain disclosures if conditions or events raise substantial doubt about the entity's ability to continue as a going concern. The ASU applies to all entities and is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The Company is currently evaluating the impact the adoption of ASU 2014-15 on the Company's financial statement presentation and disclosures.

In November 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-16, Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity. The amendments in this ASU do not change the current criteria in U.S. GAAP for determining when separation of certain embedded derivative features in a hybrid financial instrument is required. The amendments clarify that an entity should consider all relevant terms and features, including the embedded derivative feature being evaluated for bifurcation, in evaluating the nature of the host contract. The ASU applies to all entities that are issuers of, or investors in, hybrid financial instruments that are issued in the form of a share and is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted. The Company is currently evaluating the impact the adoption of ASU 2014-16 on the Company's financial statement presentation and disclosures

In January 2015, the FASB issued Accounting Standards Update (ASU) No. 2015-01 (Subtopic 225-20) - Income Statement - Extraordinary and Unusual Items. ASU 2015-01 eliminates the concept of an extraordinary item from GAAP. As a result, an entity will no longer be required to segregate extraordinary items from the results of ordinary operations, to separately present an extraordinary item on its income statement, net of tax, after income from continuing operations or to disclose income taxes and earnings-per-share data applicable to an extraordinary item. However, ASU 2015-01 will still retain the presentation and disclosure guidance for items that are unusual in nature and occur infrequently. ASU 2015-01 is effective for periods beginning after December 15, 2015. The adoption of ASU 2015-01 is not expected to have a material effect on the Company's consolidated financial statements. Early adoption is permitted.

In February, 2015, the FASB issued Accounting Standards Update (ASU) No. 2015-02, Consolidation (Topic 810): Amendments to the Consolidation Analysis. ASU 2015-02 provides guidance on the consolidation evaluation for reporting organizations that are required to evaluate whether they should consolidate certain legal entities such as limited partnerships, limited liability corporations, and securitization structures (collateralized debt obligations, collateralized loan obligations, and mortgage-backed security transactions). ASU 2015-02 is effective for periods beginning after December 15, 2015. The adoption of ASU 2015-02 is not expected to have a material effect on the Company's consolidated financial statements. Early adoption is permitted.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission ("SEC") did not or are not believed by management to have a material impact on the Company's present or future financial statements.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements and accompanying notes, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. When making these estimates and assumptions, we consider our historical experience, our knowledge of economic and market factors and various other factors that we believe to be reasonable under the circumstances. Actual results may differ under different estimates and assumptions.

The accounting estimates and assumptions discussed in this section are those that we consider to be the most critical to an understanding of our financial statements because they inherently involve significant judgments and uncertainties.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from these estimates.

Stock-Based Compensation

We periodically issue stock options and warrants to employees and non-employees in non-capital raising transactions for services and for financing costs. We adopted FASB guidance effective January 1, 2006, and are using the modified prospective method in which compensation cost is recognized beginning with the effective date (a) for all share-based payments granted after the effective date and (b) for all awards granted to employees prior to the effective date that remain unvested on the effective date. We account for stock option and warrant grants issued and vesting to non-employees in accordance with accounting guidance whereby the fair value of the stock compensation is based on the measurement date as determined at either (a) the date at which a performance commitment is reached, or (b) the date at which the necessary performance to earn the equity instrument is complete.

We estimate the fair value of stock options using the Black-Scholes option-pricing model, which was developed for use in estimating the fair value of options that have no vesting restrictions and are fully transferable. This model requires the input of subjective assumptions, including the expected price volatility of the underlying stock and the expected life of stock options. Projected data related to the expected volatility of stock options is based on the historical volatility of the trading prices of our common stock and the expected life of stock options is based upon the average term and vesting schedules of the options. Changes in these subjective assumptions can materially affect the fair value of the estimate, and therefore the existing valuation models do not provide a precise measure of the fair value of our employee stock options.

Derivative Financial Instruments

We evaluate all of our financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For stock-based derivative financial instruments, we use both a weighted average Black-Scholes-Merton and Binomial option pricing models to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date.

Contractual Obligations

We acquire assets still in development and enter into research and development arrangements with third parties that often require milestone and royalty payments to the third party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required, contingent upon the successful achievement of an important point in the development life-cycle of the pharmaceutical product (e.g., approval of the product for marketing by a regulatory agency). If required by the arrangement, we may have to make royalty payments based upon a percentage of the sales of the pharmaceutical product in the event that regulatory approval for marketing is obtained. Because of the contingent nature of these milestone payments, they are not included in the table of contractual obligations.

These arrangements may be material individually, and in the event that milestones for multiple products covered by these arrangements were reached in the same period, the aggregate charge to expense could be material to the results of operations in any one period. In addition, these arrangements often give us the discretion to unilaterally terminate development of the product, which would allow us to avoid making the contingent payments.

Our current contractual obligations as of December 31, 2014 that will require future cash payments are as follows:

Contractual obligations	Payments due by period Total	Less than 1 year	1–3 years	3–5 years	More than 5 years
Long-Term Debt Obligations	-	-	-	-	-
Capital Lease Obligations	-	-	-	-	-
NIH obligations	$ 15,830,000	$ 410,000	$ 6,900,000	$ 1,010,000	$ 7,510,00
CRADA obligations	$ 12,000,000	$ 2,000,000	$ 6,000,000	$ 2,000,000	2,000,000
Other Long-Term Liabilities Reflected on the Registrant's Balance Sheet under GAAP	-	-	-	-	-
Total	$ 27,830,000	$ 2,410,000	$ 12,900,000	$ 3,010,000	$ 9,510,000

We acquire assets still in development and enter into research and development arrangements with third parties that often require milestone and royalty payments to the third party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required, contingent upon the successful achievement of an important point in the development life-cycle of the pharmaceutical product (e.g., approval of the product for marketing by a regulatory agency). If required by the arrangement, we may have to make royalty payments based upon a percentage of the sales of the pharmaceutical product in the event that regulatory approval for marketing is obtained. These milestone payments are included in the table of contractual obligations.

Off-Balance Sheet Arrangements

At December 31, 2014, we had no obligations that would require disclosure as off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because a significant portion of our investments are in short-term debt securities issued by the U.S. government and institutional money market funds. The primary objective of our investment activities is to preserve principal. Due to the nature of our marketable securities, we believe that we are not exposed to any material market risk. We do not have any derivative financial instruments or foreign currency instruments. If interest rates had varied by 10% in the year ended December 31, 2014, it would not have had a material effect on our results of operations or cash flows for that period.

Item 8. Financial Statements and Supplementary Data

Financial Statements are referred to in Item 15, listed in the Index to Financial Statements and filed and included elsewhere herein as a part of this Annual Report on Form 10-K, and are incorporated herein by this reference.

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

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Rule 13a-15(e) under the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), defines the term “disclosure controls and procedures” as those 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 recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms and that such information is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined under Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are not effective.

Management's report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external reporting purposes in accordance with GAAP.

The Company's internal control over financial reporting 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 our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized use, acquisition, or disposition of this company's assets that could have a material effect on the consolidated financial statements.

In making its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2014, management used the criteria established in the *Internal Control — Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Based on the criteria established by COSO, the following material weaknesses have been identified in management's assessment. Material weaknesses related to the Company having insufficient monitoring and review controls over the financial reporting closing process and an insufficient number of financial reporting personnel to ensure proper segregation of duties. These deficiencies were partially remediated at December 31, 2014, but these new controls were not effective for almost all of 2014. Accordingly, as a result of the foregoing weaknesses, our chief executive officer and chief financial officer concluded that, as of December 31, 2014, the Company did not maintain effective internal control over financial reporting based on COSO.

In light of the material weaknesses described above, additional analyses and other procedures were performed to ensure that our consolidated financial statements included in this Annual Report on Form 10-K were prepared in accordance with GAAP. These measures included expanded year-end closing procedures, the dedication of significant internal resources and external consultant to scrutinize account analyses and reconciliations and management's own internal reviews and efforts to remediate the material weaknesses in internal control over financial reporting described above. As a result of these measures, management concluded that the Company's consolidated financial statements included in this Annual Report on Form 10-K present fairly, in all material respects, the Company's financial position, results of operations and cash flows as of the dates, and for the periods, presented in conformity with GAAP.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

This company's registered public accounting firm has issued an adverse report on the effectiveness of our internal control over financial reporting. This report is included in the Reports of Independent Registered Public Accounting Firms in Item 15.

Planned Remediation of Material Weakness

As noted above, the Company did implement new controls at December 31, 2014, primarily in regards to its year-end General Ledger Close and Financial Reporting procedures, by adding additional personnel to these functions. By adding additional personnel in 2015, the Company will also be able to add additional controls over its cash expenditures. The Company plans to have these new controls become effective during 2015.

Changes in Internal Control Over Financial Reporting

Other than the identification of the material weakness described above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended December 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Certain information required by Part III is omitted from this Annual Report because we will file a definitive Proxy Statement for the Annual Meeting of Stockholders pursuant to Regulation 14A of the Securities Exchange Act of 1934 (the "Proxy Statement"), not later than 120 days after the end of the fiscal year covered by this Annual Report, and the applicable information included in the Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers, and Corporate Governance

Information required by this Item 10 will be presented in the Proxy Statement and is incorporated herein by reference. Certain Information regarding our executive officers is included above in Part I of this Form 10-K under the caption "Executive Officers" pursuant to Instruction 3 to Item 401(b) of Regulation S-K and General Instruction G(3) of Form 10-K.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference to the sections entitled "Executive Compensation" and "Directors' Compensation" in the Proxy Statement.

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

The information required by this Item is incorporated herein by reference to the sections entitled "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in the Proxy Statement.

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

The information required by this Item is incorporated herein by reference to the section entitled "Certain Relationships and Related Transactions" in the Proxy Statement.

Item 14. Principal Accountant's Fees and Services

Information required by this Item is incorporated herein by reference to the section of the Proxy Statement entitled "Principal Accountant Fees and Services."

PART IV

Item 15. Exhibits, Financial Statements Schedules

The Company's financial statements and related notes thereto are listed and included in this Annual Report beginning on page F-1. The following exhibits are filed with, or are incorporated by reference into, this Annual Report.

EXHIBIT INDEX

Exhibit	Description
2.1	Agreement and Plan of Merger between Freight Management Corp. (renamed Genesis Biopharma, Inc.) and Genesis Biopharma, Inc. dated March 15, 2010 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on March 19, 2010).
2.2	Asset Purchase Agreement among Freight Management Corp. (renamed Genesis Biopharma, Inc.), Genesis Biopharma, Inc., Hamilton Atlantic and the other signatories thereto dated March 15, 2010 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on March 19, 2010).
3.1	Articles of Incorporation filed with the Nevada Secretary of State on September 7, 2007 (incorporated herein by reference to the Registrant's Registration Statement on Form SB-2 filed with the Commission on January 29, 2008).
3.2	Articles of Merger filed with the Nevada Secretary of State on March 15, 2010 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on March 19, 2010).
3.3	Certificate of Change to Articles of Incorporation filed with the Nevada Secretary of State on March 15, 2010 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on March 19, 2010).
3.4	Bylaws (incorporated herein by reference to the Registrant's Registration Statement on Form SB-2 filed with the Commission on January 29, 2008).
3.5	Amendment to Bylaws (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on May 29, 2013).
4.1	Form of Series A Common Stock Purchase Warrant dated September 17, 2010 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on September 23, 2010).
4.2	Form of Series B Common Stock Purchase Warrant dated September 17, 2010 (incorporated herein by reference to the Registrant's Form 8-K/A filed with the Commission on July 2, 2010).
4.3	Form of Warrant for Consulting Services issued to Emmes Group (incorporated herein by reference to the Registrant's Form 10-K filed with the Commission on March 30, 2012).
4.4	Form of Class "C" Warrant (incorporated herein by referenced to the Registrant's Form 8-K filed with the Commission on April 22, 2011).
4.5	Form of Warrant dated July 15, 2011 issued to Bristol Capital, LLC and Theorem Group, LLC (incorporated herein by reference to the Registrant's Form 10-K filed with the Commission on March 30, 2012).
4.6	Form of seven (7%) percent senior convertible note effective July 27, 2011 as issued by Genesis Biopharma Inc. to selling stockholders (incorporated herein by referenced to the Registrant's Form 8-K filed with the Commission on July 29, 2011).
4.7	Form of seven (7%) percent senior convertible note effective July 27, 2011 as issued by Genesis Biopharma Inc. to selling stockholders (incorporated herein by referenced to the Registrant's Form 8-K filed with the Commission on July 29, 2011).
4.8	Form of Warrant as issued to selling stockholders effective July 27, 2011 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on July 29, 2011).
4.9	Form of Tranche B seven (7%) percent senior convertible note as issued by Genesis Biopharma Inc. to selling stockholders (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on July 29, 2011).
4.10	Form of Tranche B Warrant as issued by Genesis Biopharma Inc. to selling stockholders (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on July 29, 2011).
4.11	Form of Placement Agent Warrant as issued to Cannacord Genuity, Inc. and Cowen and Company, Inc. effective July 27, 2011 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on July 29, 2011).

Exhibit	Description
4.12	Amendment No. 1 to Tranche A Unsecured Convertible Notes and Tranche B Senior Unsecured Convertible Notes (incorporated herein by referenced to the Registrant's Form 8-K filed with the Commission on December 5, 2011).
4.13	Amendment No. 1 Tranche A Warrants to Purchase Common Stock and Tranche B Warrants to Purchase Common Stock (incorporated herein by referenced to the Registrant's Form 8-K filed with the Commission on December 5, 2011).
4.14	Amendment No. 2 to Tranche A Unsecured Convertible Notes and Tranche B Senior Unsecured Convertible Notes (incorporated herein by referenced to the Registrant's Form 8-K/A filed with the Commission on December 22, 2011).
4.15	Amendment No. 2 Tranche A Warrants to Purchase Common Stock and Tranche B Warrants to Purchase Common Stock (incorporated herein by referenced to the Registrant's Form 8-K/A filed with the Commission on December 22, 2011).
4.16	Amendment No. 3 to Tranche A Unsecured Convertible Notes and Tranche B Senior Unsecured Convertible Notes (incorporated herein by referenced to the Registrant's Form 8-K/A filed with the Commission on January 10, 2011).
4.17	Amendment No. 3 Tranche A Warrants to Purchase Common Stock and Tranche B Warrants to Purchase Common Stock (incorporated herein by reference to the Registrant's Form 10-K filed with the Commission on March 30, 2012).
4.18	Amendment No. 4 to Tranche A Unsecured Convertible Notes and Tranche B Senior Unsecured Convertible Notes (incorporated herein by reference to the Registrant's Form 10-K filed with the Commission on March 30, 2012).
4.19	Amendment No. 4 Tranche A Warrants to Purchase Common Stock and Tranche B Warrants to Purchase Common Stock (incorporated herein by referenced to the Registrant's Form 8-K/A filed with the Commission on March 6, 2011).
4.20	Amendment No. 5 to Tranche A Unsecured Convertible Notes and Tranche B Senior Unsecured Convertible Notes (incorporated herein by referenced to the Registrant's Form 8-K/A filed with the Commission on February 6, 2011).
4.21	Amendment No. 6 to Tranche A Unsecured Convertible Notes and Tranche B Senior Unsecured Convertible Notes (incorporated herein by referenced to the Registrant's Form 8-K/A filed with the Commission on March 6, 2011).
10.1	Genesis Biopharma, Inc. 2010 Equity Compensation Plan (incorporated herein by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 31, 2010).
10.2	Form of Stock Option Agreement for grants under the Genesis Biopharma Inc 2010 Equity Incentive Plan (incorporated herein by reference to the Registrant's Annual Report on Form 10-K filed with the Commission on March 31, 2010).
10.3	Genesis Biopharma, Inc. 2011 Equity Compensation Plan (incorporated herein by reference to Registrant's Form 8-K filed with the Commission on October 20, 2011)
10.4	Form of ISO Stock Option Agreement for grants under the Genesis Biopharma Inc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 of the Registrant's Form 8-K filed with the Commission on October 20, 2011).
10.5	Form of NQSO Stock Option Agreement for grants under the Genesis Biopharma Inc. 2011 Equity Incentive Plan (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on October 20, 2011).
10.6	Patent and Know How License between Cancer Research Technology Limited and Genesis Biopharma, Inc. (formerly Freight Management Corp.) dated March 15, 2010 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on March 19, 2010)
10.7	Form of Private Placement Subscription Agreement dated September 17, 2010 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on September 23, 2010).
10.8	Form of Private Placement Subscription Agreement dated October 22, 2010 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on October 28, 2010).
10.9	Form of Private Placement Subscription Agreement dated December 28, 2010 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on January 3, 2011).
10.10	Consulting Agreement, dated February 15, 2011, by and between Emmes Group and Genesis Biopharma, Inc., Amendment No. 1, dated ____, 2011, Amendment No. 2, dated February 12, 2012 (incorporated herein by reference to the Registrant's Form 10-K filed with the Commission on March 30, 2012).

Exhibit	Description
10.11	Consulting Agreement, dated February 12, 2012, between Theorem and Genesis Biopharma, Inc.
10.12	Form of Securities Purchase Agreement, dated April 17, 2011(incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on April 22, 2011).
10.13	Consulting Agreement dated July 15, 2011, between Theorem and Genesis Biopharma, Inc. (incorporated herein by reference to the Registrant's Form 10-K filed with the Commission on March 30, 2012).
10.14	Consulting Agreement dated July 15, 2011, between Bristol and Genesis Biopharma, Inc. Addendum No. 1, dated ____, 2011 (incorporated herein by reference to the Registrant's Form 10-K filed with the Commission on March 30, 2012).
10.15	Form of Securities Purchase Agreement effective July 27, 2011 between Genesis Biopharma, Inc. and selling stockholders (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on July 29, 2011).
10.16	Form of Escrow Agreement between Genesis Biopharma Inc. and the selling stockholders effective July 27, 2011 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on July 29, 2011).
10.17	Form of Registration Rights Agreement between Genesis Biopharma Inc. and the selling stockholders effective July 27, 2011 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on July 29, 2011).
10.18	Patent License Agreement between the Company and the National Institutes of Health effective October 5, 2011 (incorporated herein by reference to the Registrant's Form 8-K/A filed with the Commission on December 13, 2011).*
10.19	Cooperative Research and Development Agreement for Intramural-PHS Clinical Research, dated August 5, 2011, between the U.S. Department of Health and Human Services, as represented by the National Cancer Institute and the Company. (incorporated herein by reference to the Registrant's Form 8-K/A (No.2) filed with the Commission on November 29, 2011).
10.20	Employment Agreement dated as of May 1, 2011 between the Company and Anthony J. Cataldo (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on October 20, 2011).
10.21	Employment Agreement dated as of May 1, 2011 between the Company and Michael Handelman (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on October 20, 2011).
10.22	Lonza Walkersville Inc. Letter of Intent with Genesis Biopharma Inc. effective November 4, 2011 (incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Commission on November 21, 2011).
10.24	Manufacturing Service Agreement, dated December __, 2011, by and between Lonza Walkersville and Genesis Biopharma, Inc. (incorporated herein by reference to the Registrant's Form 10-K filed with the Commission on March 30, 2012).
10.25	Form of Amendment #3 to Tranche A Senior Unsecured Convertible Notes and Tranche B Senior Unsecured Convertible Notes (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on January 10, 2012).
10.26	Form of Amendment No. 5 to Tranche A Senior Unsecured Convertible Notes and Tranche B Senior Unsecured Convertible Notes (incorporated herein by reference to the Registrant's Form 8-K/A filed with the Commission on February 6, 2012).
10.27	Form of Amendment No. 6 to Tranche A Senior Unsecured Convertible Notes and Tranche B Senior Unsecured Convertible Notes, effective as of February 29, 2012 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on March 6, 2012).
10.28	Form of Amendment No. 4 Tranche A Warrants to Purchase Common Stock and Tranche B Warrants to Purchase Common Stock (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on March 6, 2012).
10.29	Form of Amendment No. 8 to Tranche A Senior Unsecured Convertible Notes and Tranche B Senior Unsecured Convertible Notes effective March 30, 2012 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on April 5, 2012).
10.30	Form of Amendment No. 5 to the Tranche A Warrants to Purchase Common Stock and Tranche B Warrants to Purchase Common Stock effective March 30, 2012 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on April 5, 2012).

Exhibit	Description
10.31	Form of two hundred and forty five thousand ($245,000) dollar 12% Promissory Note issued by the Company to Ayer Capital Partners Master Fund, L.P. effective April 5, 2012 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on April 10, 2012).
10.32	Form of five thousand ($5,000) dollar 12% Promissory Note issued by the Company to Ayer Capital Partners Kestrel Fund, L.P. effective April 5, 2012 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on April 10, 2012).
10.33	Form of Note and Common Stock Subscription Agreement (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on May 11, 2012).
10.34	Form of Secured Promissory Note, due June 30, 2012 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on May 11, 2012).
10.35	Form of Maturity Date Extension (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on July 6, 2012).
10.36	Form of Maturity Date Extension (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on October 4, 2012).
10.37	Form of Exchange Agreement (incorporated herein by reference to the Registrant's Form 10-Q filed with the Commission on May 29, 2013).
10.38	Form of Stock Purchase Agreement (incorporated herein by reference to the Registrant's Form 10-Q filed with the Commission on May 29, 2013).
10.39	Agreement and Plan of Merger, dated July 24, 2013, between the Company, Lion Biotechnologies, Inc. and Genesis Biopharma Sub, Inc. (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on July 25, 2013).
10.40	Form of Director Stock Award Agreement (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on July 25, 2013).
10.41	Executive Employment Agreement, dated July 24, 2013, between the Company and Manish Singh.
10.42	Form of Registration Rights Agreement to be entered into by and among Lion Biotechnologies, Inc. and the Investors under the Securities Purchase Agreement (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on October 31, 2013).
10.43	Securities Purchase Agreement, dated October 30, 2013, by and among Lion Biotechnologies, Inc. and the Investors thereunder (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on October 31, 2013).
10.44	Executive Employment Agreement, dated January 6, 2014, between the Company and James Bender (incorporated herein by reference to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 filed with the Commission on January 21, 2014).
10.45	Cooperative Research and Development Agreement for the Development and Evaluation of the NCI Proprietary Adoptive Cell Transfer Immunotherapy Using Tumor Infiltrating Lymphocytes in Patients with Metastatic Melanoma, Bladder, Lung, Triple-negative Breast, and HPV-associated Cancers, Utilizing Lion Biotechnologies, Inc.'s Business Development Expertise in Adoptive Cell Transfer Immunotherapy, executed by Lion Biotechnologies, Inc. on January 22, 2015 (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on January 26, 2015).
10.46	Patent License Agreement, dated February 9, 2015, by and between the Company and the National Institutes of Health.*
10.47	Patent License Agreement, dated February 10, 2015, by and between the Company and the National Institutes of Health.*
10.48	Underwriting agreement, dated as of February 26, 2015, between Lion Biotechnologies, Inc. and Jefferies LLC, Cowen and Company, LLC and Piper Jaffray & Co., as the representatives of the underwriters (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on March 3, 2015)
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer
101	The following financial information from the Annual Report on Form 10-K of Lion Biotechnologies, Inc. for the year ended December 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (1) Balance Sheets as of December 31, 2014 and 2013; (2) Statements of Income for the years ended December 31, 2014, and 2013; (3) Statements of Shareholders' Equity for the years ended December 31, 2014, and 2013; (4) Consolidated Statements of Cash Flows for the years ended December 31, 2014, and 2013; and (5) Notes to Financial Statements

* Certain portions of the Exhibit have been omitted based upon a request for confidential treatment filed by us with the Commission. The omitted portions of the Exhibit have been separately filed by us with the Commission.

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.

LION BIOTECHNOLOGIES, INC.

Date: March 16, 2015

By: /s/ Elma Hawkins
Name: Elma Hawkins
Title: Chief Executive 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.

Signature	Title	Date
/s/ Elma Hawkins Elma Hawkins	Chief Executive Officer (Principal Executive Officer) and Director	March 16, 2015
/s/ Michael Handelman Michael Handelman	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 16, 2015
/s/ Merrill A. McPeak Merrill A. McPeak	Director	March 16, 2015
/s/ Jay Venkatesan Jay Venkatesan	Director	March 16, 2015
/s/ Sanford J. Hillsberg Sanford J. Hillsberg	Director	March 16, 2015
/s/ Ryan D. Maynard Ryan D. Maynard	Director	March 16, 2015

LION BIOTECHNOLOGIES, INC.
FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2014 AND 2013

Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Lion Biotechnologies, Inc.

We have audited the accompanying balance sheets of Lion Biotechnologies, Inc. as of December 31, 2014 and 2013, and the related statements of operations, stockholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Lion Biotechnologies, Inc. as of December 31, 2014 and 2013, 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Lion Biotechnologies, Inc.'s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 16, 2015 expressed an adverse opinion thereon.

/s/ Weinberg & Company, P.A

Weinberg & Company, P.A.
Los Angeles, California
March 16, 2015

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The Board of Directors and Stockholders of
Lion Biotechnologies, Inc.

We have audited Lion Biotechnologies, Inc. internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Lion Biotechnologies, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting 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 only 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. Also, 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.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment. Material weaknesses related to the Company having insufficient monitoring and review controls over the financial reporting closing process and an insufficient number of financial reporting personnel to ensure proper segregation of duties. These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2014 financial statements, and this report does not affect our report dated March 16, 2015, which expressed an unqualified opinion on those financial statements.

In our opinion, because of the effect of the aforementioned material weaknesses described above on the achievement of the objectives of the control criteria, Lion Biotechnologies, Inc. has not maintained effective internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) the balance sheets of Lion Biotechnologies, Inc. as of December 31, 2014 and 2013, and related statements of operations, stockholders' equity and cash flows for the years then ended and our report dated March 16, 2015, expressed an unqualified opinion.

/s Weinberg & Company, P.A.

Weinberg & Company, P.A.
Los Angeles, California
March 16, 2015

LION BIOTECHNOLOGIES, INC.
Balance Sheets

	December 31, 2014	December 31, 2013
ASSETS		
Current Assets		
Cash and cash equivalents	$ 44,909,147	$ 19,672,177
Prepaid expenses and other current assets	66,134	173,716
Total Current Assets	44,975,281	19,845,893
Property and equipment, net of accumulated depreciation of $104,223 and $16,002	1,531,566	27,756
Total Assets	$ 46,506,847	$ 19,873,649
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 1,248,413	$ 412,976
Accrued expenses	327,847	1,518,225
Accrued payable to officers and former directors	85,500	338,731
Total Current Liabilities	1,661,760	2,269,932
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, $0.001 par value; 50,000,000 shares authorized, 5,694 shares and 17,000 shares issued and outstanding, respectively	6	17
Common stock, $0.000041666 par value; 150,000,000 shares authorized, 33,750,188 and 20,023,958 shares issued and outstanding, respectively	1,407	835
Common stock to be issued, 303,125 shares	245,153	245,153
Additional paid-in capital	121,160,415	81,884,897
Accumulated deficit	(76,561,894)	(64,527,185)
Total Stockholders' Equity	44,845,087	17,603,717
Total Liabilities and Stockholders' Equity	$ 46,506,847	$ 19,873,649

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

LION BIOTECHNOLOGIES, INC.
Statements of Operations

	For the Years Ended December 31,	
	2014	**2013**
Revenues	$ -	$ -
Costs and expenses		
Operating expenses (including $3,813,831 and $2,750,223 in share based compensation costs)	9,335,772	4,655,149
Research and development	2,704,597	1,329,367
Cost of Lion transaction	-	16,656,250
Total costs and expenses	12,040,369	22,640,766
Loss from operations	(12,040,369)	(22,640,766)
Other income		
Interest (expense) income	5,660	(444,729)
Cost to induce exchange transaction	-	(2,295,868)
Total other (expense) income	5,660	(2,740,597)
Net Loss	(12,034,709)	(25,381,363)
Deemed dividend related to beneficial conversion feature of convertible preferred stock	-	(8,461,627)
Net Loss Attributable to Common Stockholders	$ (12,034,709)	$ (33,842,990)
Net Loss Per Share, Basic and Diluted	$ (0.48)	$ (3.47)
Weighted-Average Common Shares Outstanding, Basic and Diluted	24,985,542	9,762,513

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

LION BIOTECHNOLOGIES, INC.
Statements of Stockholders' Equity
For the years ended December 31, 2014 and 2013

	Preferred Stock		Common Stock		Common Stock to	Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Be Issued	Capital	Deficit	Equity
Balance - January 1, 2013	-	$ -	818,806	$ 34	$ 245,153	$ 19,119,532	$ (30,684,195)	$ (11,319,476)
Common stock issued in settlement of notes payable and accrued interest and penalty			9,267,641	386		9,267,255		9,267,641
Common stock issued for cash under the restructuring, net of offering costs of $109,990			1,350,000	57		1,239,953		1,240,010
Fair value of common stock issued for cancellation of outstanding warrants			122,734	5		122,729		122,734
Fair value of vested stock options						747,241		747,241
Common stock issued to induce exchange transaction			2,173,134	91		2,173,044		2,173,135
Common stock issued for Lion transaction			2,690,000	112		16,656,138		16,656,250
Common stock issued to directors			400,596	17		2,002,965		2,002,982
Common stock issued to consultants for services			50,000	2		273,998		274,000
Common stock sold in private placement at $2.00 per share, November 2013, net of offering costs of $403,797			3,145,300	131		5,886,672		5,886,803
Preferred stock sold in private placement at $2.00 per share, November 2013, net of offering costs of $1,091,240	17,000	17				15,908,743		15,908,760
Common stock issued for settlement of payable			5,747	0		25,000		25,000
Deemed dividend on beneficial conversion feature of preferred stock						8,461,627	(8,461,627)	-
Net loss							(25,381,363)	(25,381,363)
Balance - December 31, 2013	17,000	17	20,023,958	835	245,153	81,884,897	(64,527,185)	17,603,717
Fair value of vested stock options						2,558,512		2,558,512
Common stock issued upon exercise of warrants			1,288,730	54		3,221,771		3,221,825
Common stock issued upon conversion of preferred shares	(11,306)	(11)	5,653,000	236		(224)		-
Common stock issued for services			784,500	32		1,255,287		1,255,319
Common stock sold in private placement @$5.75 per share, net of offering costs of $2,259,578			6,000,000	250		32,240,172		32,240,422
Net loss							(12,034,709)	(12,034,709)
Balance - December 31, 2014	5,694	$ 6	33,750,188	$ 1,407	$ 245,153	$ 121,160,415	$ (76,561,894)	$ 44,845,087

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

LION BIOTECHNOLOGIES, INC.
Statements of Cash Flows

	For the Years Ended December 31,	
	2014	**2013**
Cash Flows From Operating Activities		
Net loss	$ (12,034,709)	$ (25,381,363)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	88,221	7,087
Fair value of vested stock options	2,558,512	747,241
Common stock issued for services	1,255,319	274,000
Common stock issued to induce conversion of warrants	-	122,734
Common stock issued to induce exchange transaction	-	2,173,135
Common stock issued for Lion transaction	-	16,656,250
Common stock issued to directors	-	2,002,982
Changes in assets and liabilities:		
Prepaid expenses and other current assets	107,582	(166,441)
Accounts payable and accrued expenses	(354,941)	(587,210)
Accounts payable to officers and former directors	(253,231)	43,650
Accrued interest and penalty	-	445,743
Net Cash Used In Operating Activities	(8,633,247)	(3,662,192)
Cash Flows From Investing Activities		
Purchases of property and computer equipment	(1,592,030)	(12,705)
Net Cash Used In Investing Activities	(1,592,030)	(12,705)
Cash Flows From Financing Activities		
Proceeds from the issuance of common stock upon exercise of warrants	3,221,825	-
Proceeds from the issuance of common stock, net	32,240,422	7,126,813
Proceeds from the issuance of convertible notes, net	-	311,500
Proceeds from the issuance of preferred stock, net	-	15,908,760
Net Cash Provided By Financing Activities	35,462,247	23,347,073
Net Increase In Cash And Cash Equivalents	25,236,970	19,672,177
Cash and Cash Equivalents, Beginning of Period	19,672,177	-
Cash and Cash Equivalents, End of Period	$ 44,909,147	$ 19,672,177
Supplemental Disclosures of Cash Flow Information:		
Common stock issued upon conversion of convertible notes	$ -	$ 6,792,750
Settlement of accounts payable through issuance of common stock	$ -	$ 25,000
Common stock issued upon conversion of accrued interest and penalty	$ -	$ 2,474,891

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

NOTE 1. GENERAL ORGANIZATION AND BUSINESS

Lion Biotechnologies, Inc. (the "Company," "we," "us" or "our") is an emerging biotechnology company focused on developing and commercializing adoptive cell therapy (ACT) using autologous tumor infiltrating lymphocytes (TIL) for the treatment of metastatic melanoma and other solid cancers. ACT utilizes T-cells harvested from a patient to treat cancer in that patient. TIL, a kind of anti-tumor T-cells that are naturally present in a patient's tumors, are collected from individual patient tumor samples. The TIL are then activated and expanded ex vivo and then infused back into the patient to fight their tumor cells. The Company was originally incorporated under the laws of the state of Nevada on September 17, 2007. Until March 2010, we were an inactive company known as Freight Management Corp. On March 15, 2010, we changed our name to Genesis Biopharma, Inc., and in 2011 we commenced our current business.

On September 26, 2013, we amended and restated our Articles of Incorporation to, among other things, change our name to Lion Biotechnologies, Inc., effect a 1-for-100 reverse stock split (pro-rata reduction of outstanding shares) of our common stock, After the reverse stock split we increased the number of our authorized number of shares of common stock to 150,000,000 shares, in addition we authorized authorize the issuance of 50,000,000 shares of "blank check" preferred stock, $0.001 par value per share. References in these financial statements and related notes to numbers of shares of common stock, prices per share of common stock, and weighted average number of shares of common stock outstanding prior to the reverse stock splits have been adjusted to reflect the reverse stock splits for all periods presented, unless otherwise noted.

The Company is considered a development stage company at December 31, 2014, as the Company has not yet commenced any revenue-generating operations, does not have any cash flows from operations, and is dependent on debt and equity funding to finance its operations. In June 2014, as discussed in Note, 2, the Financial Accounting Standards Board ("FASB") issued new guidance that removed all incremental financial reporting requirements from generally accepted accounting principles in the United States for development stage entities. The Company early adopted this new guidance effective June 30, 2014, as a result of which all inception-to-date financial information and disclosures have been omitted from this report.

Liquidity

We are currently engaged in the development of therapeutics to fight cancer, we do not have any commercial products and have not yet generated any revenues from our biopharmaceutical business. We currently do not anticipate that we will generate any revenues during 2015 from the sale or licensing of any products. In addition, we have not generated any revenues from our prior business plans.

We have not had any revenues and are still in the development stage. As shown in the accompanying financial statements, we have incurred a net loss of $12,034,709 for the year ended December 31, 2014 and used $8,633,247 of cash in our operating activities during the year ended December 31, 2014. As of December 31, 2014, we had $44,909,147 of cash or cash equivalents on hand, stockholders' equity of $44,845,087 and had working capital of $43,313,521.

During 2015, we expect to further ramp up our operations, which will increase the amount of cash we will use in our operations. Our budget for 2015 includes increased spending on research and development activities, higher payroll expenses as we increase our professional staff, the costs associated with establishing and operating our new Tampa, Florida, research facility, as well as ongoing payments under the Cooperative Research and Development Agreement (CRADA) we have entered into with the National Cancer Institute (NCI). Based on the funds we had available on December 31, 2014, we believe that we have sufficient capital to fund our anticipated operating expenses for at least twenty-four months.

In March 2015, the Company sold 9,200,000 shares of its common stock in an underwritten public offering at $8.00 per share for net proceeds of $68.2 million, after deducting expenses of the offering. The closing of the offering took place on March 8, 2015. In December 2014, the Company sold 6,000,000 shares of its common stock in an underwritten public offering at $5.75 per share for net proceeds of $32.2 million after deducting expenses of the offering. The closing of the offering took place on December 22, 2014. On November 5, 2013, we completed a $23.3 million private placement of our securities to various institutional and individual accredited investors. Despite the amount of funds that we have raised, the estimated cost of completing the development of our TIL-based therapy, and of obtaining all required regulatory approvals to market those product candidates, may be substantially greater than the amount of funds we have available. Therefore, while we believe that our existing cash balances will be sufficient to fund our currently planned level of operations for at least twelve months, we will have to obtain additional funds in the future to complete our development plans. We intend to seek this additional funding through various financing sources, including possible sales of our securities, and in the longer term through strategic alliances with other pharmaceutical or biopharmaceutical companies.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING PRACTICES

Loss per Share

Basic earnings (loss) per share is computed by dividing the net income (loss) applicable to common stockholders by the weighted average number of shares of common stock outstanding during the period. The Company excludes shares issued but unvested from the calculation of basic loss per share and weighted average shares outstanding. Diluted earnings (loss) per share is computed by dividing the net income (loss) applicable to common stockholders by the weighted average number of common shares outstanding plus the number of additional common shares that would have been outstanding if all dilutive potential common shares had been issued. For the years ended December 31, 2014 and 2013, the calculations of basic and diluted loss per share are the same because inclusion of potential dilutive securities in the computation would have an anti-dilutive effect due to the net losses.

The potentially dilutive securities at December 31, 2014 consist of options to acquire 1,857,877 shares of the Company's common stock, warrants to acquire 11,084,426 shares of common stock, and preferred stock that can convert into 2,847,000 shares of common stock. The potentially dilutive securities at December 31, 2013 consisted of options to acquire 278,750 shares of the Company's common stock,warrants to acquire 12,373,156 shares of common stock, and preferred stock that can be converted into 8,500,000 shares of the Company's common stock.

Fair Value Measurements

The Company uses various inputs in determining the fair value of certain assets and liabilities and measures these on a recurring basis. Financial assets and liabilities recorded at fair value in the balance sheets are categorized by the level of objectivity associated with the inputs used to measure their fair value. Authoritative guidance provided by the Financial Accounting Standards Board (the "FASB") defines the following levels directly related to the amount of subjectivity associated with the inputs to fair valuation of these financial assets and liabilities:

Level 1—Quoted prices in active markets for identical assets or liabilities.
Level 2—Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.
Level 3—Unobservable inputs based on the Company's assumptions.

We are required to use observable market data if such data is available, without undue cost and effort. At December 31, 2014 and 2013, the fair value of cash and cash equivalents and accounts payable approximate their carrying values based on their short term nature.

Derivative Financial Instruments

The Company evaluates all of its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within twelve months of the balance sheet date.

On May 22, 2013, upon the completed restructuring of the Company's debt and equity securities ("financial instruments") (see Notes 4), financial instruments held at that time that were accounted for as a derivative liability were converted into shares of the Company's common stock. The Company has no derivatives outstanding at the end of 2013 or 2014.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 revenue and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include accounting for potential liabilities and the assumptions made in valuing stock instruments issued for services.

Stock-Based Compensation

The Company periodically grants stock options and warrants to employees and non-employees in non-capital raising transactions for as compensation for services rendered. The Company accounts for stock option grants to employees based on the authoritative guidance provided by the Financial Accounting Standards Board where the value of the award is measured on the date of grant and recognized over the vesting period. The Company accounts for stock option grants to non-employees in accordance with the authoritative guidance of the Financial Accounting Standards Board where the value of the stock compensation is determined based upon the measurement date as at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. Non-employee stock-based compensation charges generally are amortized over the vesting period on a straight-line basis. In certain circumstances where there are no future performance requirements by the non-employee, option grants are immediately vested and the total stock-based compensation charge is recorded in the period of the measurement date.

The fair value of the Company's common stock option grants are estimated using a Black-Scholes option pricing model, which uses certain assumptions related to risk-free interest rates, expected volatility, expected life of the common stock options, and future dividends. Compensation expense is recorded based upon the value derived from the Black-Scholes option pricing model, and based on actual experience. The assumptions used in the Black-Scholes option pricing model could materially affect compensation expense recorded in future periods.

Cash and Cash Equivalents

The Company considers all highly liquid instruments with maturity of three months or less at the time of issuance to be cash equivalents.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. The cost of property and equipment is depreciated or amortized on the straight-line method over the following estimated useful lives:

Computer equipment	2 years
Office furniture and equipment	5 years
Lab equipment	2 years
Leasehold improvements	5 years

Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the lease term.

Research and Development

Research and development costs consist primarily of fees paid to consultants and outside service providers, patent fees and costs, and other expenses relating to the acquisition, design, development and testing of the Company's treatments and product candidates. Research and development costs are expensed as incurred over the life of the underlying contracts on the straight-line basis, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate. The Company reviews the status of its research and development contracts on a quarterly basis

Concentrations

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash.

The Company maintains cash balances at one bank. At times, the amount on deposit exceeds the federally insured limits. Management believes that the financial institution that holds the Company's cash is financially sound and, accordingly, minimal credit risk exists. As of December 31, 2014 and 2013, the Company's cash balances were in excess of insured limits maintained at the bank.

Recent Accounting Pronouncements

On June 10, 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2014-10 (ASU 2014-10), Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation. ASU 2014-10 eliminates the requirement to present inception-to-date information about income statement line items, cash flows, and equity transactions, and clarifies how entities should disclose the risks and uncertainties related to their activities. ASU 2014-10 also eliminates an exception provided to development stage entities in Consolidations (ASC Topic 810) for determining whether an entity is a variable interest entity on the basis of the amount of investment equity that is at risk. The presentation and disclosure requirements in Topic 915 are no longer required for interim and annual reporting periods beginning after December 15, 2014. The revised consolidation standards will take effect in annual periods beginning after December 15, 2015, however, early adoption is permitted. The Company adopted the provisions of ASU 2014-10 starting with its quarterly report on Form 10-Q for the six months ended June 30, 2014.

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers. ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current U.S. GAAP and replace it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. The ASU also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for reporting periods beginning after December 15, 2016, and early adoption is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. Management is currently assessing the impact the adoption of ASU 2014-09 and has not determined the effect of the standard on our ongoing financial reporting.

In April 2014, the FASB issued Accounting Standards Update No. (ASU) 2014-08, Presentation of Financial Statements (Topic 205) and Property, Plant and Equipment (Topic 360). ASU 2014-08 amends the requirements for reporting discontinued operations and requires additional disclosures about discontinued operations. Under the new guidance, only disposals representing a strategic shift in operations or that have a major effect on the Company's operations and financial results should be presented as discontinued operations. This new accounting guidance is effective for annual periods beginning after December 15, 2014. The Company is currently evaluating the impact of adopting ASU 2014-08 on the Company's results of operations or financial condition.

In August 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, which provides guidance on determining when and how to disclose going-concern uncertainties in the financial statements. The new standard 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. An entity must provide certain disclosures if conditions or events raise substantial doubt about the entity's ability to continue as a going concern. The ASU applies to all entities and is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The Company is currently evaluating the impact the adoption of ASU 2014-15 on the Company's financial statement presentation and disclosures.

In November 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-16, Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity. The amendments in this ASU do not change the current criteria in U.S. GAAP for determining when separation of certain embedded derivative features in a hybrid financial instrument is required. The amendments clarify that an entity should consider all relevant terms and features, including the embedded derivative feature being evaluated for bifurcation, in evaluating the nature of the host contract. The ASU applies to all entities that are issuers of, or investors in, hybrid financial instruments that are issued in the form of a share and is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted. The Company is currently evaluating the impact the adoption of ASU 2014-16 on the Company's financial statement presentation and disclosures

In January 2015, the FASB issued Accounting Standards Update (ASU) No. 2015-01 (Subtopic 225-20) - Income Statement - Extraordinary and Unusual Items. ASU 2015-01 eliminates the concept of an extraordinary item from GAAP. As a result, an entity will no longer be required to segregate extraordinary items from the results of ordinary operations, to separately present an extraordinary item on its income statement, net of tax, after income from continuing operations or to disclose income taxes and earnings-per-share data applicable to an extraordinary item. However, ASU 2015-01 will still retain the presentation and disclosure guidance for items that are unusual in nature and occur infrequently. ASU 2015-01 is effective for periods beginning after December 15, 2015. The adoption of ASU 2015-01 is not expected to have a material effect on the Company's consolidated financial statements. Early adoption is permitted.

In February, 2015, the FASB issued Accounting Standards Update (ASU) No. 2015-02, Consolidation (Topic 810): Amendments to the Consolidation Analysis. ASU 2015-02 provides guidance on the consolidation evaluation for reporting organizations that are required to evaluate whether they should consolidate certain legal entities such as limited partnerships, limited liability corporations, and securitization structures (collateralized debt obligations, collateralized loan obligations, and mortgage-backed security transactions). ASU 2015-02 is effective for periods beginning after December 15, 2015. The adoption of ASU 2015-02 is not expected to have a material effect on the Company's consolidated financial statements. Early adoption is permitted.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission ("SEC") did not or are not believed by management to have a material impact on the Company's present or future financial statements.

NOTE 3 - PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31, 2014	December 31, 2013
Computer equipment	$ 72,368	$ 43,758
Office furniture and equipment	112,776	-
Lab equipment	688,484	-
Leasehold improvements	762,161	-
Total Property and equipment, cost	1,635,789	43,758
Less: Accumulated depreciation and amortization	(104,223)	(16,002)
Property and equipment, net	$ 1,531,566	$ 27,756

Depreciation expense for the years ended December 31, 2014 and 2013 was $88,221 and $7,087, respectively.

NOTE 4. 2013 RESTRUCTURING OF DEBT

Effective May 22, 2013, the Company completed a restructuring of its unregistered debt and equity securities (the "Restructuring") resulting in the issuance of shares of common stock in exchange for *(i)* the cancellation of the 12% Secured Promissory Notes, *(ii)* 7% Senior Secured Notes, *(iii)* September 2012 Secured Promissory Notes, *(iv)* 18% Notes and certain other indebtedness, *(v)* and the receipt of $1.35 million from the sale of shares of common stock (the "Restructuring"). To effect the Restructuring, the Company entered into an exchange agreement (the "Exchange Agreement") and a stock purchase agreement (the "Stock Purchase Agreement"). The Exchange Agreement, Stock Purchase Agreement and the transactions contemplated thereby are described in further detail below. The terms of the Restructuring were determined in negotiations between the Company and the creditors and investors party thereto, and were approved by the Board of Directors, including a majority of the disinterested directors. The securities issued pursuant the Restructuring are exempt from registration under Section 4(2) of the Securities Act of 1933 (the "Securities Act") and Rule 506 of Regulation D because, among other reasons, all offerees are "accredited investors" under Section 2(15) of the Securities Act, all participants were existing security holders of the Company, and no general solicitation or public advertisement was conducted in connection with the Restructuring. The terms of the Restructuring are as follows:

Exchange Agreement

Before the Exchange Agreement was entered into on May 22, 2013, the Company had outstanding promissory notes payable, and accrued interest and penalties thereon, in the aggregate amount of $9,267,641. Under the Exchange Agreement, these creditors of the Company converted the outstanding debt into 9,267,641 shares of Common Stock at a conversion price of $1.00 per share.

This Exchange Agreement terminated all outstanding promissory notes and warrants originally issued with these notes, and any anti-dilution protection thereunder. In addition, all creditors and placement agents provided a release of all claims against the Company with respect to all rights and ownership of the Debt and warrants, in consideration of the shares issued pursuant to this Exchange Agreement.

Stock Purchase Agreement

In addition to the exchange agreement, certain creditors entered into a Stock Purchase Agreement that resulted in the sale of 1,100,000 shares of common stock at a price of $1.00 per share. Furthermore, certain creditors purchased an additional of 250,000 shares of Common Stock at a purchase price of $1.00 per share under the exchange agreement, resulting in aggregate subscription of 1,350,000 shares of common stock for proceeds to the Company of $1,240,010, net of legal fees of $109,990.

In addition, any investor participating in and purchasing a minimum amount of Common Stock in the financing received, for no further consideration, the number of shares of Common Stock that such Investor would have received in debt or equity transactions if the price per share of Common Stock in prior transactions where they purchased stock or convertible notes would have been $1.00 per share (the "Repricing Issuance"). As such, the Company issued 2,173,134 shares of common stock to these investors, and reflected the fair value of such shares of $2,173,134 (based on a value of a $1.00 per share) as cost to induce the exchange in the accompanying statement of operations for the year ended December 31, 2013.

In addition, certain creditors and certain placement agents associated with the Debt, together holding warrants to purchase 40,800 shares of capital stock of the Company, exchanged such warrants and received one share of Common Stock in exchange for each share of capital stock of the Company underlying the warrants. All Investors and other parties holding warrants to purchase 81,934 shares of capital stock of the Company exchanged such warrants and received one share of Common Stock in exchange for each share of capital stock of the Company underlying the warrants. In the aggregate, warrants to acquire 122,734 shares of common stock were cancelled and exchanged for 122,734 shares of common stock, which were valued at $122,734 and reflected as a cost to induce the exchange in the accompanying statement of operations for the year ended December 31, 2013.

In the aggregate, the Stock Purchase Agreement resulted in the issuance of 3,645,868 shares of common stock.

NOTE 5. 2013 EQUITY RESTRUCTURING

Pursuant to the Restructuring discussed in Note 3, the Company underwent a significant change in ownership of its shares. Under the Restructuring, certain creditors, Investors, placement agents and consultants were issued approximately 94% of the Company's outstanding voting equity interests, with Ayer Capital Partners Master Fund, L.P. together with certain of its affiliates (the "Ayer Funds") and Bristol Investment Fund, Ltd., together with certain of its affiliates ("Bristol"), who owned approximately 41% and 29% respectively of the Company's outstanding voting securities immediately after the Restructuring. Prior to the Restructuring, control of the Company was widely disseminated among various stockholders, including the Investors. No single shareholder currently holds more than 25.4% of the voting shares after the Restructuring.

On May 20, 2013, Martin Schroeder resigned from the Board of Directors. In connection with the Restructuring, on May 22, 2013, Anthony Cataldo, Michael Handelman and William Andrews resigned from our Board of Directors. Finally, on May 24, 2013, our stockholders removed Dr. L. Stephen Coles from the Board and elected Paul Kessler to serve as an additional director on the Board. Mr. Kessler is a director of Bristol Investment Fund, Ltd. and a manager of Bristol Capital, LLC who, collectively, hold approximately 27.5% of our currently outstanding shares of common stock. Under the Restructuring, Bristol converted approximately $2.92 million in Debt (including accrued interest and penalties) into shares of Common Stock, invested $341,111 in the Financing, received a Repricing Issuance, and exchanged 45,325 warrants for shares of capital stock of the Company into shares of Common Stock, collectively resulting in the issuance of approximately 3,910,000 shares of Common Stock to Bristol.

Agreement with Lion Biotechnologies, Inc. (Related Party)

On July 24, 2013, we entered into an Agreement and Plan of Merger (the "Lion Agreement") with Lion Biotechnologies, Inc. ("Lion"), a privately owned Delaware corporation, and Genesis Biopharma Sub, Inc., our newly formed Delaware subsidiary. Lion was a non-operating entity with no assets and liabilities, and their only account balances were the shares held by its two (2) owners.

In the Lion Agreement, Lion's stockholders received, in exchange for all of their issued and outstanding shares of common stock, an aggregate of 1,340,000 shares of our Common Stock with a fair value of $6,700,000. The acquisition was done to acquire access to technical and managerial resources to build our current and future products, which we believed would enhance or future operations and enable us to obtain additional funding. The technical resources that we acquired included access to next generation T-cell technologies (including term sheets for such technologies), access to cancer vaccine technologies that Lion was evaluating at Harvard University, NIH, Baylor University and other institutions, and other proprietary technologies and ideas on novel T-cell manufacturing technologies that Lion was designing. The value of these shares of $6,700,000 was recognized and recorded as an expense during the year ended December 31, 2013.

In addition, the Lion stockholders had the ability to receive an additional 1,350,000 shares of Common Stock upon the achievement of two milestones related to the Company's financial performance and position. In November and December 2013 both of the milestones were met and, accordingly, the Company was required to issue the remaining 1,350,000 shares of Common Stock to the Lion Biotechnologies' former stockholders. These additional shares were issued in the fourth quarter of 2013, and the Company determined their fair value on the dates of issuance to be $9,956,250 in the aggregate, based on the trading prices of the Company's stock at the date of achievement of the two milestones. The aggregate fair value of all shares issued under the Lion transaction of $16,656,250 was recognized and recorded as Cost of Lion transaction on the Company's accompanying statement of operations for the year ended December 31, 2013.

As part of the Lion transaction, Dr. Manish Singh entered into an employment agreement with us whereby we appointed him as our Chief Executive Officer and Chairman of the Board of the Company. We also agreed to reconstitute our Board of Directors, which changes became effective on September 3, 2013. In connection with his appointment as Chief Executive Officer and Chairman of the Board, we entered into an employment agreement with Dr. Singh pursuant to which we were required to pay Dr. Singh an annual base salary of $34,000 until this Company raised at least $1,000,000 in additional financing. Effective November 6, 2013, upon the closing of a Private Placement with proceeds of $23.3 million to the Company (see Note 5), Dr. Singh's annual salary increased to $350,000. In addition to his base salary, Dr. Singh was eligible to participate in the Company's annual incentive compensation program, with a target potential bonus of 30% of Dr. Singh's salary, conditioned upon the satisfaction of individual and company objectives. Dr. Singh was also entitled to health and other benefits programs and, on July 24, 2014, he was eligible to receive stock option grants under the Company's stock option plan.

On February 5, 2014, the Compensation Committee awarded Dr.Singh, a cash bonus of $100,000 under his Employment Agreement for his services rendered in 2013, which was included in accrued expenses in the accompanying balance sheet as of the year ended December 31, 2013. During the year ended December 31, 2014, the Company's Compensation Committee awarded Dr. Singh, a cash bonus of $84,000, still pursuant to his Employment Agreement for his services rendered in 2014.

On November 12, 2014, Dr. Singh resigned as the member of the Company's Board of Directors, and effective December 31, 2014, Dr. Singh also resigned as the Company's Chief Executive Officer.

Amended and Restated Articles

Effective September 26, 2013, the Company amended and restated its articles of incorporation. The Amended and Restated Articles of Incorporation effected the following:

(1) a 1-for-100 reverse stock split (pro-rata reduction of outstanding shares) of Common Stock (the "Reverse Stock Split"). All share and per share amounts included in these financial statements have been retroactively restated to reflect the reverse stock split as if it had occurred at the beginning of the earliest period presented.

(2) to fix the number of authorized shares of Common Stock after the Reverse Stock Split at one hundred and fifty million (150,000,000) shares of Common Stock, which change resulted in an increase in the authorized number of shares of Common Stock.

(3) to authorize the issuance of fifty million (50,000,000) shares of "blank check" preferred stock, $0.001 par value per share, to be issued in series, and all properties of such preferred stock to be determined by the Company's Board.

(4) to change the name of the Company to "Lion Biotechnologies, Inc."

(5) to add indemnification and limit the personal liability of officers and members of the Company's Board of Directors.

Amendment to 2011 Plan

The Company's Board of Directors and the holders of a majority of the issued and outstanding shares of common stock approved an amendment to the Company's 2011 Equity Incentive Plan (the "2011 Plan") (a) to increase the number of shares of common stock authorized for issuance under the 2011 Plan from 180,000 shares of common stock to 1,700,000 shares of common stock, (b) increasing the maximum number of shares eligible for issuance under the 2011 Plan in any twelve-month period from 50,000 shares of common stock to 300,000 shares of common stock.

Director Stock Awards

On July 24, 2013, the Company entered into a Director Stock Award Agreement (the "Award Agreement") with each of General Merrill McPeak, Matrix Group International, Inc. (on behalf of David Voyticky) ("*Matrix*") and Bristol Capital, LLC (on behalf of Paul Kessler) ("*Bristol*") whereby General McPeak, Matrix and Bristol each received 133,532 shares of Common Stock or an aggregate of 400,596 shares with a fair value of $2,002,982 for consideration of services rendered as directors and recorded as expense in the accompanying statements of operations for the year ended December 31, 2013. The terms of the Award Agreement were approved by a majority of the Company's stockholders, including a majority of the disinterested stockholders. The securities issued pursuant the Award Agreement are exempt from registration under Section 4(2) of the Securities Act of 1933 (the "Securities Act") because, among other reasons, all offerees are "accredited investors" under Section 2(15) of the Securities Act and no general solicitation or public advertisement was conducted in connection with the issuance.

NOTE 6. STOCKHOLDERS' EQUITY

Year Ended December 31, 2014

Public Offering

On December 22, 2014 we completed an underwritten public offering of 6,000,000 shares of our common stock at a price of $5.75 per share.. The net proceeds to us from the offering were $32,240,222, after deducting underwriting discounts and commissions and offering expenses payable by us. The offering was made pursuant to a shelf registration statement on Form S-3, which was filed with the SEC on November 20, 2014 and declared effective on December 10, 2014, and a prospectus supplement thereunder.

Issuance of common stock for services

In January 2014, the Company issued 2,000 shares of common stock with a fair value of $17,700 for services. The shares of common stock issued were valued at the market price on the date of issuance.

Issuance of common stock for services with vesting terms

During the year ended December 31, 2014, the Company granted 782,500 shares of its restricted common stock to nine of its employees in accordance with the terms of their employment agreements. The 782,500 shares vest over a period of three years. As these shares were granted to employees, the Company calculated the aggregate fair value of these 782,500 shares based on the trading prices of the Company's stock at their grant dates and determined it to be $4,515,590. The allocable portion of the fair value of the stock that vested during the year ended December 31, 2014 amounted to $1,237,619 and was recognized as expense in the accompanying statements of operations.

Shares of restricted stock granted above are subject to forfeiture to the Company or other restrictions that will lapse in accordance with a vesting schedule determined by our Board. In the event a recipient's employment or service with the Company terminates, any or all of the shares of common stock held by such recipient that have not vested as of the date of termination under the terms of the restricted stock agreement are forfeited to the Company in accordance with such restricted grant agreement.

Rights to acquire shares of common stock under the restricted stock purchase or grant agreement shall be transferable by the recipient only upon such terms and conditions as are set forth in the restricted stock agreement, as the Board shall determine in its discretion, so long as shares of common stock awarded under the restricted stock agreement remains subject to the terms of the such agreement.

Issuance of common stock upon conversion of preferred stock

During the year ended December 31, 2014, the Company issued 5,653,000 shares of common stock upon the conversion of 11,306 shares of Series A Convertible Preferred Stock. The conversion shares issued was determined on a formula basis of 500 common shares for each Series A Convertible Preferred Stock held.

Year ended December 31, 2013

Sale of Common stock, Series A Convertible Preferred Stock, and Warrants to Purchase Shares of Common Stock under a Private Placement.

On October 30, 2013, the Company, entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with the institutional and other accredited investors identified therein (each, an "Investor" and collectively, the "Investors"), relating to a private placement (the "Private Placement") through the sale of the Company's Common stock, Series A Convertible Preferred Stock ("Preferred stock"), and Warrants to Purchase Common Stock ("Warrants") for an aggregate gross proceeds of $23,290,600. Under the Securities Purchase Agreement, the Investors agreed to purchase units consisting of either (i) 3,145,300 shares of Common Stock, and Warrants to purchase an aggregate of 3,145,300 shares of Common stock at a purchase price of $2.00 per unit resulting in gross proceeds of $6,290,600; or (ii) 17,000 shares of Series A Convertible Preferred Stock, and Warrants to purchase 8,500,000 shares of Common Stock at a purchase price of $1,000 per unit, resulting in gross proceeds to the Company of $17,000,000.

In connection with the Private Placement, the Company incurred $1,495,037 of direct offering costs, resulting in net proceeds to the Company of $21,795,563. In addition, the Company granted warrants to purchase an aggregate of 726,856 shares of the Company's common stock to the placement agents.

The Warrants are exercisable in whole or in part, at an initial exercise price per share of $2.50, and may be exercised in a cashless exercise if, after six months, there is no effective Registration Statement registering, or no current prospectus available for, the resale of the Warrant shares. The exercise price and number of shares of Common Stock issuable under the Warrants are subject to adjustments for stock dividends, splits, combinations and similar events. The Warrants may be exercised at any time upon the election of the holder, beginning on the date of issuance and ending on the fifth anniversary of the date of issuance.

Series A Convertible Preferred Stock

A total of 17,000 shares of Series A Convertible Preferred Stock (the "Series A Preferred Stock") have been authorized for issuance under the Certificate Of Designation Of Preferences And Rights Of Series A Convertible Preferred Stock (the "Certificate of Designation"). The shares of Series A Preferred Stock have a stated value of $1,000 per share and are initially convertible into shares of Common Stock at a price of $2.00 per share (subject to adjustment as described below). Under the Certificate of Designation, the holders of the Series A Preferred Stock have the following rights, preferences and privileges:

> The Series A Preferred Stock may, at the option of the Investor, be converted at any time or from time to time into fully paid and non-assessable shares of Common Stock at the conversion price in effect at the time of conversion; provided, that a holder of Series A Preferred Stock may at any given time convert only up to that number of shares of Series A Preferred Stock so that, upon conversion, the aggregate beneficial ownership of the Company's Common Stock (calculated pursuant to Rule 13d-3 of the Securities Exchange Act of 1934, as amended) of such Investor and all persons affiliated with such Investor, is not more than 4.99% of the Company's Common Stock then outstanding (subject to adjustment up to 9.99% solely at the Investor's discretion upon 60 days' prior notice). The number of shares into which one share of Series A Preferred Stock shall be convertible is determined by dividing the stated value of $1,000 per share by the initial Conversion Price. The "Conversion Price" per share for the Series A Preferred Stock is initially equal to $2.00 (subject to appropriate adjustment for certain events, including stock splits, stock dividends, combinations, recapitalizations or other recapitalizations affecting the Series A Preferred Stock).

The Series A Preferred Stock will automatically be converted into Common Stock at the then applicable Conversion Price (i) upon the written consent of the Investors holding at least a majority of the outstanding shares of Series A Preferred Stock or (ii) if required by the Company for the Company to list its Common Stock on a national securities exchange; provided, any such conversions will continue to be limited by, and subject to the beneficial ownership conversion limitations set forth above.

Except as otherwise required by law, the holders of shares of Series A Preferred Stock shall not have the right to vote on matters that come before the stockholders; provided, that the Company will not, without the prior written consent of a majority of the outstanding Series A Preferred Stock: (i) amend, alter, or repeal any provision of the Articles of Incorporation (including the Certificate of Designation setting forth the rights of the Series A Preferred Stock) or Bylaws in a manner adverse to the Series A Preferred Stock; (ii) create or authorize the creation of or issue any other security convertible into or exercisable for any equity security, having rights, preferences or privileges senior to or on parity with the Series A Preferred Stock, or increase the authorized number of shares of Series A Preferred Stock; (iii) issue or sell any equity or debt securities for one year after the initial sale of the Series A Preferred Stock, subject to certain specified and other customary exceptions; or (iv) enter into any agreement with respect to any of the foregoing.

In the event of any dissolution or winding up of the Company, whether voluntary or involuntary, the proceeds shall be paid pari passu among the holders of the shares of Common Stock and Preferred Stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to Common Stock.

The Company may not declare, pay or set aside any dividends on shares of any class or series of capital stock of the Company (other than dividends on shares of Common Stock payable in shares of Common Stock) unless the holders of the Series A Preferred Stock shall first receive, or simultaneously receive, an equal dividend on each outstanding share of Series A Preferred Stock.

In accordance with ASC 470-20, the Company determined that the common stock into which the Series A Preferred on the date of issuance of the Series A Preferred was convertible at less than the fair value of the common shares using the relative fair method, resulting in a beneficial conversion feature that the Company recognized as an increase to additional paid-in capital and a deemed dividend to the Series A Preferred stockholders of $8,461,627.

Issuance of common stock for services

On October 31, 2013, the Company granted 50,000 shares of common stock for consulting services. These shares were valued at $274,000 based on the trading price of the Company's common stock at the date of the agreement.

On November 14, 2013, the Company also issued 5,747 shares of common stock to a creditor as payment for outstanding obligations. The fair value of the 5,747 shares issued was $25,000 based on the trading price of the Company's common stock at the date of settlement of the obligation, which was reduced by the total fair value of the shares issued of $25,000.

NOTE 7. STOCK OPTIONS AND WARRANTS

Stock Options

As of October 14, 2011, the Company's Board of Directors, based upon the approval and recommendation of the Compensation Committee, approved by unanimous written consent the Company's 2011 Equity Incentive Plan (the "2011 Plan") and form of option agreements for grants under the 2011 Plan. Employees, directors, consultants and advisors of the Company are eligible to participate in the 2011 Plan. The 2011 Plan will be administered by the Board of Directors or the Company's Compensation Committee and has 1,900,000 shares of common stock reserved for issuance in the form of non-qualified options, restricted stock and the grant appreciation rights. No person eligible to participate in the 2011 Plan shall be granted options or other awards during a twelve month period that exceeds 300,000 shares. No options, restricted stock or stock appreciation rights may be granted after ten years of the adoption of the 2011 Plan by the Board of Directors, nor may any option have a term of more than ten years from the date of grant. The exercise price of non qualified options and the base value of a stock appreciation right shall not be less than the fair market value of the common stock on the date of grant. The Company's stockholders did not approve the 2011 Plan within the required one-year period. Accordingly, the Company cannot grant incentive stock options under the 2011 Plan.

A summary of the status of stock options at December 31, 2014 and 2013, and the changes during the year then ended, is presented in the following table:

	Shares Under Option	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at January 1, 2013	93,750	$ 109.0	8.5 years	$ 217,063
Granted	225,000	104.0		
Exercised				
Expired/Forfeited/Cancelled	(40,000)	92.0		
Outstanding at December 31, 2013	278,750	$ 23.10	9.1 years	$ 1,176,063
Granted	1,604,127	6.58	8.5 years	
Exercised	-			
Expired/Forfeited/Cancelled	(25,000)	125.00	7.0 years	
Outstanding at December 31, 2014	1,857,877	$ 7.31	8.5 years	$ 2,874,378
Exercisable at December 31, 2014	305,163	$ 12.20	7.8 years	$ 472,127

During the year ended December 31, 2014, the Company granted employees and directors options to purchase an aggregate of 1,544,127 shares of the Company's common stock that expire ten years from date of grant, with vesting periods ranging from 12 months to 36 months. The fair value of each option award was estimated on the date of grant using the Black-Scholes option pricing model based on the following assumptions: (i) volatility rates ranging from 218% to 236%, (ii) discount rates ranging from 2% to 3%, (iii) zero expected dividend yield, and (iv) expected life ranging from 5 years to 7 years, which is the average of the term of the option and the vesting period. The total fair value of these option grants to employees at grant dates was approximately $10,193,000.

During the year ended December 31, 2013, the Company granted employees and directors options to purchase an aggregate of 140,000 shares of the Company's common stock that expire ten years from date of grant, with vesting periods ranging from 9 months to 24 months. The fair value of each option award was estimated on the date of grant using the Black-Scholes option pricing model based on the following assumptions: (i) volatility rate of 236% (ii) discount rate of 2.67% (iii) zero expected dividend yield, and (iv) expected life of ranging from 5.38 to 6 years, which are the average of the term of the option and the vesting period. The total fair value of these option grants to employees and directors at grant dates was approximately $1,200,000.

During the year ended December 31, 2014, the Company also granted consultants options to purchase 60,000 shares of the Company's common stock that expire 4 years from date of grant, and all of which vested immediately at grant dates. The fair value of these options granted to consultants was estimated, as the options vest, using the Black-Scholes option pricing model based on the following assumptions: (i) volatility rate of 236%, (ii) discount rate of 1.5%, (iii) zero expected dividend yield, and (iv) expected life of 4 years. The total fair value of these option grants to consultants at current valuation date was approximately $323,000.

During the year ended December 31, 2013, the Company also granted a consultant option to purchase 5,000 shares of the Company's common stock that expire 5 years from date of grant, and vested immediately at grant date. The fair value of this option granted to consultant was estimated, as the options vest, using the Black-Scholes option pricing model based on the following assumptions: (i) volatility rate of 236%, (ii) discount rate of 2.67 %, (iii) zero expected dividend yield, and (iv) expected life of 5 years. The total fair value of these option grants to consultants at current valuation date was approximately $28,000.

During the years ended December 31, 2014 and 2013, the Company recorded compensation costs of $2,558,512 and $747,241, respectively, relating to the vesting of the stock options. As of December 31, 2014, the aggregate value of unvested options was approximately $9,000,000, which will continue to be amortized as compensation cost as the options vest over terms ranging from three months to three years, as applicable.

Warrants

A summary of the status of stock warrants at December 31, 2014, and the changes during the year then ended, is presented in the following table:

	Shares Under Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at January 1, 2013	108,734	123.0	3.5 years	-
Issued	12,387,156	2.5		
Exercised				
Expired	(122,734)			
Outstanding at December 31, 2013	12,373,156	$ 2.51	4.11 years	$ 31,056,390
Issued	-			
Exercised	(1,288,730)	2.50		
Expired	-			
Outstanding and exercisable at December 31, 2014	11,084,426	$ 2.51	3.85 years	$ 59,517,998

The Company issued warrants to purchase an aggregate 12,372,156 shares of the Company's common stock, in connection with the sale of its securities for cash under the October 30, 2013 Private Placement (see Note 6). All of these warrant grants have an exercise price per share of $2.50, were fully vested, and will expire in 2018

During the year ended December 31, 3014, 1,288,730 warrants were exercised to purchase an aggregate of 1,288,730 shares of the Company's common stock for total proceeds to the Company of $3,221,825 based on the warrants' exercise price of $2.50 per share.

NOTE 8. INCOME TAXES

The Company has no tax provision for any period presented due to our history of operating losses. As of December 31, 2014, the Company had net operating loss carry forwards of approximately $24,557,630 that may be available to reduce future years' taxable income through 2034. Future tax benefits which may arise as a result of these losses have not been recognized in these financial statements, as management has determined that their realization is not likely to occur and accordingly, the Company has recorded a valuation allowance for the deferred tax asset relating to these tax loss carry-forwards.

Significant components of the Company's deferred income tax assets are as follows as of:

	December 31, 2014	December 31, 2013
Deferred income tax asset:		
Net operating loss carry forward	$ 8,428,156	$ 3,679,022
Valuation allowance	(8,428,156)	(3,679,022)
Net deferred income tax asset	$ —	$ —

Reconciliation of the effective income tax rate to the U.S. statutory rate is as follows:

	Year Ended December 31,	
	2014	2013
Federal Statutory tax rate	(34)%	(34)%
State tax, net of federal benefit	(5)%	(5)%
	(39)%	(39)%
Valuation allowance	39%	39%
Effective tax rate	-%	-%

The Company adopted accounting rules which address the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under these rules, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement. These accounting rules also provide guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. As of December 31, 2014, no liability for unrecognized tax benefits was required to be recorded.

NOTE 9. LICENSES AND COMMITMENTS

National Institutes of Health and the National Cancer Institute

Effective August 5, 2011, the Company signed a Cooperative Research and Development Agreement (CRADA) with the National Institutes of Health and the National Cancer Institute (NCI). Under the terms of the five-year cooperative research and development agreement, the Company will work with Steven A. Rosenberg, M.D., Ph.D., chief of NCI's Surgery Branch, to develop adoptive cell immunotherapies that are designed to destroy metastatic melanoma cells using a patient's tumor infiltrating lymphocytes.

The Company will pay the NCI $250,000 per quarter ($1,000,000 per year) under the CRADA for Dr. Rosenberg to use for technical, statistical, and administrative support, and research activities, as well as to pay for supplies and travel expenses. Although the CRADA has a five year term, either party to the CRADA has the right to terminate the CRADA upon 60 days' notice to the other party.

During the years ended December 31, 2014 and 2013, the Company recognized $1,000,000 and $1,000,000, respectively, of CRADA expenses, which were recorded as part of research and development expenses in the statement of operations. As of December 31, 2014, $250,000 of these CRADA expenses were outstanding and included in the balance of accrued expenses on the accompanying balance sheet.

National Institutes of Health

Effective October 5, 2011, the Company entered into a Patent License Agreement (the "License Agreement") with the National Institutes of Health, an agency of the United States Public Health Service within the Department of Health and Human Services ("NIH"). Pursuant to the License Agreement, NIH granted to the Company a non-exclusive worldwide right and license to develop and manufacture certain proprietary autologous tumor infiltrating lymphocyte adoptive cell therapy products for the treatment of metastatic melanoma, ovarian cancer, breast cancer, and colorectal cancer. The License Agreement required the Company to pay the NIH approximately $723,000 of upfront licensing fees and expense reimbursements in 2011, which amounts were included in Research and Development expenses in fiscal 2011. In addition, the Company will have to pay royalties of six percent (6%) of net sales (subject to certain annual minimum royalty payments), a percentage of revenues from sublicensing arrangements, and lump sum benchmark royalty payments on the achievement of certain clinical and regulatory milestones for each of the various indications and other direct cost incurred by NIH pursuant to the agreement. The Company initially intends to focus on the development of licensed products in the metastatic melanoma field of use. If the Company achieves all benchmarks for metastatic melanoma, up to and including the product's first commercial sale in the United States, the total amount of such benchmark payments will be $6,050,000. The benchmark payments for the other three indications, if all benchmarks are achieved, will be $6,050,000 for ovarian cancer, $12,100,000 for breast cancer, and $12,100,000 for colorectal cancer. Accordingly, if the Company achieves all benchmarks for all four licensed indications, the aggregate amount of benchmark royalty payments that the Company will have to make to NIH will be $36,300,000.

During the years ended December 31, 2014 and 2013, there were no net sales subject to certain annual minimum royalty payments or sales that would require us to pay a percentage of revenues from sublicensing arrangements. In addition there were no benchmarks or milestones achieved that would require payment under the lump sum benchmark royalty payments on the achievement of certain clinical and regulatory milestones for each of the various indications.

During the years ended December 31, 2014 and 2013, the Company recognized $52,662 and $329,367, respectively, under the License Agreement with NIH, which were recorded as part of research and development expenses in the statement of operations for the years then ended. As of December 31, 2014 and 2013, $0 and $941,659 of these NIH expenses, respectively, were outstanding and included in the balance of accrued expenses on the accompanying balance sheets of the years then ended.

Exclusive License Agreement

On July 21, 2014, the Company entered into an Exclusive License Agreement (the "Moffitt License Agreement"), effective as of June 28, 2014, with the H. Lee Moffitt Cancer Center and Research Institute, Inc. ("Moffitt") under which the Company received an exclusive, world-wide license to Moffitt's rights in and to two patent-pending technologies related to methods for improving tumor-infiltrating lymphocytes for adoptive cell therapy. Unless earlier terminated, the term of the license extends until the earlier of the expiration of the last patent related to the licensed technology or 20 years after the effective date of the license agreement.

Pursuant to the Moffitt License Agreement, the Company paid an upfront licensing fee of $25,000 within 30 days of the effective date of the Moffitt License Agreement, which was recognized as research and development expense during the year ended December 31, 2014. A patent issuance fee will also be payable under the Moffitt License Agreement, upon the issuance of the first U.S. patent covering the subject technology. In addition, the Company agreed to pay milestone license fees upon completion of specified milestones, customary royalties based on a specified percentage of net sales (which percentage is in the low single digits) and sublicensing payments, as applicable, and annual minimum royalties beginning with the first sale of products based on the licensed technologies, which minimum royalties will be credited against the percentage royalty payments otherwise payable in that year. The Company will also be responsible for all costs associated with the preparation, filing, maintenance and prosecution of the patent applications and patents covered by the Moffitt License Agreement related to the treatment of any cancers in the United States, Europe and Japan and in other countries selected that the Company and Moffitt agreed to.

Manufacturing Service Agreement

In December 2011, the Company entered into a Manufacturing Services Agreement with Lonza Walkersville, Inc. (Lonza) pursuant to which Lonza has agreed to manufacture, package, ship and perform quality assurance and quality control of our TIL therapy. This agreement was amended on March 13, 2014. Lonza has commenced developing a commercial-scale manufacturing process for the TIL therapy. The goal is to develop and establish a manufacturing process for the large-scale production of TIL that is in accord with current Good Manufacturing Practices (cGMP).

On June 1, 2014 we issued a new statement of work (SOW) to Lonza under the Manufacturing Services Agreement. The total cost for services to be provided under the SOW is approximately $738,000. During the year ended December 31, 2014, the Company recognized $890,684 of expenses under the Manufacturing Services Agreement with Lonza, which included a $100,000 in upfront costs required under the (SOW), and were recorded as part of research and development expenses in the statement of operations for the year then ended.

In September, 2015 we entered into a research collaboration agreement with the H. Lee Moffitt Cancer Center and Research Institute, Inc. to jointly engage in transitional research and development of adoptive tumor-infiltrating lymphocyte cell therapy with improved anti-tumor properties and process. The total obligation under the agreement is $1,432,797 with 25%, or $358,199, paid at execution.

Tampa Lease

On July 18, 2014, the Company entered into a five -year lease with the University of South Florida Research Foundation for an approximately 5,200 square foot facility located at 3802 Spectrum Boulevard Tampa, Florida 33612. The new facility is part of the University of South Florida research park and will be used as the Company's research and development facilities. The new space currently is being developed and furbished for the Company's research needs and we took possession of the premise in January 2015. Accordingly, we did not recognize any rent expense on this lease until January 2015. The monthly base rent for this facility during the first year of the lease is $10,443, which amount will increase by 3% annually. The Company has the option to extend the lease term of this facility for an additional five-year period on the same terms and conditions, except that the base rent for the renewal term will be increased in accordance with the applicable consumer price index.

The minimum lease payments are as follows:

Year	Amount
2015	$ 125,316
2016	129,075
2017	132,948
2018	135,936
2019	$ 141,044
	664,319

NOTE 10. RELATED PARTY TRANSACTIONS

Accrued Payroll and Fees

As of December 31, 2014 and 2013, the Company had accrued the unpaid salaries of its officers and fees due to former members of the Company's board of directors in the amount of $85,500 and $338,731, respectively.

Settlement with Mr. Cataldo

On June 19, 2013, the Company entered into a Settlement Agreement and General Release of All Claims (the "Settlement Agreement") with Anthony Cataldo, this Company's former Chief Executive Officer. Under the Settlement Agreement, the Company agreed to pay Mr. Cataldo a cash payment of $370,000 when the Company obtains financing of more than $5,000,000. The $370,000 was to be paid as follows: (a) a payment of $120,000, less all appropriate federal and state income and employment taxes, would be paid in cash, and (b) and another payment of $250,000, less all appropriate federal and state income and employment taxes, would be paid in the same securities as sold in the next financing. On November 5, 2013, the Company completed a financing of more than $5,000,000 and, as a result, the foregoing $370,000 payment became due and payable. On November 18, 2013, the Company and Mr. Cataldo agreed to revise the terms of the Settlement Agreement and to reduce the foregoing $370,000 payment to $250,000, payable in cash as payment in full for all amounts owed to him under the Settlement Agreement. The $250,000 payment was made in the year ended December 31, 2013.

NOTE 11. LEGAL PROCEEDINGS

On April 23, 2014, the Company received a subpoena from the Securities Exchange Commission (the "SEC") that stated that the staff of the SEC is conducting an investigation *In the Matter of Galena Biopharma, Inc. File No. HO 12356 (now known as "In the Matter of Certain Stock Promotions")* and that the subpoena was issued to the Company as part of the foregoing investigation. The SEC's subpoena and accompanying letter do not indicate whether the Company is, or is not, under investigation. The Company has contacted the SEC's staff regarding the subpoena, and the Company is cooperating with the SEC.

The subpoena requires the Company to give the SEC, among other materials, all communications between anyone at the Company and certain persons and entities (which include investor-relations firms and persons associated with the investor-relations firms), all documents related to the listed persons and entities, all articles regarding the Company posted on certain equity research or other financial websites, and documents and communications related to individuals who post or have posted articles regarding the Company on equity research or other financial websites.

Theorem Group, LLC vs. Lion Biotechnologies, Inc. (Case No.: BC550529). On July 2, 2014, Theorem Group, LLC filed a complaint for damages against the Company in the Superior Court of the State of California, Los Angeles County. Prior to relocating its offices to its current location in Woodland Hills, California, the Company subleased its offices from Theorem Group, LLC. In addition, Theorem Group, LLC occasionally made loans to the Company. In its complaint, Theorem Group, LLC alleges that the Company breached the sublease and owes Theorem Group, LLC $138,719 under the sublease for unpaid rent and other expenses. In addition, Theorem Group, LLC alleges that it made a $10,000 loan to the Company on March 18, 2013, and that Theorem Group, LLC and the Company orally agreed that Theorem Group, LLC could convert the $10,000 loan in the May 2013 restructuring into shares of the Company's common stock (which conversion was at a price of $1.00 per share). Theorem Group, LLC alleges that the $10,000 loan was neither repaid nor converted in the restructuring and, as a result, that Theorem Group, LLC is entitled to damages of $150,000. The foregoing complaint was served on July 23, 2014. On November 12, 2014, the matter was settled for $110,000, for which the Company has provided for in accrued expenses on the accompanying December 31, 2014 balance sheet.

There are no other pending legal proceedings to which the Company is a party or of which its property is the subject.

NOTE 12. SUBSEQUENT EVENTS

Amendment to NIH/NCI CRADA

On January 22, 2015, we executed an amendment (the "Amendment") to the CRADA we have with the NIH and NCI to include four new indications. As amended, in addition to metastatic melanoma, the CRADA now also includes the development of TIL therapy for the treatment of patients with bladder, lung, triple-negative breast, and HPV-associated cancers. Under the Amendment, the NCI also has agreed to provide us with samples of all tumors covered by the Amendment for performing studies related to improving TIL selection and/or TIL scale-out production and process development.

To fund the NCI's expanded development efforts and support, the annual payments we are required to make to the NCI have increased from $1 million to $2 million, to be paid in quarterly installments of $500,000. We paid the first quarterly installment of a prorated amount in February 2015.

Amendment to NIH License Agreement

On February 9, 2015, we entered into an amendment to our License Agreement with the NIH pursuant to which our non-exclusive license to melanoma was converted into an exclusive license.

In consideration for the exclusive rights granted under the amendment to the License Agreement, we agreed to pay the NIH a non-refundable upfront licensing fee of $350,000 within 60 days after the effective date of the amendment, to pay customary royalties based on a percentage of net sales (which percentage is in the mid-single digits), a percentage of revenues from sublicensing arrangements, and lump sum benchmark payments upon the successful completion of our first Phase 2 clinical study, the successful completion of our first Phase 3 clinical study, the receipt of the first FDA approval or foreign equivalent for a licensed product or process resulting from the licensed technologies, the first commercial sale of a licensed product or process in the United States, and the first commercial sale of a licensed product or process in any foreign country.

Exclusive License to Next-Generation TIL Technologies

On February 10, 2015, we entered into an exclusive Patent License Agreement with the NIH under which we received an exclusive, world-wide license to the NIH's rights in and to two patent-pending technologies related to methods for improving tumor-infiltrating lymphocytes for adoptive cell therapy. The licensed technologies relate to the more potent and efficient production of TIL from melanoma tumors by selecting for T-cell populations that express various inhibitory receptors. Unless terminated sooner, the license shall remain in effect until the last licensed patent right expires.

In consideration for the exclusive rights granted under the exclusive Patent License Agreement, we agreed to pay the NIH a non-refundable upfront licensing fee of $40,000 within 60 days after the effective date of the agreement, and to pay customary royalties based on a percentage of net sales (which percentage is in the mid-single digits), a percentage of revenues from sublicensing arrangements, and lump sum benchmark payments upon the successful completion of our first Phase 2 clinical study, the successful completion of our first Phase 3 clinical study, the receipt of the first FDA approval or foreign equivalent for a licensed product or process resulting from the licensed technologies, the first commercial sale of a licensed product or process in the United States, and the first commercial sale of a licensed product or process in any foreign country.

March 2015 Public Offering

March 3, 2015 we completed an underwritten public offering of 9,200,000 shares of our common stock at a price of $8.00 per share of common stock. The net proceeds to us from the offering were $68.2 million, after deducting underwriting discounts and commissions and offering expenses. The offering was made pursuant to our existing shelf registration statement on Form S-3, including a base prospectus, which was filed with the SEC on November 20, 2014 and declared effective on December 10, 2014, a preliminary prospectus supplement thereunder, and a registration statement on Form S-3 filed with the SEC on February 26, 2015.

Share Issuances

In the first quarter of 2015, the Company received $329,875 in cash from the exercise of warrants for the purchase of 131,950 shares of its common stock.

In the first quarter of 2015, the Company issued 1,000,000 common shares upon the exercise of 2,000 preferred shares.

Exhibit 10.46

Text Marked By [* * *] Has Been Omitted Pursuant To A Request For Confidential Treatment And Was Filed Separately With The Securities And Exchange Commission.

THE NATIONAL INSTITUTES OF HEALTH

PATENT LICENSE AGREEMENT – *EXCLUSIVE*

COVER PAGE

For the **NIH** internal use only:

License Number: L-108-2015/0

License Application Number: A-079-2014

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

U.S. Patent Application No. 61/771,247 filed March 1, 2013 [E-059-2013/0-US-01]
PCT Patent Application No. PCT/US2013/038799 filed April 30, 2013 [E-059-2013/0-US-01]

Licensee: Lion Biotechnologies, Inc.

Cooperative Research and Development Agreement (CRADA) Number: C-057-2011 (NCI 02734)

Public Benefit(s):

The public will benefit from the development of **Licensed Products** by the **Licensee** that are granted FDA approval. There is a long felt need for better treatments for metastatic melanoma. The development of novel TIL-based therapies will provide patients with new cancer treatment options in the realm of personalized medicine to support public health.

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options). The Parties to this **Agreement** are:

1) The National Institutes of Health ("**NIH**"), an agency within the Department of Health and Human Services ("**HHS**"); and

2) The person, corporation, or institution identified above or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as the "**Licensee**".

The **NIH** and the **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, the **NIH** or the **FDA** investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from **NIH** or **FDA** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by the **NIH** or the **FDA**.

1.3 The Secretary of **HHS** has delegated to the **NIH** the authority to enter into this **Agreement** for the licensing of rights to these inventions.

1.4 The **NIH** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 The **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.1 "**Affiliate(s)**" means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.

2.2 "**Benchmarks**" mean the performance milestones that are set forth in Appendix D.

2.3 "**Commercial Development Plan**" means the written commercialization plan attached as Appendix E.

2.4 "**CRADA"** means a Cooperative Research and Development Agreement.

2.5 "**FDA**" means the Food and Drug Administration.

2.6 "**First Commercial Sale**" means the initial transfer by or on behalf of the **Licensee** or its sublicensees of the **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of the **Licensee** or its sublicensees in a country after obtaining regulatory approval by the U.S. Food and Drug Administration or any foreign equivalent necessary for the marketing and sale of such **Licensed Product** or practice of such **Licensed Process** in exchange for cash or some equivalent consideration to which value can be assigned for the purpose of determining **Net Sales**.

2.7 "**Government**" means the Government of the United States of America.

2.8 "**Licensed Fields of Use**" means the fields of use identified in Appendix B.

2.9 "**Licensed Patent Rights**" shall mean:

(a) Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of these patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.9(a):

(i) continuations-in-part of 2.9(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations;

(iv) priority patent application(s) of 2.9(a); and

(v) any reissues, reexaminations, and extensions of these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.9(a): all counterpart foreign and U.S. patent applications and patents to 2.9(a) and 2.9(b), including those listed in Appendix A; and

(d) **Licensed Patent Rights** shall *not* include 2.9(b) or 2.9(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.9(a).

2.10 "**Licensed Processes**" means processes which, in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.11 "**Licensed Products**" means tangible materials which, in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.12 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.13 "**Net Sales**" means the total gross receipts received by **Licensee** for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of the **Licensee** or its sublicensees, and from leasing, renting, or otherwise making the **Licensed Products** available to others for consideration without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the **Licensee**, or sublicensees, and on its payroll, or for the cost of collections. "**Net Sales**" shall not include the supply of **Licensed Products** or use of **Licensed Processes**, for use in pre-clinical or clinical studies, or for process development, quality control or assurance, storage as safety stock, transfer as a charitable donation or any other transaction for which no gross revenue is received.

2.14 "**Practical Application**" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms not inconsistent with the terms applicable to similar products or processes and taking into account the efficacy and safety profile of the **Licensed Product** or the utility of the **Licensed Process** and other relevant commercial, scientific, technical and other factors.

2.15 "**Research License**" means a nontransferable, nonexclusive license to make and to use the **Licensed Products** or the **Licensed Processes** as defined by the **Licensed Patent Rights** for purposes of research only and not for purposes of commercial sale, manufacture or distribution or in lieu of purchase.

2.16 "**Genesis License**" means the **PHS** Patent License Agreement -Nonexclusive (License No. L-129-2011/0) between **PHS** and **Licensee**, as may be amended from time to time.

3. GRANT OF RIGHTS

3.1 The **NIH** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Process(es)** in the **Licensed Fields of Use**.

3.2 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the **NIH** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

4. SUBLICENSING

4.1 Upon written approval, which shall include prior review of any sublicense agreement by the **NIH** and which shall not be unreasonably withheld or delayed, the **Licensee** may enter into sublicensing agreements under the **Licensed Patent Rights**.

4.2 The **Licensee** agrees that any sublicenses shall provide that the obligations to the **NIH** of Paragraphs 5.1-5.4, 8.1, 10.1, 10.2, 12.5, and 13.8-13.10 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement**. The **Licensee** further agrees to attach copies of these Paragraphs to all sublicense agreements.

4.3 Any sublicenses granted by the **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and the **NIH**, at the option of the sublicensee, upon termination of this **Agreement** under Article 13. This conversion is subject to the **NIH** approval, which will not be unreasonably denied or delayed. and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.

4.4 The **Licensee** agrees to forward to the **NIH** a complete copy of each fully executed sublicense agreement postmarked within thirty (30) days of the execution of the agreement. To the extent permitted by law, the **NIH** agrees to maintain each sublicense agreement in confidence.

5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

(a) the **NIH** reserves on behalf of the **Government** an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of all inventions licensed under the **Licensed Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the **Government** is a signatory. Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the **NIH** with reasonable quantities of the **Licensed Products** or materials made through the **Licensed Processes** for **NIH** research use, including pre-clinical and clinical studies undertaken at the NIH; and

(b) in the event that the **Licensed Patent Rights** are Subject Inventions made under **CRADA**, the **Licensee** grants to the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(A), a nonexclusive, nontransferable, irrevocable, paid-up license to practice the **Licensed Patent Rights** or have the **Licensed Patent Rights** practiced throughout the world by or on behalf of the **Government**. In the exercise of this license, the **Government** shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. §552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party. Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the **NIH** with reasonable quantities of the **Licensed Products** or materials made through the **Licensed Processes** for **NIH** research use.

5.2 The **Licensee** agrees that products used or sold in the United States embodying the **Licensed Products** or produced through use of the **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the **NIH**.

5.3 The **Licensee** acknowledges that the **NIH** may enter into future **CRADAs** under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this **Agreement**. The **Licensee** agrees not to unreasonably deny requests for a **Research License** from future collaborators with the **NIH** when acquiring these rights is necessary in order to make a **CRADA** project feasible. The **Licensee** may request an opportunity to join as a party to the proposed **CRADA**.

5.4 (a) in addition to the reserved license of Paragraph 5.1, the **NIH** reserves the right to grant **Research Licenses** directly or to require the **Licensee** to grant **Research Licenses** on reasonable terms. The purpose of these **Research Licenses** is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the **Licensed Patent Rights**, however, the **NIH** shall consult with the **Licensee** before granting to commercial entities a **Research License** or providing to them research samples of materials made through the **Licensed Processes**; and

(b) in exceptional circumstances, and in the event that the **Licensed Patent Rights** are Subject Inventions made under a **CRADA**, the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(B), retains the right to require the **Licensee** to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the **Licensed Patent Rights** in the **Licensed Field of Use** on terms that are reasonable under the circumstances, or if the **Licensee** fails to grant this license, the **Government** retains the right to grant the license itself. The exercise of these rights by the **Government** shall only be in exceptional circumstances and only if the **Government** determines:

(i) the action is necessary to meet health or safety needs that are not reasonably satisfied by the **Licensee**;

(ii) the action is necessary to meet requirements for public use specified by Federal regulations, and these requirements are not reasonably satisfied by the **Licensee**; or

(iii) the **Licensee** has failed to comply with an agreement containing provisions described in 15 U.S.C. §3710a(c)(4)(B); and

(c) the determination made by the **Government** under this Paragraph 5.4 is subject to administrative appeal and judicial review under 35 U.S.C. §203(b).

6. ROYALTIES AND REIMBURSEMENT

6.1 The **Licensee** agrees to pay the **NIH** a noncreditable, nonrefundable license issue royalty as set forth in Appendix C.

6.2 The **Licensee** agrees to pay the **NIH** a nonrefundable minimum annual royalty as set forth in Appendix C.

6.3 The **Licensee** agrees to pay the **NIH** earned royalties as set forth in Appendix C.

6.4 The **Licensee** agrees to pay the **NIH** benchmark royalties as set forth in Appendix C.

6.5 The **Licensee** agrees to pay the **NIH** sublicensing royalties as set forth in Appendix C.

6.6 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that:

(a) the application has been abandoned and not continued;

(b) the patent expires or irrevocably lapses, or

(c) the patent has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

6.7 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.

6.8 On sales of the **Licensed Products** by the **Licensee** to sublicensees or on sales made in other than an arms-length transaction, the value of the **Net Sales** attributed under this Article 6 to this transaction shall be that which would have been received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.

6.9 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **NIH** prior to the effective date of this **Agreement**, the **Licensee** shall pay the **NIH**, as an additional royalty, within sixty (60) days of the **NIH's** submission of a statement and request for payment to the **Licensee**, an amount equivalent to these unreimbursed expenses previously paid by the **NIH**.

6.10 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **NIH** on or after the effective date of this **Agreement**, the **NIH**, at its sole option, may require the **Licensee**:

(a) to pay the **NIH** on an annual basis, within sixty (60) days of the **NIH's** submission of a statement and request for payment, a royalty amount equivalent to these unreimbursed expenses paid during the previous calendar year(s);

(b) to pay these unreimbursed expenses directly to the law firm employed by the **NIH** to handle these functions. However, in this event, the **NIH** and not the **Licensee** shall be the client of the law firm; or

(c) in limited circumstances, the **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights**. In that event, the **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide the **NIH** with copies of each invoice associated with these services as well as documentation that these invoices have been paid.

6.11 The **NIH** agrees, upon written request, to provide the **Licensee** with summaries of patent prosecution invoices for which the **NIH** has requested payment from the **Licensee** under Paragraphs 6.9 and 6.10. The **Licensee** agrees that all information provided by the **NIH** related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a third party (other than its **Affiliates**) except as required by law or a court of competent jurisdiction.

6.12 The **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon ninety (90) days written notice to the **NIH** and owe no payment obligation under Paragraph 6.10 for patent-related expenses incurred in that country after ninety (90) days of the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 Except as otherwise provided in this Article 7, the **NIH** agrees to take responsibility for, but to consult with, the **Licensee** in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall furnish copies of relevant patent-related documents to the **Licensee**.

7.2 Upon the **NIH's** written request, the **Licensee** shall assume the responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall, on an ongoing basis, promptly furnish copies of all patent-related documents to the **NIH**. In this event, the **Licensee** shall, subject to the prior approval of the **NIH**, select registered patent attorneys or patent agents to provide these services on behalf of the **Licensee** and the **NIH**. The **NIH** shall provide appropriate powers of attorney and other documents necessary to undertake this action to the patent attorneys or patent agents providing these services. The **Licensee** and its attorneys or agents shall consult with the **NIH** in all aspects of the preparation, filing, prosecution and maintenance of patent applications and patents included within the **Licensed Patent Rights** and shall provide the **NIH** sufficient opportunity to comment on any document that the **Licensee** intends to file or to cause to be filed with the relevant intellectual property or patent office.

7.3 At any time, after **Licensee** has assumed responsibility for the preparation, filing, prosecution, and maintenance of **Licensed Patent Rights** as provided in Section 7.2, the **NIH** may provide the **Licensee** with written notice that the **NIH** wishes to re-assume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**. If the **NIH** elects to reassume these responsibilities, the **Licensee** agrees to cooperate fully with the **NIH**, its attorneys, and agents in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and to provide the **NIH** with complete copies of any and all documents or other materials in **Licensee's** possession or control that the **NIH** deems necessary to undertake such responsibilities. The **Licensee** shall be responsible for all costs associated with transferring patent prosecution responsibilities to an attorney or agent of the **NIH's** choice.

7.4 Each party shall promptly inform the other as to all material matters that come to its attention that may affect the preparation, filing, prosecution, or maintenance of the **Licensed Patent Rights** and permit each other to provide comments and suggestions with respect to the preparation, filing, prosecution, and maintenance of the **Licensed Patent Rights**, which comments and suggestions shall be considered by the other party.

8. RECORD KEEPING

8.1 The **Licensee** agrees to keep accurate and correct records of the **Licensed Products** made, used, sold, or imported and the **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due the **NIH**. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection, at the expense of the **NIH**, by an accountant or other designated auditor selected by the **NIH** for the sole purpose of verifying reports and royalty payments hereunder. Licensee may require such auditor or accountant to enter into a confidentiality agreement with Licensee containing reasonable terms and conditions for the protection of Licensee's non-public and proprietary information. The accountant or auditor shall only disclose to the **NIH** information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then the **Licensee** shall reimburse the **NIH** for the cost of the inspection at the time the **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within sixty (60) days of the date the **NIH** provides to the **Licensee** notice of the payment due.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.1 Prior to signing this **Agreement**, the **Licensee** has provided the **NIH** with the **Commercial Development Plan** in Appendix E, under which the **Licensee** intends to bring **Licensed Product(s)** or **Licensed Process(es)** within the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix D.

9.2 The **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for each of the **Licensed Fields of Use** within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, sublicensing, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. The **NIH** also encourages these reports to include information on any of the **Licensee's** public service activities that relate to the **Licensed Patent Rights**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, the **Licensee** shall explain the reasons for these differences. In the annual report, the **Licensee** may propose amendments to the **Commercial Development Plan**, acceptance of which by the **NIH** may not be denied unreasonably. The **Licensee** agrees to provide any additional information reasonably required by the **NIH** to evaluate the **Licensee's** performance under this **Agreement**. The **Licensee** may amend the **Benchmarks** at any time upon written approval by the **NIH**. The **NIH** shall not unreasonably withhold approval of any request of the **Licensee** to extend the time periods of this schedule if the request is supported by a reasonable showing by the **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application** as defined in 37 C.F.R. §404.3(d). The **Licensee** shall amend the **Commercial Development Plan** and **Benchmarks** at the request of the **NIH** to address any **Licensed Fields of Use** not specifically addressed in the plan originally submitted.

9.3 The **Licensee** shall report to the **NIH** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.

9.4 Following the **First Commercial Sale, t**he **Licensee** shall submit to the **NIH**, within sixty (60) days after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of the **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, the **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to the **NIH** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of the **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.13 to determine **Net Sales** made under Article 6 to determine royalties due. The royalty report shall also identify the site of manufacture for the **Licensed Product(s)** sold in the United States.

9.5 The **Licensee** agrees to forward semi-annually to the **NIH** a copy of these reports received by the **Licensee** from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to the **NIH** by the **Licensee** for activities under the sublicense.

9.6 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day preceding the day that the payment is due. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the **Licensee**. The royalty report required by Paragraph 9.4 shall be mailed to the **NIH** at its address for **Agreement** Notices indicated on the Signature Page.

9.7 The **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay the tax and be responsible for all filings with appropriate agencies of foreign governments. As reasonably requested by **Licensee**, **NIH** shall cooperate with **Licensee** in applying for any valid exemption or obtaining any valid refund of such taxes paid by **Licensee**.

9.8 Additional royalties may be assessed by the **NIH** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by the **NIH** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the **NIH** from exercising any other rights it may have as a consequence of the lateness of any payment.

9.9 All plans and reports required by this Article 9 and marked "confidential" by the **Licensee** shall, to the extent permitted by law, be treated by the **NIH** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **NIH** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 C.F.R. §5.65(d).

10. PERFORMANCE

10.1 The **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and the **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include reasonable adherence to the **Commercial Development Plan** in Appendix E and performance of the **Benchmarks** in Appendix D in each case as either may be amended from time to time. The efforts of a sublicensee or an **Affiliate** of **Licensee** shall be considered the efforts of the **Licensee**.

10.2 Upon the **First Commercial Sale** in the United States, until the expiration or termination of this **Agreement**, the **Licensee** shall use its reasonable commercial efforts to make the **Licensed Products** and the **Licensed Processes** reasonably accessible to the United States public.

10.3 The **Licensee** agrees, after its **First Commercial Sale,** to make reasonable quantities of the **Licensed Products** or materials produced through the use of the **Licensed Processes** within the **Licensed Fields of Use** available to patient assistance programs.

10.4 The **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.

10.5 The **Licensee** agrees to supply, to the Mailing Address for **Agreement** Notices indicated on the Signature Page, the Office of Technology Transfer, **NIH** with inert samples of the **Licensed Products** or the **Licensed Processes** or their packaging for educational and display purposes only.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.1 The **NIH** and the **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as, any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either party becomes aware.

11.2 Pursuant to this **Agreement** and the provisions of 35 U.S.C. Chapter 29, the **Licensee** may:

(a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the **Licensed Patent Rights**;

(b) in any suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; or

(c) settle any claim or suit for infringement of the **Licensed Patent Rights** provided, however, that the **NIH** and appropriate **Government** authorities shall have the first right to take such actions; and

(d) if the **Licensee** desires to initiate a suit for patent infringement, the **Licensee** shall notify the **NIH** in writing. If the **NIH** does not notify the **Licensee** of its intent to pursue legal action within ninety (90) days, the **Licensee** shall be free to initiate suit. The **NIH** shall have a continuing right to intervene in the suit. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any suit for patent infringement. The **Licensee** may request the **Government** to initiate or join in any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of the motion or other action, including all costs incurred by the **Government** in opposing the motion or other action. In all cases, the **Licensee** agrees to keep the **NIH** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **NIH** and give careful consideration to the views of the **NIH** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.3 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the **Licensed Patent Rights** shall be brought against the **Licensee** or raised by way of counterclaim or affirmative defense in an infringement suit brought by the **Licensee** under Paragraph 11.2, pursuant to this **Agreement** and the provisions of 35 U.S.C. Part 29 or other statutes, the **Licensee** may:

(a) defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the **Licensed Patent Rights**;

(b) in any suit, ultimately to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; and

(c) settle any claim or suit for declaratory judgment involving the **Licensed Patent Rights**-provided, however, that the **NIH** and appropriate **Government** authorities shall have the first right to take these actions and shall have a continuing right to intervene in the suit; and

(d) if the **NIH** does not notify the **Licensee** of its intent to respond to the legal action within a reasonable time, the **Licensee** shall be free to do so. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. The **Licensee** may request the **Government** to initiate or to join any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit by motion or any other action of the **Licensee**, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. If the **Licensee** elects not to defend against the declaratory judgment action, the **NIH**, at its option, may do so at its own expense. In all cases, the **Licensee** agrees to keep the **NIH** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **NIH** and give careful consideration to the views of the **NIH** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.4 In any action under Paragraphs 11.2 or 11.3 the expenses including costs, fees, attorney fees, and disbursements, shall be paid by the **Licensee**. The value of any recovery made by the **Licensee** through court judgment or settlement actually collected shall first be applied by **Licensee** to reimburse it for all of its costs and expenses (including attorneys' fees, expert witness fees, and any reimbursement payments made to **NIH** or the **Government**) and the balance shall be treated as **Net Sales** and subject to earned royalties as provided in Appendix C when and as collected.

11.5 The **NIH** shall cooperate fully with the **Licensee** in connection with any action under Paragraphs 11.2 or 11.3. The **NIH** agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by the **Licensee**.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1 The **NIH** offers no warranties other than those specified in Article 1.

12.2 The **NIH** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.3 THE **NIH** MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.

12.4 The **NIH** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

12.5 The **Licensee** shall indemnify and hold the **NIH**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

(a) the use by or on behalf of the **Licensee**, its sublicensees, directors, employees, or third parties of any **Licensed Patent Rights**; or

(b) the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes** or materials by the **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.

12.6 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 14.16 are not fulfilled, and shall extend to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.

13.2 In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, or if not reasonably capable of remedy within such period, **Licensee** has not taken substantial steps to remedy the alleged default within such ninety (90) day period, the **NIH** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

13.3 In the event that the **Licensee (i)** becomes insolvent, (ii) files a petition in bankruptcy, or has such a petition filed against it and, in either case, such petition is not dismissed within sixty (60) days, the **Licensee** shall immediately notify the **NIH** in writing.

13.4 The **Licensee** shall have a unilateral right to terminate this **Agreement** or any licenses in any country or territory by giving the **NIH** sixty (60) days written notice to that effect.

13.5 The **NIH** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if the **NIH** determines that the **Licensee**:

(a) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to the **NIH's** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve the **Practical Application** of the **Licensed Products** or the **Licensed Processes**;

(b) has not achieved and is not reasonably likely to achieve the **Benchmarks** as may be modified under Paragraph 9.2;

(c) has willfully made a material false statement of, or willfully omitted a material fact in the license application or in any report required by this **Agreement**;

(d) has committed a material breach of a covenant or agreement contained in this **Agreement**;

(e) is not keeping the **Licensed Products** or the **Licensed Processes** within the scope of the **Licensed Fields of Use** reasonably accessible to the public after commercial use commences;

(f) cannot reasonably satisfy unmet health and safety needs; or

(g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2 unless waived.

13.6 In making the determination referenced in Paragraph 13.5, the **NIH** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by the **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, the **NIH** shall give written notice to the **Licensee** providing the **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, the **NIH's** concerns as to the items referenced in 13.5(a)-13.5(g). If the **Licensee** fails to alleviate the **NIH's** reasonable concerns as to the items referenced in 13.5(a)-13.5(g) or fails to initiate corrective action to the **NIH's** reasonable satisfaction, the **NIH** may terminate this **Agreement**.

13.7 When the public health and safety so require, and after written notice to the **Licensee** providing the **Licensee** a sixty (60) day opportunity to respond, the **NIH** shall have the right to require the **Licensee** to grant sublicenses to responsible applicants, on commercially reasonable terms, in any **Licensed Fields of Use** under the **Licensed Patent Rights**, unless the **Licensee** can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the **Licensed Patent Rights**. The **NIH** shall not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with the **Licensee** for a sublicense on commercially reasonable terms and conditions.

13.8 The **NIH** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** if it is determined that this action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the **Licensee**.

13.9 Within thirty (30) days of receipt of written notice of the **NIH's** unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of 37 C.F.R. §404.11, appeal the decision by written submission to the designated **NIH** official. The decision of the designated **NIH** official shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

13.10 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expenses, due to the **NIH** shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with the **NIH** pursuant to Paragraph 4.3. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, the **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to the **NIH** or provide the **NIH** with certification of the destruction thereof. The **Licensee** may not be granted additional **NIH** licenses if the final reporting requirement is not fulfilled.

14. GENERAL PROVISIONS

14.1 Neither party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by that party or excuse a similar subsequent failure to perform any of these terms or conditions by the that party.

14.2 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, the **Licensed Products** and the **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

14.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

14.4 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

14.5 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

14.6 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by the other party. **Agreement** notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

14.7 This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the **Licensee's Affiliate(s)** without the prior written consent of the **NIH**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable. In the event that the **NIH** approves a proposed assignment, the **Licensee** shall pay the **NIH**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this **Agreement** within sixty (60) days of the assignment.

14.8 The **Licensee** agrees in its use of any **NIH**-supplied biological materials that are supplied under this Agreement to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use such biological materials for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. The **Licensee** agrees not to use such biological materials for research involving human subjects or clinical trials outside of the United States without notifying the **NIH**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the **NIH** of research involving such biological materials in human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of the research or trials.

14.9 The **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of these items may require a license from the appropriate agency of the U.S. **Government** or written assurances by the **Licensee** that it shall not export these items to certain foreign countries without prior approval of this agency. The **NIH** neither represents that a license is or is not required or that, if required, it shall be issued.

14.10 The **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All the **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve the **NIH's** patent rights in those countries.

14.11 By entering into this **Agreement**, the **NIH** does not directly or indirectly endorse any product or service provided, or to be provided, by the **Licensee** whether directly or indirectly related to this **Agreement**. The **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, the **NIH**, any other **Government** organizational unit, or any **Government** employee. Additionally, the **Licensee** shall not use the names of the **NIH**, the **FDA** or the **HHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of the **NIH**.

14.12 The parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. The **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **NIH** official, or designee, whose decision shall be considered the final agency decision. Thereafter, the **Licensee** may exercise any administrative or judicial remedies that may be available.

14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 C.F.R. Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.14 Any formal recordation of this **Agreement** required by the laws of any **Licensed Territory** as a prerequisite to enforceability of the **Agreement** in the courts of any foreign jurisdiction or for other reasons shall be carried out by the **Licensee** at its expense, and appropriately verified proof of recordation shall be promptly furnished to the **NIH**.

14.15 Paragraphs 4.3, 8.1, 9.5-9.8, 9.9 12.1-12.5, 13.9, 13.10, 14.12 and 14.15 of this **Agreement** shall survive termination of this **Agreement**.

14.16 The terms and conditions of this **Agreement** shall, at the **NIH's** sole option, be considered by the **NIH** to be withdrawn from the **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by the **NIH** within sixty (60) days from the date of the **NIH's** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

NIH PATENT LICENSE AGREEMENT – *EXCLUSIVE*

SIGNATURE PAGE

For the **NIH**:

/s/ Richard U. Rodriguez ___2/9/2015_____
Richard U. Rodriguez Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address or E-mail Address for **Agreement** notices and reports:

Chief, Monitoring & Enforcement Branch
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

E-mail: LicenseNotices_Reports@mail.nih.gov

For the **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in this document are truthful and accurate.):

by:
/s/ Elma Hawkins ___2/10/2015_____
Signature of Authorized Official Date

Elma Hawkins, Ph.D.
Printed Name

President and CEO
Title

I. Official and Mailing Address for **Agreement** notices:

Peter Ho, Ph.D.
Director, Business Development
21900 Burbank Blvd., 3rd Floor
Woodland Hills, CA 91367
Phone: 818-992-3127
Fax: 818-475-5194
Email: peter.ho@lionbio.com

II.Official and Mailing Address for Financial notices (the **Licensee's** contact person for royalty payments)

Peter Ho, Ph.D.
Director, Business Development
21900 Burbank Blvd., 3rd Floor
Woodland Hills, CA 91367
Phone: 818-992-3127
Fax: 818-475-5194
Email: peter.ho@lionbio.com

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

I. U.S. Patent Application No. 61/771,247 filed March 1, 2013 [E-059-2013/0-US-01]

II. PCT Patent Application No. PCT/US2013/038799 filed April 30, 2013 [E-059-2013/0-PCT-02]

APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

I. **Licensed Fields of Use:**

The use of the **Licensed Patent Rights** to develop and manufacture autologous tumor infiltrating lymphocyte adoptive cell therapy products for the treatment of metastatic melanoma.

Tumor infiltrating lymphocytes (TIL) are a subset of T lymphocytes (T cells) that migrate and are located within a tumor site. TIL isolated from these tumor sites exhibit natural anti-tumor activity without genetic modifications. For the avoidance of doubt, cell therapy products involving genetically modified tumor infiltrating lymphocytes are excluded from **Licensed Fields of Use**.

II. **Licensed Territory:** Worldwide

APPENDIX C – ROYALTIES

Royalties:

I. The **Licensee** agrees to pay to the **NIH** a noncreditable, nonrefundable license issue royalty in the amount of **[* * *]** within sixty (60) days from the effective date of this **Agreement.**

II. The **Licensee** agrees to pay to the **NIH** a nonrefundable minimum annual royalty in the amount of **[* * *]** as follows:

(a) The first minimum annual royalty is due within sixty (60) days of the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1; and

(b) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year.

(c) In the case of each of (a) and (b) above, such payments shall be due so long a **Licensee** has not terminated this Agreement pursuant to Paragraph 13.4.

III. The **Licensee** agrees to pay the **NIH** earned royalties of **[* * *]** on **Net Sales** by or on behalf of **Licensee** or its sublicensees. **Licensee** shall be entitled to a credit of **[* * *]** against the earned royalty rate for each percent point in excess of **[* * *]** that **Licensee** must pay to an unaffiliated licensor(s) for the manufacture and sale of **Licensed Product(s)** and **Licensed Process(es)**. Said credit however, shall not reduce the earned royalty rate due to **NIH** for **Licensed Product(s)** and **Licensed Process(es)** below **[* * *]**.

Notwithstanding anything in this **Agreement** to the contrary, the earned royalties set forth in this Section III do not apply to, and are not otherwise due or payable with respect to, any **Licensed Products** or **Licensed Processes** that also fall within the scope of one or more claims of the patents licensed to the **Licensee** by the **NIH** under the **Genesis License**. In the event that any products developed and sold or processes practiced by or on behalf of the **Licensee** or any of its sublicensees under this **Agreement** both qualify as a **Licensed Product** or **Licensed Process** under this **Agreement** and fall within the scope of one or more claims of the patents licensed to the **Licensee** under the **Genesis License**, then the **Licensee** will not be obligated to pay any of the earned royalties set forth in this Section III with respect to such **Licensed Products** or **Licensed Processes** and the only earned royalties payable by **Licensee** to the **NIH** with respect to such **Licensed Products** and **Processes** (if any) will be due and payable in accordance with and pursuant to the terms of the **Genesis License**.

IV. The **Licensee** agrees to pay the **NIH Benchmark** royalties within sixty (60) days of achieving each **Benchmark**:

(a) **[* * *]** for successful completion of the first Phase 2 clinical study. For purposes of this Agreement "successful completion" shall mean a clinical trial that yields data that is statistically significant and otherwise sufficient to permit Licensee to file a New Drug Application (NDA).

(b) **[* * *]** for successful completion of the first Phase 3 clinical study.

(c) **[* * *]** upon the first FDA approval or foreign equivalent for a Licensed Product or Licensed Process.

(d) **[* * *]** for the First Commercial Sale of a Licensed Product or Licensed Process in the United States.

(e) **[* * *]** for the First Commercial Sale of a Licensed Product or Licensed Process in any foreign country for either of Licensed Field of Use.

Notwithstanding anything in this **Agreement** to the contrary, the **NIH Benchmark** royalties set forth in this Section IV do not apply to, and are not otherwise due or payable with respect to, any **Licensed Products** that also fall within the scope of one or more claims of the patents licensed to the **Licensee** by the **NIH** under the **Genesis License**. In the event that any products developed and sold by or on behalf of the **Licensee** or any of its sublicensees under this **Agreement** both qualify as **Licensed Products** under this **Agreement** and fall within the scope of one or more claims of the patents licensed to the **Licensee** under the **Genesis License**, the **Licensee** will not be obligated to pay any of the **NIH Benchmark** royalties set forth in this Section IV with respect to such **Licensed Products** and the only **NIH Benchmark** royalties payable by the **Licensee** to the **NIH** with respect to such **Licensed Products** (if any) will be due and payable in accordance with and pursuant to the terms of the **Genesis License**.

V. The **Licensee** agrees to pay the **NIH**:

(a) additional sublicensing royalties of **[* * *]** on the fair market value of any consideration received for granting each sublicense within sixty (60) days of the execution of each sublicense if any such sublicense is executed prior to FDA approval or foreign equivalent for a Licensed Product or Licensed Process within each Licensed Field of Use from Appendix B; and

(b) additional sublicensing royalties of **[* * *]** on the fair market value of any consideration received for granting each sublicense within sixty (60) days of the execution of each sublicense if any such sublicense is executed following FDA approval or foreign equivalent for a Licensed Product or Licensed Process within each Licensed Field of Use from Appendix B.

(c) Notwithstanding anything in this Agreement to the contrary, any such consideration will not include the following:

(1) Bona fide support for research and development activities corresponding directly to the development of **Licensed Product(s)** and/or **Licensed Process(es),** which do not exceed Licensee's fully-burdened cost for undertaking such research and development, and limited to support which is received after the effective date of this Agreement specifically excluding any support which is used by Licensee to offset research and development expenses which are incurred prior to the effective date of this Agreement;

(2) Proceeds derived from debt financing received after the effective date of this Agreement, to the extent that such financing is at market rates;

(3) As earned royalties on Net Sales or sales by sublicensee(s).

Notwithstanding anything in this **Agreement** to the contrary**,** in the event that the **Licensee** grants any third party a sublicense both under Article 4 of this **Agreement** and under the license rights granted to it in the **Background License**, then the **Licensee** will not be obligated to pay to the **NIH** any portion of any **Non-Royalty Sublicense Income** received by it for granting such sublicense pursuant to this Section V and the **Licensee** will only be obligated to pay to the **NIH** the percentage of any such sublicensing royalties set forth in Appendix C to the **Background License,** in accordance with the terms of the **Background License**.

APPENDIX D – BENCHMARKS AND PERFORMANCE

The **Licensee** agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify the **NIH** that the **Benchmark** has been achieved.

	Benchmark	Deadline
I.	**[* * *]**	**[* * *]**
II.	**[* * *]**	**[* * *]**
III.	**[* * *]**	**[* * *]**
IV.	**[* * *]**	**[* * *]**
V.	**[* * *]**	**[* * *]**
VI.	**[* * *]**	**[* * *]**

APPENDIX E – COMMERCIAL DEVELOPMENT PLAN

Licensee intends to use the licensed technology to develop and commercialize a product (based an enriched population of T cells from tumors or enriched TILs) to treat melanoma.

[* * *]

APPENDIX F – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- OTT license reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

Example

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500
			Total Gross Sales	153,250
			Less Deductions:	
			Freight	3,000
			Returns	7,000
			Total Net Sales	143,250
			Royalty Rate	8%
			Royalty Due	11,460
			Less Creditable Payments	10,000
			Net Royalty Due	**1,460**

APPENDIX G – ROYALTY PAYMENT OPTIONS

The OTT License Number MUST appear on payments, reports and correspondence.

Automated Clearing House (ACH) for payments through U.S. banks only

The **NIH** encourages its licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). Submit your ACH payment through the U.S. Treasury web site located at: **https://www.pay.gov.** Locate the "**NIH** Agency Form" through the Pay.gov "Agency List".

Electronic Funds Wire Transfers

The following account information is provided for wire payments. In order to process payment via Electronic Funds Wire Transfer sender MUST supply the following information within the transmission:

Drawn on a **U.S. bank account** via FEDWIRE should be sent directly to the following account:

Beneficiary Account:	Federal Reserve Bank of New York or TREAS NYC
Bank:	Federal Reserve Bank of New York
ABA#	021030004
Account Number:	75080031
Bank Address:	33 Liberty Street, New York, NY 10045
Payment Details:	License Number (L-XXX-XXXX) Name of the Licensee

Drawn on a **foreign bank account** should be sent directly to the following account. Payment must be sent in **U.S. Dollars (USD)** using the following instructions:

Beneficiary Account:	Federal Reserve Bank of New York/ITS or FRBNY/ITS
Bank:	Citibank N.A. (New York)
SWIFT Code:	CITIUS33
Account Number:	36838868
Bank Address:	388 Greenwich Street, New York, NY 10013
Payment Details (Line 70):	**NIH** 75080031 License Number (L-XXX-XXXX) Name of the Licensee
Detail of Charges (line 71a):	Charge Our

Checks

All checks should be made payable to "NIH Patent Licensing"

Checks drawn on a **U.S. bank account** and sent by US Postal Service should be sent directly to the following address:

National Institutes of Health (**NIH**)
P.O. Box 979071
St. Louis, MO 63197-9000

Checks drawn on a U.S. bank account and sent by **overnight or courier** should be sent to the following address:

US Bank
Government Lockbox SL-MO-C2GL
1005 Convention Plaza
St. Louis, MO 63101
Phone: 314-418-4087

Checks drawn on a **foreign bank account** should be sent directly to the following address:

National Institutes of Health (**NIH**)
Office of Technology Transfer
Royalties Administration Unit
6011 Executive Boulevard
Suite 325, MSC 7660
Rockville, Maryland 20852

Exhibit 10.47

Text Marked By [* * *] Has Been Omitted Pursuant To A Request For Confidential Treatment And Was Filed Separately With The Securities And Exchange Commission.

THE NATIONAL INSTITUTES OF HEALTH

PATENT LICENSE AGREEMENT – *EXCLUSIVE*

COVER PAGE

For the **NIH** internal use only:

License Number: L-107-2015/0

License Application Number: A-286-2014

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

Group A

I. U.S. Provisional Patent Application No. 61/237,889, filed August 26, 2009 entitled "Adoptive cell therapy with young T cells" (HHS Ref No. E-273-2009/0-US-01);

II. U.S. Patent No. 8,383,099 issued February 26, 2013 entitled "Adoptive cell therapy with young T cells" (HHS Ref No. E-273-2009/0-US-02);

III. U.S. Patent Application No. 13/742,541 filed January 16, 2013 entitled "Adoptive cell therapy with young T cells" (HHS Ref No. E-273-2009/0-US-03);

IV. U.S. Provisional Patent Application No. 61/466,200 filed March 22, 2011entitled "Methods of growing tumor infiltrating lymphocytes in gas-permeable containers" (HHS Ref No. E-114-2011/0-US-01);

V. PCT Application No. PCT/US2012/029744 filed March 20, 2012 entitled "Methods of growing tumor infiltrating lymphocytes in gas-permeable containers" (HHS Ref No. E-114-2011/0-PCT-02);

VI. U.S. Patent Application No. 13/424,646 filed May 20, 2012 entitled "Methods of growing tumor infiltrating lymphocytes in gas-permeable containers" (HHS Ref No. E-114-2011/0-US-03);

Group B

I. U.S. Provisional Patent Application No. 60/408,681, filed September 6, 2002 entitled "Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy" (HHS Ref No. E-275-2002/0-US-01);

II. PCT Application No. PCT/US2012/029744 filed September 5, 2003 entitled "Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy" (HHS Ref No. E-275-2002/1-PCT-01); A-286-2014

III. U.S. Patent No. 8,034,334 issued October 11, 2011 entitled "Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy" (HHS Ref No. E-275-2002/1-US-02);

IV. European Patent Application No. 03794636.5 filed April 4, 2005 entitled "Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy" (HHS Ref No. E-275-2002/1-EP-03);

V. Canadian Patent No. 2,497,552 issued May 27, 2014 entitled "Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy" (HHS Ref No. E-275-2002/1-CA-04);

VI. Australian Patent No. 2003265948 issued September 3, 2009 entitled "Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy" (HHS Ref No. E-275-2002/1-AU-05);

VII. U.S. Patent No. 8,287,857 issued October 16, 2012 entitled "Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy" (HHS Ref No. E-275-2002/1-US-06);

Licensee: Lion Biotechnologies, Inc.

Cooperative Research and Development Agreement (CRADA) Number: C-057-2011 (NCI 02734)

Public Benefit(s):

The public will benefit from the development of **Licensed Products** by the **Licensee** that are granted FDA approval. There is a long felt need for better treatments for metastatic melanoma. The development of novel TIL-based therapies will provide patients with new cancer treatment options in the realm of personalized medicine to support public health.

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options). The Parties to this **Agreement** are:

1) The National Institutes of Health ("**NIH**"), an agency within the Department of Health and Human Services ("**HHS**"); and

2) The person, corporation, or institution identified above or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as the "**Licensee**".

The **NIH** and the **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, the **NIH** or the **FDA** investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from **NIH** or **FDA** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by the **NIH** or the **FDA**.

1.3 The Secretary of **HHS** has delegated to the **NIH** the authority to enter into this **Agreement** for the licensing of rights to these inventions.

1.4 The **NIH** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 The **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.1 "**Affiliate(s)**" means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.

2.2 "**Benchmarks**" mean the performance milestones that are set forth in Appendix D.

2.3 "**Commercial Development Plan**" means the written commercialization plan attached as Appendix E.

2.4 "**CRADA"** means a Cooperative Research and Development Agreement.

2.5 "**FDA**" means the Food and Drug Administration.

2.6 "**First Commercial Sale**" means the initial transfer by or on behalf of the **Licensee** or its sublicensees of the **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of the **Licensee** or its sublicensees in a country after obtaining regulatory approval by the U.S. Food and Drug Administration or any foreign equivalent necessary for the marketing and sale of such **Licensed Product** or practice of such **Licensed Process** in exchange for cash or some equivalent consideration to which value can be assigned for the purpose of determining **Net Sales**.

2.7 "**Government**" means the Government of the United States of America.

2.8 "**Licensed Fields of Use**" means the fields of use identified in Appendix B.

2.9 "**Licensed Patent Rights**" shall mean:

(a) Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of these patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.9(a):

(i) continuations-in-part of 2.9(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations;

(iv) priority patent application(s) of 2.9(a); and

(v) any reissues, reexaminations, and extensions of these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.9(a): all counterpart foreign and U.S. patent applications and patents to 2.9(a) and 2.9(b), including those listed in Appendix A; and

(d) **Licensed Patent Rights** shall *not* include 2.9(b) or 2.9(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.9(a).

2.10 "**Licensed Processes**" means processes which, in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.11 "**Licensed Products**" means tangible materials which, in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.12 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.13 "**Net Sales**" means the total gross receipts received by **Licensee** for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of the **Licensee** or its sublicensees, and from leasing, renting, or otherwise making the **Licensed Products** available to others for consideration without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the **Licensee**, or sublicensees, and on its payroll, or for the cost of collections. "**Net Sales**" shall not include the supply of **Licensed Products** or use of **Licensed Processes**, for use in pre-clinical or clinical studies, or for process development, quality control or assurance, storage as safety stock, transfer as a charitable donation or any other transaction for which no gross revenue is received.

2.14 "**Practical Application**" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms not inconsistent with the terms applicable to similar products or processes and taking into account the efficacy and safety profile of the **Licensed Product** or the utility of the **Licensed Process** and other relevant commercial, scientific, technical and other factors.

2.15 "**Research License**" means a nontransferable, nonexclusive license to make and to use the **Licensed Products** or the **Licensed Processes** as defined by the **Licensed Patent Rights** for purposes of research only and not for purposes of commercial sale, manufacture or distribution or in lieu of purchase.

2.16 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by **Licensee** with respect to any objective, the reasonable, diligent, good faith efforts to accomplish such objective as **Licensee** would normally use to accomplish a similar objective under similar circumstances. It is understood and agreed that with respect to the research, development and sale of **Licensed Products** or **Licensed Process(es)** by **Licensee**, such efforts shall be substantially equivalent to those efforts and resources commonly used by **Licensee** for products owned by it or to which it has rights, which product is at a similar stage in its development or product life cycle. **Commercially Reasonable Efforts** shall be determined on a market-by-market basis, and it is anticipated that the level of effort will be different for different markets, and will change over time, reflecting changes in the status of the **Licensed Products** or **Licensed Process(es)** and the market(s) involved.

3. GRANT OF RIGHTS

3.1 The **NIH** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license to Group A of the **Licensed Patent Rights** and a non-exclusive license to Group B of the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Process(es)** in such **Licensed Fields of Use**.

3.2 The **NIH** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a non-exclusive license to Groups A and B of the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** (b-d) in Appendix B and to practice and have practiced any **Licensed Process(es)** in such **Licensed Fields of Use**.

3.3 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the **NIH** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

4. SUBLICENSING

4.1 Upon written approval, which shall include prior review of any sublicense agreement by the **NIH** and which shall not be unreasonably withheld or delayed, the **Licensee** may enter into sublicensing agreements under the **Licensed Patent Rights**.

4.2 The **Licensee** agrees that any sublicenses shall provide that the obligations to the **NIH** of Paragraphs 5.1-5.4, 8.1, 10.1, 10.2, 12.5, and 13.8-13.10 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement**. The **Licensee** further agrees to attach copies of these Paragraphs to all sublicense agreements.

4.3 Any sublicenses granted by the **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and the **NIH**, at the option of the sublicensee, upon termination of this **Agreement** under Article 13. This conversion is subject to the **NIH** approval, which will not be unreasonably denied or delayed. and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.

4.4 The **Licensee** agrees to forward to the **NIH** a complete copy of each fully executed sublicense agreement postmarked within thirty (30) days of the execution of the agreement. To the extent permitted by law, the **NIH** agrees to maintain each sublicense agreement in confidence.

5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1 (a) the **NIH** reserves on behalf of the **Government** an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of all inventions licensed under the **Licensed Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the **Government** is a signatory. Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the **NIH** with reasonable quantities of the **Licensed Products** or materials made through the **Licensed Processes** for **NIH** research use. Given the nature of the envisioned **Licensed Products** as personalized autologous cell therapy products, if any **Licensed Products** and/or materials made through the **Licensed Processes** are not available in reasonable quantities for **NIH** research use, they shall not be subject to the foregoing obligation; and

(b) in the event that the **Licensed Patent Rights** are Subject Inventions made under **CRADA**, the **Licensee** grants to the **Government**, pursuant to 15 U.S.C §3710a(b)(1)(A), a nonexclusive, nontransferable, irrevocable, paid-up license to practice the **Licensed Patent Rights** or have the **Licensed Patent Rights** practiced throughout the world by or on behalf of the **Government**. In the exercise of this license, the **Government** shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. §552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party. Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the **NIH** with reasonable quantities of the **Licensed Products** or materials made through the **Licensed Processes** for **NIH** research use. Given the nature of the envisioned **Licensed Products** as personalized autologous cell therapy products, if any **Licensed Products** and/or materials made through the **Licensed Processes** are not available in reasonable quantities for **NIH** research use, they shall not be subject to the foregoing obligation.

5.2 The **Licensee** agrees that products used or sold in the United States embodying the **Licensed Products** or produced through use of the **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the **NIH**.

5.3 The **Licensee** acknowledges that the **NIH** may enter into future **CRADAs** under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this **Agreement**. The **Licensee** agrees not to unreasonably deny requests for a **Research License** from future collaborators with the **NIH** when acquiring these rights is necessary in order to make a **CRADA** project feasible. The **Licensee** may request an opportunity to join as a party to the proposed **CRADA**.

5.4 (a) in addition to the reserved license of Paragraph 5.1, the **NIH** reserves the right to grant **Research Licenses** directly or to require the **Licensee** to grant **Research Licenses** on reasonable terms. The purpose of these **Research Licenses** is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the **Licensed Patent Rights**, however, the **NIH** shall consult with the **Licensee** before granting to commercial entities a **Research License** or providing to them research samples of materials made through the **Licensed Processes**; and

(b) in exceptional circumstances, and in the event that the **Licensed Patent Rights** are Subject Inventions made under a **CRADA**, the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(B), retains the right to require the **Licensee** to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the **Licensed Patent Rights** in the **Licensed Field of Use** on terms that are reasonable under the circumstances, or if the **Licensee** fails to grant this license, the **Government** retains the right to grant the license itself. The exercise of these rights by the **Government** shall only be in exceptional circumstances and only if the **Government** determines:

(i) the action is necessary to meet health or safety needs that are not reasonably satisfied by the **Licensee**;

(ii) the action is necessary to meet requirements for public use specified by Federal regulations, and these requirements are not reasonably satisfied by the **Licensee**; or

(iii) the **Licensee** has failed to comply with an agreement containing provisions described in 15 U.S.C. §3710a(c)(4)(B); and

(c) the determination made by the **Government** under this Paragraph 5.4 is subject to administrative appeal and judicial review under 35 U.S.C. §203(b).

6. ROYALTIES AND REIMBURSEMENT

6.1 The **Licensee** agrees to pay the **NIH** a noncreditable, nonrefundable license issue royalty as set forth in Appendix C.

6.2 The **Licensee** agrees to pay the **NIH** a nonrefundable minimum annual royalty as set forth in Appendix C.

6.3 The **Licensee** agrees to pay the **NIH** earned royalties as set forth in Appendix C.

6.4 The **Licensee** agrees to pay the **NIH** benchmark royalties as set forth in Appendix C.

6.5 The **Licensee** agrees to pay the **NIH** sublicensing royalties as set forth in Appendix C.

6.6 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that:

(a) the application has been abandoned and not continued;

(b) the patent expires or irrevocably lapses, or

(c) the patent has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

6.7 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.

6.8 On sales of the **Licensed Products** by the **Licensee** to sublicensees or on sales made in other than an arms-length transaction, the value of the **Net Sales** attributed under this Article 6 to this transaction shall be that which would have been received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.

6.9 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents to the extent included within the **Licensed Patent Rights** and paid by the **NIH** prior to the effective date of this **Agreement**, the **Licensee** shall pay the **NIH**, as an additional royalty, within sixty (60) days of the **NIH's** submission of a statement and request for payment to the **Licensee**, an amount equivalent to these unreimbursed expenses previously paid by the **NIH**.

6.10 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents to the extent included within the **Licensed Patent Rights** and paid by the **NIH** on or after the effective date of this **Agreement**, the **NIH**, at its sole option, may require the **Licensee**:

(a) to pay the **NIH** on an annual basis, within sixty (60) days of the **NIH's** submission of a statement and request for payment, a royalty amount equivalent to these unreimbursed expenses paid during the previous calendar year(s) provided, however, that if the **NIH** grants a commercialization license under the **Licensed Patent Rights** to one or more third parties, then the **Licensee** shall pay the **NIH** a pro-rated portion of such unreimbursed expenses calculated by dividing the total patent costs paid during the previous calendar year(s) by the number of commercialization licensees of record whose licenses have a **Licensed Field of Use** which includes the development of therapeutic or diagnostic products and falls within the scope of the **Licensed Patent Rights** as of the date of this statement. For avoidance of doubt, if the **Licensee** is the only commercialization licensee of record whose license has a **Licensed Field of Use** which includes the development of therapeutic or diagnostic products and falls within the scope of the **Licensed Patent Rights** as of the date of this statement, the **Licensee** shall pay **NIH** a royalty amount equivalent to one hundred percent (100%) of these unreimbursed expenses paid during the previous calendar year(s);

(b) to pay these unreimbursed expenses directly to the law firm employed by the **NIH** to handle these functions. However, in this event, the **NIH** and not the **Licensee** shall be the client of the law firm; or

(c) in limited circumstances, the **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights**. In that event, the **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide the **NIH** with copies of each invoice associated with these services as well as documentation that these invoices have been paid.

6.11 The **NIH** agrees, upon written request, to provide the **Licensee** with summaries of patent prosecution invoices for which the **NIH** has requested payment from the **Licensee** under Paragraphs 6.9 and 6.10. The **Licensee** agrees that all information provided by the **NIH** related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a third party (other than its **Affiliates**) except as required by law or a court of competent jurisdiction.

6.12 The **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon ninety (90) days written notice to the **NIH** and owe no payment obligation under Paragraph 6.10 for patent-related expenses incurred in that country after ninety (90) days of the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 Except as otherwise provided in this Article 7, the **NIH** agrees to take responsibility for, but to consult with, the **Licensee** in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall furnish copies of relevant patent-related documents to the **Licensee**.

7.2 Upon the **NIH's** written request, the **Licensee** shall assume the responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall, on an ongoing basis, promptly furnish copies of all patent-related documents to the **NIH**. In this event, the **Licensee** shall, subject to the prior approval of the **NIH**, select registered patent attorneys or patent agents to provide these services on behalf of the **Licensee** and the **NIH**. The **NIH** shall provide appropriate powers of attorney and other documents necessary to undertake this action to the patent attorneys or patent agents providing these services. The **Licensee** and its attorneys or agents shall consult with the **NIH** in all aspects of the preparation, filing, prosecution and maintenance of patent applications and patents included within the **Licensed Patent Rights** and shall provide the **NIH** sufficient opportunity to comment on any document that the **Licensee** intends to file or to cause to be filed with the relevant intellectual property or patent office.

7.3 At any time, after **Licensee** has assumed responsibility for the preparation, filing, prosecution, and maintenance of **Licensed Patent Rights** as provided in Section 7.2, the **NIH** may provide the **Licensee** with written notice that the **NIH** wishes to re-assume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**. If the **NIH** elects to reassume these responsibilities, the **Licensee** agrees to cooperate fully with the **NIH**, its attorneys, and agents in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and to provide the **NIH** with complete copies of any and all documents or other materials in **Licensee's** possession or control that the **NIH** deems necessary to undertake such responsibilities. The **Licensee** shall be responsible for all costs associated with transferring patent prosecution responsibilities to an attorney or agent of the **NIH's** choice.

7.4 Each party shall promptly inform the other as to all material matters that come to its attention that may affect the preparation, filing, prosecution, or maintenance of the **Licensed Patent Rights** and permit each other to provide comments and suggestions with respect to the preparation, filing, prosecution, and maintenance of the **Licensed Patent Rights**, which comments and suggestions shall be considered by the other party.

8. RECORD KEEPING

8.1 The **Licensee** agrees to keep accurate and correct records of the **Licensed Products** made, used, sold, or imported and the **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due the **NIH**. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection, at the expense of the **NIH**, by an accountant or other designated auditor selected by the **NIH** for the sole purpose of verifying reports and royalty payments hereunder. Licensee may require such auditor or accountant to enter into a confidentiality agreement with Licensee containing reasonable terms and conditions for the protection of Licensee's non-public and proprietary information. The accountant or auditor shall only disclose to the **NIH** information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then the **Licensee** shall reimburse the **NIH** for the cost of the inspection at the time the **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within sixty (60) days of the date the **NIH** provides to the **Licensee** notice of the payment due.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.1 Prior to signing this **Agreement**, the **Licensee** has provided the **NIH** with the **Commercial Development Plan** in Appendix E, under which the **Licensee** intends to use **Commercially Reasonable Efforts** to bring **Licensed Product(s)** or **Licensed Process(es)** within the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix D.

9.2 The **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for each of the **Licensed Fields of Use** within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, sublicensing, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. The **NIH** also encourages these reports to include information on any of the **Licensee's** public service activities that relate to the **Licensed Patent Rights**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, the **Licensee** shall explain the reasons for these differences. In the annual report, the **Licensee** may propose amendments to the **Commercial Development Plan**, acceptance of which by the **NIH** may not be denied unreasonably. The **Licensee** agrees to provide any additional information reasonably required by the **NIH** to evaluate the **Licensee's** performance under this **Agreement**. The **Licensee** may amend the **Benchmarks** at any time upon written approval by the **NIH**. The **NIH** shall not unreasonably withhold approval of any request of the **Licensee** to extend the time periods of this schedule if the request is supported by a reasonable showing by the **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application** as defined in 37 C.F.R. §404.3(d). The **Licensee** shall amend the **Commercial Development Plan** and **Benchmarks** at the request of the **NIH** to address any **Licensed Fields of Use** not specifically addressed in the plan originally submitted.

9.3 The **Licensee** shall report to the **NIH** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.

9.4 Following the **First Commercial Sale,** the **Licensee** shall submit to the **NIH**, within sixty (60) days after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of the **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, the **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to the **NIH** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of the **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.13 to determine **Net Sales** made under Article 6 to determine royalties due. The royalty report shall also identify the site of manufacture for the **Licensed Product(s)** sold in the United States.

9.5 The **Licensee** agrees to forward semi-annually to the **NIH** a copy of these reports received by the **Licensee** from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to the **NIH** by the **Licensee** for activities under the sublicense.

9.6 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day preceding the day that the payment is due. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the **Licensee**. The royalty report required by Paragraph 9.4 shall be mailed to the **NIH** at its address for **Agreement** Notices indicated on the Signature Page.

9.7 The **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay the tax and be responsible for all filings with appropriate agencies of foreign governments. As reasonably requested by **Licensee**, **NIH** shall cooperate with **Licensee** in applying for any valid exemption or obtaining any valid refund of such taxes paid by **Licensee**.

9.8 Additional royalties may be assessed by the **NIH** on any payment that is more than ninety (90) days overdue at the rate of **[* * *]** per month. This **[* * *]** per month rate may be applied retroactively from the original due date until the date of receipt by the **NIH** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the **NIH** from exercising any other rights it may have as a consequence of the lateness of any payment.

9.9 All plans and reports required by this Article 9 and marked "confidential" by the **Licensee** shall, to the extent permitted by law, be treated by the **NIH** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **NIH** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 C.F.R. §5.65(d).

10. PERFORMANCE

10.1 The **Licensee** shall use its **Commercially Reasonable Efforts** to bring the **Licensed Products** and the **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include reasonable adherence to the **Commercial Development Plan** in Appendix E and performance of the **Benchmarks** in Appendix D in each case as either may be amended from time to time. The efforts of a sublicensee or an **Affiliate** of **Licensee** shall be considered the efforts of the **Licensee**.

10.2 Upon the **First Commercial Sale** in the United States, until the expiration or termination of this **Agreement**, the **Licensee** shall use its **Commercially Reasonable Efforts** to make the **Licensed Products** and the **Licensed Processes** reasonably accessible to the United States public.

10.3 The **Licensee** agrees, after its **First Commercial Sale,** to make reasonable quantities of the **Licensed Products** or materials produced through the use of the **Licensed Processes** within the **Licensed Fields of Use** available to patient assistance programs.

10.4 The **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.

10.5 The **Licensee** agrees to supply, to the Mailing Address for **Agreement** Notices indicated on the Signature Page, the Office of Technology Transfer, **NIH** with inert samples of the **Licensed Products** or the **Licensed Processes** or their packaging for educational and display purposes only.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.1 The **NIH** and the **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as, any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either party becomes aware.

11.2 Pursuant to this **Agreement** and the provisions of 35 U.S.C. Chapter 29, the **Licensee** may:

(a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the **Licensed Patent Rights**;

(b) in any suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; or

(c) settle any claim or suit for infringement of the **Licensed Patent Rights** provided, however, that the **NIH** and appropriate **Government** authorities shall have the first right to take such actions; and

(d) if the **Licensee** desires to initiate a suit for patent infringement, the **Licensee** shall notify the **NIH** in writing. If the **NIH** does not notify the **Licensee** of its intent to pursue legal action within ninety (90) days, the **Licensee** shall be free to initiate suit. The **NIH** shall have a continuing right to intervene in the suit. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any suit for patent infringement. The **Licensee** may request the **Government** to initiate or join in any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of the motion or other action, including all costs incurred by the **Government** in opposing the motion or other action. In all cases, the **Licensee** agrees to keep the **NIH** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **NIH** and give careful consideration to the views of the **NIH** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.3 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the **Licensed Patent Rights** shall be brought against the **Licensee** or raised by way of counterclaim or affirmative defense in an infringement suit brought by the **Licensee** under Paragraph 11.2, pursuant to this **Agreement** and the provisions of 35 U.S.C. Part 29 or other statutes, the **Licensee** may:

(a) defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the **Licensed Patent Rights**;

(b) in any suit, ultimately to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; and

(c) settle any claim or suit for declaratory judgment involving the **Licensed Patent Rights**-provided, however, that the **NIH** and appropriate **Government** authorities shall have the first right to take these actions and shall have a continuing right to intervene in the suit; and

(d) if the **NIH** does not notify the **Licensee** of its intent to respond to the legal action within a reasonable time, the **Licensee** shall be free to do so. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. The **Licensee** may request the **Government** to initiate or to join any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit by motion or any other action of the **Licensee**, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. If the **Licensee** elects not to defend against the declaratory judgment action, the **NIH**, at its option, may do so at its own expense. In all cases, the **Licensee** agrees to keep the **NIH** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **NIH** and give careful consideration to the views of the **NIH** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.4 In any action under Paragraphs 11.2 or 11.3 the expenses including costs, fees, attorney fees, and disbursements, shall be paid by the **Licensee**. The value of any recovery made by the **Licensee** through court judgment or settlement actually collected shall first be applied by **Licensee** to reimburse it for all of its costs and expenses (including attorneys' fees, expert witness fees, and any reimbursement payments made to **NIH** or the **Government**) and the balance shall be treated as **Net Sales** and subject to earned royalties as provided in Appendix C when and as collected.

11.5 The **NIH** shall cooperate fully with the **Licensee** in connection with any action under Paragraphs 11.2 or 11.3. The **NIH** agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by the **Licensee**.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1 The **NIH** offers no warranties other than those specified in Article 1.

12.2 The **NIH** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.3 THE **NIH** MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.

12.4 The **NIH** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

12.5 The **Licensee** shall indemnify and hold the **NIH**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

(a) the use by or on behalf of the **Licensee**, its sublicensees, directors, employees, or third parties of any **Licensed Patent Rights**; or

(b) the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes** or materials by the **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.

12.6 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 14.16 are not fulfilled, and shall extend to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.

13.2 In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, or if not reasonably capable of remedy within such period, **Licensee** has not taken substantial steps to remedy the alleged default within such ninety (90) day period, the **NIH** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

13.3 In the event that the **Licensee (i)** becomes insolvent, (ii) files a petition in bankruptcy, or has such a petition filed against it and, in either case, such petition is not dismissed within sixty (60) days, the **Licensee** shall immediately notify the **NIH** in writing.

13.4 The **Licensee** shall have a unilateral right to terminate this **Agreement** or any licenses in any country or territory by giving the **NIH** sixty (60) days written notice to that effect.

13.5 The **NIH** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if the **NIH** determines that the **Licensee**:

(a) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to the **NIH's** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve the **Practical Application** of the **Licensed Products** or the **Licensed Processes**;

(b) has not achieved and is not reasonably likely to achieve the **Benchmarks** as may be modified under Paragraph 9.2;

(c) has willfully made a material false statement of, or willfully omitted a material fact in the license application or in any report required by this **Agreement**;

(d) has committed a material breach of a covenant or agreement contained in this **Agreement**;

(e) is not keeping the **Licensed Products** or the **Licensed Processes** within the scope of the **Licensed Fields of Use** reasonably accessible to the public after commercial use commences;

(f) cannot reasonably satisfy unmet health and safety needs; or

(g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2 unless waived.

13.6 In making the determination referenced in Paragraph 13.5, the **NIH** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by the **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, the **NIH** shall give written notice to the **Licensee** providing the **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, the **NIH's** concerns as to the items referenced in 13.5(a)-13.5(g). If the **Licensee** fails to alleviate the **NIH's** reasonable concerns as to the items referenced in 13.5(a)-13.5(g) or fails to initiate corrective action to the **NIH's** reasonable satisfaction, the **NIH** may terminate this **Agreement**.

13.7 When the public health and safety so require, and after written notice to the **Licensee** providing the **Licensee** a sixty (60) day opportunity to respond, the **NIH** shall have the right to require the **Licensee** to grant sublicenses to responsible applicants, on commercially reasonable terms, in any **Licensed Fields of Use** under the **Licensed Patent Rights**, unless the **Licensee** can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the **Licensed Patent Rights**. The **NIH** shall not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with the **Licensee** for a sublicense on commercially reasonable terms and conditions.

13.8 The **NIH** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** if it is determined that this action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the **Licensee**.

13.9 Within thirty (30) days of receipt of written notice of the **NIH's** unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of 37 C.F.R. §404.11, appeal the decision by written submission to the designated **NIH** official. The decision of the designated **NIH** official shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

13.10 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expenses, due to the **NIH** shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with the **NIH** pursuant to Paragraph 4.3. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, the **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to the **NIH** or provide the **NIH** with certification of the destruction thereof. The **Licensee** may not be granted additional **NIH** licenses if the final reporting requirement is not fulfilled.

14. GENERAL PROVISIONS

14.1 Neither party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by that party or excuse a similar subsequent failure to perform any of these terms or conditions by the that party.

14.2 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, the **Licensed Products** and the **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

14.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

14.4 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

14.5 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

14.6 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by the other party. **Agreement** notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

14.7 This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the **Licensee's Affiliate(s)** without the prior written consent of the **NIH**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable. In the event that the **NIH** approves a proposed assignment, the **Licensee** shall pay the **NIH**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this **Agreement** within sixty (60) days of the assignment.

14.8 The **Licensee** agrees in its use of any **NIH**-supplied biological materials that are supplied under this Agreement to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use such biological materials for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. The **Licensee** agrees not to use such biological materials for research involving human subjects or clinical trials outside of the United States without notifying the **NIH**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the **NIH** of research involving such biological materials in human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of the research or trials.

14.9 The **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of these items may require a license from the appropriate agency of the U.S. **Government** or written assurances by the **Licensee** that it shall not export these items to certain foreign countries without prior approval of this agency. The **NIH** neither represents that a license is or is not required or that, if required, it shall be issued.

14.10 The **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All the **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve the **NIH's** patent rights in those countries.

14.11 By entering into this **Agreement**, the **NIH** does not directly or indirectly endorse any product or service provided, or to be provided, by the **Licensee** whether directly or indirectly related to this **Agreement**. The **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, the **NIH**, any other **Government** organizational unit, or any **Government** employee. Additionally, the **Licensee** shall not use the names of the **NIH**, the **FDA** or the **HHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of the **NIH**.

14.12 The parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. The **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **NIH** official, or designee, whose decision shall be considered the final agency decision. Thereafter, the **Licensee** may exercise any administrative or judicial remedies that may be available.

14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 C.F.R. Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.14 Any formal recordation of this **Agreement** required by the laws of any **Licensed Territory** as a prerequisite to enforceability of the **Agreement** in the courts of any foreign jurisdiction or for other reasons shall be carried out by the **Licensee** at its expense, and appropriately verified proof of recordation shall be promptly furnished to the **NIH**.

14.15 Paragraphs 4.3, 8.1, 9.5-9.8, 9.9 12.1-12.5, 13.9, 13.10, 14.12 and 14.15 of this **Agreement** shall survive termination of this **Agreement**.

14.16 The terms and conditions of this **Agreement** shall, at the **NIH's** sole option, be considered by the **NIH** to be withdrawn from the **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by the **NIH** within sixty (60) days from the date of the **NIH's** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

NIH PATENT LICENSE AGREEMENT – *EXCLUSIVE*

SIGNATURE PAGE

For the **NIH**:

/S/ RICHARD U. RODRIGUEZ — 02/09/15
Richard U. Rodriguez — Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address or E-mail Address for **Agreement** notices and reports:

Chief, Monitoring & Enforcement Branch
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

E-mail: LicenseNotices_Reports@mail.nih.gov

For the **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in this document are truthful and accurate.):

by:

/S/ ELMA HAWKINS — 02/09/15
Signature of Authorized Official — Date

Elma Hawkins, Ph.D.
Printed Name

President and CEO
Title

I. Official and Mailing Address for **Agreement** notices:

Peter Ho, Ph.D.
Director, Business Development
21900 Burbank Blvd., 3rd Floor
Woodland Hills, CA 91367
Phone: 818-992-3127
Fax: 818-475-5194
Email: peter.ho@lionbio.com

II. Official and Mailing Address for Financial notices (the **Licensee's** contact person for royalty payments)

Peter Ho, Ph.D.
Director, Business Development
21900 Burbank Blvd., 3rd Floor
Woodland Hills, CA 91367
Phone: 818-992-3127
Fax: 818-475-5194
Email: peter.ho@lionbio.com

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

Group A

I. U.S. Provisional Patent Application No. 61/237,889, filed August 26, 2009 entitled "Adoptive cell therapy with young T cells" (HHS Ref No. E-273-2009/0-US-01);

II. U.S. Patent No. 8,383,099 issued February 26, 2013 entitled "Adoptive cell therapy with young T cells" (HHS Ref No. E-273-2009/0-US-02);

III. U.S. Patent Application No. 13/742,541 filed January 16, 2013 entitled "Adoptive cell therapy with young T cells" (HHS Ref No. E-273-2009/0-US-03);

IV. U.S. Provisional Patent Application No. 61/466,200 filed March 22, 2011entitled "Methods of growing tumor infiltrating lymphocytes in gas-permeable containers" (HHS Ref No. E-114-2011/0-US-01);

V. PCT Application No. PCT/US2012/029744 filed March 20, 2012 entitled "Methods of growing tumor infiltrating lymphocytes in gas-permeable containers" (HHS Ref No. E-114-2011/0-PCT-02);

VI. U.S. Patent Application No. 13/424,646 filed May 20, 2012 entitled "Methods of growing tumor infiltrating lymphocytes in gas-permeable containers" (HHS Ref No. E-114-2011/0-US-03);

Group B

I. U.S. Provisional Patent Application No. 60/408,681, filed September 6, 2002 entitled "Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy" (HHS Ref No. E-275-2002/0-US-01);

II. PCT Application No. PCT/US2012/029744 filed September 5, 2003 entitled "Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy" (HHS Ref No. E-275-2002/1-PCT-01);

III. U.S. Patent No. 8,034,334 issued October 11, 2011 entitled "Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy" (HHS Ref No. E-275-2002/1-US-02);

IV. European Patent Application No. 03794636.5 filed April 4, 2005 entitled "Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy" (HHS Ref No. E-275-2002/1-EP-03);

V. Canadian Patent No. 2,497,552 issued May 27, 2014 entitled "Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy" (HHS Ref No. E-275-2002/1-CA-04);

VI. Australian Patent No. 2003265948 issued September 3, 2009 entitled "Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy" (HHS Ref No. E-275-2002/1-AU-05);

VII. U.S. Patent No. 8,287,857 issued October 16, 2012 entitled "Immunotherapy with in vitro-selected antigen-specific lymphocytes after nonmyeloablative lymphodepleting chemotherapy" (HHS Ref No. E-275-2002/1-US-06);

APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

I. **Licensed Fields of Use:**

(a) The use of the **Licensed Patent Rights** to develop, manufacture, and sale autologous tumor infiltrating lymphocyte adoptive cell therapy products for the treatment of metastatic melanoma.

Tumor infiltrating lymphocytes (TIL) are a subset of T lymphocytes (T cells) that migrate and are located within a tumor site. TIL isolated from these tumor sites exhibit natural anti-tumor activity without genetic modifications. For the avoidance of doubt, cell therapy products involving genetically modified TIL or TIL isolated by cancer-specific mutations are excluded from the **Licensed Fields of Use**, unless the cell therapy products are a combination of TIL therapy with the **Licensee's** proprietary technologies or the **Licensee's** in-licensed technologies.

II. **Licensed Territory:** Worldwide

APPENDIX C – ROYALTIES

Royalties:

I. The **Licensee** agrees to pay to the **NIH** a noncreditable, nonrefundable license issue royalty in the amount of **[* * *]** within sixty (60) days from the effective date of this **Agreement.**

II. The **Licensee** agrees to pay to the **NIH** a nonrefundable minimum annual royalty in the amount of **[* * *]**as follows:

(a) The first minimum annual royalty is due within sixty (60) days of the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1; and

(b) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year.

(c) In the case of each of (a) and (b) above, such payments shall be due so long as **Licensee** has not terminated this Agreement pursuant to Paragraph 13.4.

III. The **Licensee** agrees to pay the **NIH** earned royalties of **[* * *]** on **Net Sales** by or on behalf of **Licensee** or its sublicensees. **Licensee** shall be entitled to a credit of **[* * *]** against the earned royalty rate for each percent point in excess of **[* * *]** that **Licensee** must pay to an unaffiliated licensor(s) for the manufacture and sale of **Licensed Product(s)** and **Licensed Process(es)**. Said credit however, shall not reduce the earned royalty rate due to **NIH** for **Licensed Product(s)** and **Licensed Process(es)** below **[* * *]**.

IV. The **Licensee** agrees to pay the **NIH Benchmark** royalties within sixty (60) days of achieving each **Benchmark** by **Licensee** or its sublicensees for each **Licensed Product**:

(a) **[* * *]** for successful completion of the first **Licensee**-sponsored Phase 2 clinical study.

(b) **[* * *]** for successful completion of the first **Licensee**-sponsored Phase 3 clinical study.

(c) **[* * *]** upon the first FDA approval or foreign equivalent for a **Licensed Product** or **Licensed Process**.

(d) **[* * *]** for the First Commercial Sale of a **Licensed Product** or **Licensed Process** in the United States.

(e) **[* * *]** for the First Commercial Sale of a Licensed Product or Licensed Process in any foreign country for either of Licensed Field of Use.

For purposes of this **Agreement**, "successful completion of a **Licensee**-sponsored Phase 2 Clinical Study" shall mean, with respect to a specified construct, formulation and dose of a specified **Licensed Product** in a specified cancer indication, the statistical demonstration in a pivotal Phase 2 Clinical Study of safety and efficacy, sufficient to support a Phase 3 clinical trial submission by the **Licensee** for such specified construct, formulation and dose of such specified **Licensed Product** for the treatment of such specified cancer indication.

For purposes of this **Agreement**, "successful completion of a **Licensee**-sponsored Phase 3 Clinical Study" shall mean, with respect to a specified construct, formulation and dose of a specified **Licensed Product** in a specified cancer indication, the statistical demonstration in a pivotal Phase 3 Clinical Study of safety and efficacy, sufficient to support a BLA submission by the **Licensee** for such specified construct, formulation and dose of such specified **Licensed Product** for the treatment of such specified cancer indication.

V. The **Licensee** agrees to pay the **NIH**:

(a) additional sublicensing royalties of **[* * *]** on the fair market value of any consideration received for granting each sublicense within sixty (60) days of the execution of each sublicense if any such sublicense is executed prior to FDA approval or foreign equivalent for a Licensed Product or Licensed Process within each Licensed Field of Use from Appendix B; and

(b) additional sublicensing royalties of **[* * *]** on the fair market value of any consideration received for granting each sublicense within sixty (60) days of the execution of each sublicense if any such sublicense is executed following FDA approval or foreign equivalent for a Licensed Product or Licensed Process within each Licensed Field of Use from Appendix B.

(c) Notwithstanding anything in this Agreement to the contrary, any such consideration will not include the following:

(1) Bona fide support research and development activities corresponding directly to the development of **Licensed Product(s)** and/or **Licensed Process(es),** which do not exceed Licensee's fully-burdened cost for undertaking such research and development, and limited to support which is received after the effective date of this Agreement specifically excluding any support which is used by Licensee to offset research and development expenses which are incurred prior to the effective date of this Agreement;

(2) Proceeds derived from debt financing received after the effective date of this Agreement, to the extent that such financing is at market rates;

(3) Consideration received after the effective date of this Agreement for the purchase of an equity interest in Licensee to the extent that the price per share paid for such equity does not exceed by more than twenty-five pecent (25%) the average closing price of such equity on the stock exchange for the thirty (30) consecutive business days immediately preceding the date on which said stock is transferred, or if such equity is not so traded, then the fair market value of such equity as reasonably agreed to by the parties or as determined in the same financing round involving non-sublicensee investors;

(4) As earned royalties on Net Sales or sales by sublicensee(s); and

(5) Any non-monetary consideration which is specifically in the form of license(s) received in exchange for the grant of a sublicense, if such license(s) are necessary or useful for the development of Licensed Product(s) and/or Licensed Process(es).

APPENDIX D – BENCHMARKS AND PERFORMANCE

The **Licensee** agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify the **NIH** that the **Benchmark** has been achieved.

	Benchmark	Deadline
I.	**[* * *]**	**[* * *]**
II.	**[* * *]**	**[* * *]**
III.	**[* * *]**	**[* * *]**
IV.	**[* * *]**	**[* * *]**
V.	**[* * *]**	**[* * *]**

APPENDIX E – COMMERCIAL DEVELOPMENT PLAN

Licensee intends to use the licensed technology to develop and commercialize a product based on T cells derived from tumors or tumor-infiltrating lymphocytes (TILs) to treat patients with melanoma, HPV cancers, bladder cancer, breast cancer, lung cancer, and other solid tumors.

In August 2011, **Licensee** entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) to develop and evaluate improved adoptive cell transfer (ACT) based immunotherapies using TILs to treat patients with metastatic melanoma utilizing the business development expertise and resources of **Licensee** (C-057-2011, NCI 02734). The CRADA includes the development of improved methods for the generation and selection of TIL, standard operating procedures (SOPs) for large-scale TIL growth, selection and testing to support the FDA approval of an ACT/TIL therapy approach. It further includes clinical trials designed and implemented to evaluate the clinical effectiveness of ACT/TIL therapy resulting from large-scale techniques in patients with metastatic melanoma based on the proprietary NCI Surgery Branch technology and approaches developed as part of the CRADA. In January 2015, **Licensee** and the NCI amended the CRADA to add HPV cancers (such as cervical, anal, and head and neck cancers), bladder cancer, breast cancer, and lung cancer.

The overall strategy for commercial development and program prioritization for an ACT/TIL product for the treatment of metastatic melanoma is summarized below:

[* * *]

APPENDIX F – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- OTT license reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

Example

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500
			Total Gross Sales	153,250
			Less Deductions:	
			Freight	3,000
			Returns	7,000
			Total Net Sales	143,250
			Royalty Rate	8%
			Royalty Due	11,460
			Less Creditable Payments	10,000
			Net Royalty Due	**1,460**

APPENDIX G – ROYALTY PAYMENT OPTIONS

The OTT License Number MUST appear on payments, reports and correspondence.

Automated Clearing House (ACH) for payments through U.S. banks only

The **NIH** encourages its licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). Submit your ACH payment through the U.S. Treasury web site located at: **https://www.pay.gov.** Locate the "**NIH** Agency Form" through the Pay.gov "Agency List".

Electronic Funds Wire Transfers

The following account information is provided for wire payments. In order to process payment via Electronic Funds Wire Transfer sender MUST supply the following information within the transmission:

Drawn on a **U.S. bank account** via FEDWIRE should be sent directly to the following account:

Beneficiary Account:	Federal Reserve Bank of New York or TREAS NYC
Bank:	Federal Reserve Bank of New York
ABA#	021030004
Account Number:	75080031
Bank Address:	33 Liberty Street, New York, NY 10045
Payment Details:	License Number (L-XXX-XXXX) Name of the Licensee

Drawn on a **foreign bank account** should be sent directly to the following account. Payment must be sent in **U.S. Dollars (USD)** using the following instructions:

Beneficiary Account:	Federal Reserve Bank of New York/ITS or FRBNY/ITS
Bank:	Citibank N.A. (New York)
SWIFT Code:	CITIUS33
Account Number:	36838868
Bank Address:	388 Greenwich Street, New York, NY 10013
Payment Details (Line 70):	NIH 75080031 License Number (L-XXX-XXXX) Name of the Licensee
Detail of Charges (line 71a):	Charge Our

Checks

All checks should be made payable to "NIH Patent Licensing"

Checks drawn on a **U.S. bank account** and sent by US Postal Service should be sent directly to the following address:

National Institutes of Health (**NIH**)
P.O. Box 979071
St. Louis, MO 63197-9000

Checks drawn on a U.S. bank account and sent by **overnight or courier** should be sent to the following address:

US Bank
Government Lockbox SL-MO-C2GL
1005 Convention Plaza
St. Louis, MO 63101
Phone: 314-418-4087

Checks drawn on a **foreign bank account** should be sent directly to the following address:

National Institutes of Health (**NIH**)
Office of Technology Transfer
Royalties Administration Unit
6011 Executive Boulevard
Suite 325, MSC 7660
Rockville, Maryland 20852

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Registration Statement No. 333-200418 on Form S-3 of Lion Biotechnologies, Inc. of our reports dated March 16, 2015, relating to the financial statements and effectiveness of internal control over financial reporting, which appear in this Form 10-K.

/s/ Weinberg & Company, P.A.

Los Angeles, California
March 16, 2015

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Elma Hawkins, certify that:

1. I have reviewed this Annual Report on Form 10-K of Lion Biotechnologies, Inc.

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

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

4. The registrant's other certifying officer 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 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.

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.

Date: March 16, 2015

/s/ Elma Hawkins
Elma Hawkins
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Handelman, certify that:

1. I have reviewed this Annual Report on Form 10-K of Lion Biotechnologies, Inc.

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

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

4. The registrant's other certifying officer 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 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.

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.

Date: March 16, 2015

/s/ Michael Handelman
Michael Handelman
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

I, Elma Hawkins, Chief Executive Officer of Lion Biotechnologies, Inc. (Company), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- the Annual Report on Form 10-K of the Company for the year ended December 31, 2014 (Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: March 16, 2015

/s/ Elma Hawkins
Elma Hawkins
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

I, Michael Handelman, Chief Financial Officer of Lion Biotechnologies, Inc. (Company), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- the Annual Report on Form 10-K of the Company for the year ended December 31, 2014 (Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: March 16, 2015

/s/ Michael Handelman
Michael Handelman
Chief Financial Officer
(Principal Financial Officer)