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

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015
or

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

For the transaction period from _____ to _____

Commission file number: 001-36860

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.)
112 West 34th Street, 17th Floor, New York, New York	**10120**
(Address of Principal Executive Offices)	(Zip Code)

(212) 946-4856
(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. Yes ☐ No ☒

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, 2015, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $314,385,000. 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 February 29, 2016, there were 48,567,720 shares of the registrant's common stock outstanding.

Documents Incorporated By Reference

Portions of registrant’s proxy statement relating to registrant’s 2016 annual meeting of stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the close of the registrant’s fiscal year, are incorporated by reference in Part III of this annual report on Form 10-K.

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“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, expectations about the trials, regulatory approvals, manufacturing arrangements, 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

Overview

We are a clinical-stage biotechnology 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. We are also pursuing the development of TIL for other solid tumor cancer indications. In February 2016, we announced that the US Food and Drug Administration (FDA) allowed our Investigational New Drug (IND) application to conduct clinical studies using our TIL therapy in cervical and head and neck cancers, we plan to initiate clinical trials in at least one of these indications during 2016.

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 better able to search out and potentially eradicate the tumor.

During the second half of 2015, we opened enrollment in a Phase 2 clinical trial of our lead product candidate, LN-144, for the treatment of refractory metastatic melanoma. This single-arm study is for patients with metastatic melanoma whose disease has progressed following treatment with at least one systemic therapy. The trial opened for enrollment during the second half of 2015 and will be conducted at up to ten sites. The purpose of the study is to evaluate the safety, efficacy and feasibility of our autologous TIL infusion (LN-144). The trial's primary endpoints include safety and feasibility of LN-144 production using our central manufacturing process. Secondary outcome measures include an additional feasibility measure of number of patients successfully infused with LN-144 and the best overall response rate.

In September 2015, Dr. Steven Rosenberg, M.D., Ph.D., Chief of the Surgery Branch of the National Cancer Institute (NCI) and a recognized pioneer in immuno-oncology and adoptive cell therapy using TIL, presented updated data from a Phase 2 clinical trial of TIL therapy in metastatic melanoma at the American Association for Cancer Research Inaugural International Cancer Immunotherapy Conference. Data was presented from a 101 patient, Phase 2 clinical trial conducted at the NCI. In the trial, patients with advanced metastatic melanoma were equally divided in two groups. Both groups were treated according to standard TIL protocol using chemo-ablation, with the second group also receiving total body irradiation. 54% of the patients 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. Out of the 101 patients, 24 (24%) had experienced a complete remission and 23 of the 24 (96%) showed durability of this response at 30 to 47 months following treatment. Median follow-up time was approximately 35 months. Overall survival (OS) was approximately 80% at 12 months, and median OS had not yet been achieved. Median progression-free survival was approximately 10 months, and 35% of patients were without disease progression at 4 years.

In further support of our internal research and clinical development activities, 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 TIL research and clinical trials that are being conducted by Dr. Steven Rosenberg. This five-year CRADA expires in August 2016 unless the parties agree to extend it. We anticipate that we will begin discussions to renew the agreement with the NCI during the first half of 2016.

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, which was amended in 2015 to include the exclusive license of this intellectual property for the treatment of lung cancer, HPV-associated cancers, breast cancer, and bladder cancer. We also have an exclusive license from the NIH for intellectual property relating to a TIL-based therapy for use in melanoma in which TIL that express various inhibitory receptors such as 4-1BB (also known as CD137), PD-1, TIM-3 and LAG-3 are selected and expanded for infusion into the patient. TIL that express these proteins are associated with higher tumor reactivity than other TIL populations, so fewer cells may be needed to be therapeutically effective.

During 2015, we received orphan drug designation for LN-144 in the United States to treat metastatic melanoma. This designation provides 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 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 74,000 patients diagnosed and 9,900 deaths each year in the United States according to the American Cancer Society's Cancer Estimated 2015 Facts and Figures. According to the NCI's Surveillance, Epidemiology and End Results (SEER) program, about 4-7% 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 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 112 West 34th Street, 18th Floor, New York, New York 10120, and our telephone number at that address is (212) 946-4856. 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 21, 2015 we announced a collaboration to conduct clinical and preclinical research in immuno-oncology with MedImmune. Lion will fund and conduct two Phase 2 clinical trials combining MedImmune's investigational PD-L1 inhibitor durvalumab with TIL for the treatment of patients with metastatic melanoma and head and neck cancer.

On December 31, 2015, we filed an IND application with the FDA seeking authorization to initiate a company-sponsored, multicenter Phase 2 study of LN-145 for the treatment of cervical cancer and head and neck squamous cell carcinoma (HNSCC).

On February 1, 2016 we announced the allowance of our IND by the FDA to begin clinical trials in cervical cancer, and head and neck squamous cell carcinoma (HNSCC).

On February 4, 2016 we announced the hiring of Dr. Steven Fischkoff as our Chief Medical Officer.

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 began enrollment of this study in the second half of 2015.

If data from this company-sponsored Phase 2 trial are consistent with previous results from the NCI, we will initiate a multicenter, registration trial. Assuming the results from the registration trial are positive, we will discuss with the FDA the filing of a Biologic License Application (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 an objective response rate, because such response rate is considered reasonably likely to predict a real clinical benefit of longer life. We believe our accelerated approval strategy may 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 by the FDA.

Continue collaboration with our partners, and increase our internal research and development activities, to improve and develop adoptive cell therapy technologies

Since September 2014, we have hired 12 positions within our research and development group in addition to opening our R&D facility in Tampa, Florida. We anticipate further hiring in 2016 in support of expanding our research activities. In addition, our Cooperative Research and Development Agreement (“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. In early 2016, we received the allowance of our IND in head and neck cancer and cervical cancer. The INDs are 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 work 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, and obtain regulatory marketing approval for 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 capabilities of current and future pipeline products

We continue to invest in improving the process and efficiency of manufacturing our product candidates. We plan to use contract manufacturing organizations (CMOs) to supply our TIL-based products for our clinical trials in the near term. 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 cost structure, and reduce the long-term cost of manufacturing our products, although there can be no assurance that we will be able to reduce our manufacturing costs to commercially attractive levels.

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, or not operating optimally, 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.

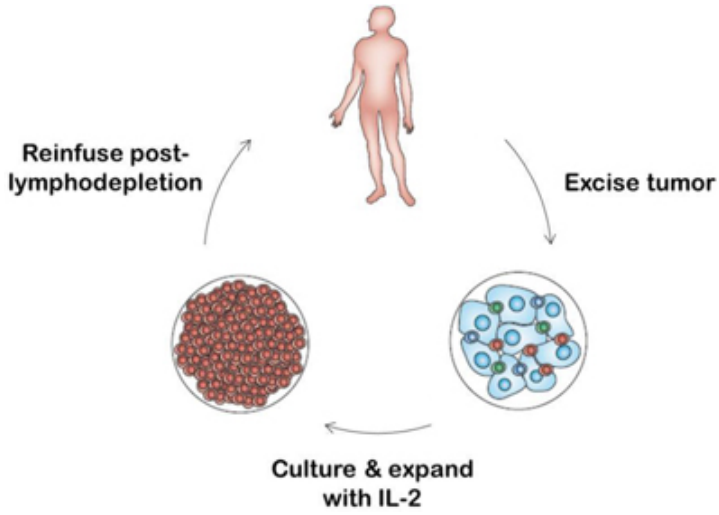
Cancer immunotherapy

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: (i) in many solid tumors, multiple genes (as many as hundreds of genes) are mutated, and solid tumors are heterogeneous, (ii) it is not always clear which particular mutations are critical, and (iii) 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 for cancer can be deleterious to T cells' ability to kill cancer.

We believe that 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 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 five to six 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.

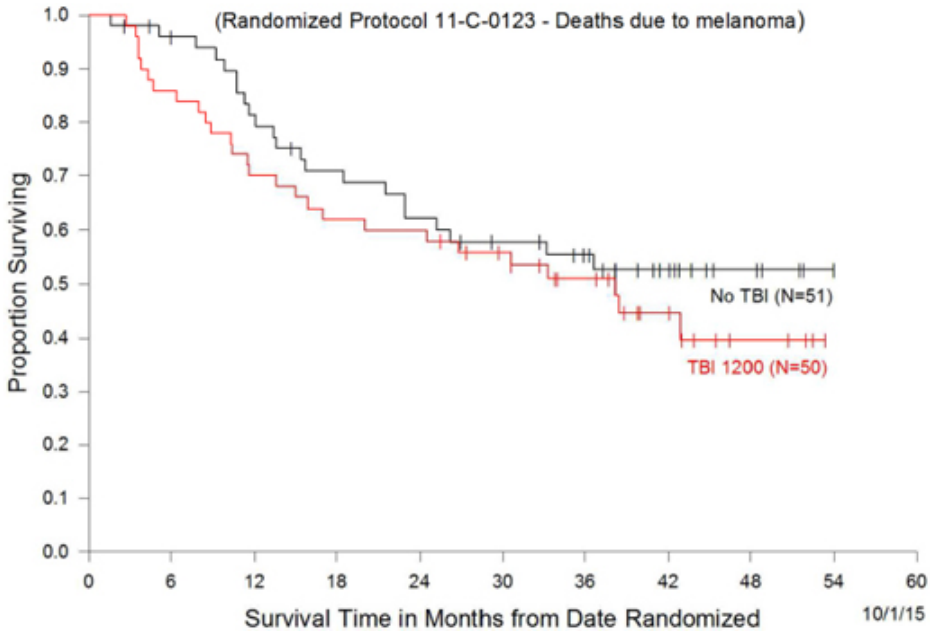


Clinical results with TIL in metastatic melanoma

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: approximately half of the melanoma patients treated with TIL have an objective response (i.e. tumor regression of 50% or more), and approximately 10-24 percent of patients have a complete response with no evidence of disease remaining after only one administration). Many patients respond to TIL therapy despite experiencing tumor progression after previously being treated with other therapies.

In September 2015, Dr. Steven Rosenberg, presented updated data from a Phase 2 clinical trial of Til therapy in metastatic melanoma at the American Association for Cancer Research Inaugural International Cancer Immunotherapy Conference. Data was presented from a 101-patient, Phase 2 clinical trial conducted at the NCI. In this trial, patients with advanced metastatic melanoma were equally divided in two groups. Both groups were treated according to standard TIL protocol using chemo-ablation, with the second group also receiving total body irradiation. 54% of the patients 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. Out of the 101 patients, 24 (24%) had experienced a complete remission and 23 of the 24 patients (96%) showed durability of this response at 30 to 47 months following treatment. Median follow-up time was approximately 35 months. Overall survival (OS) was approximately 80% at 12 months, and median OS had not yet been achieved. Median progression-free survival was approximately 10 months, and 35% of patients were without disease progression at 4 years. The chart below shows the overall response rate at 54 months as of October 1, 2015 including the results of those patients receiving total body irradiation (TBI) and those that didn't.

Survival of Patients with Metastatic Melanoma Treated with Autologous Tumor Infiltrating Lymphocytes and IL-2



Source: Steven A. Rosenberg, Society of Immunotherapy of Cancer, 2015

In a publication in Clinical Cancer Research in July 2011, data was presented from 93 patients with metastatic melanoma who were treated at the NCI with TIL therapy (after a lymphodepletion regimen of either chemotherapy alone or with two different doses of radiation) followed by IL-2. Of these patients, 20 out of 93 (22%) achieved a complete tumor regression, and 32 (34%) patients achieved a partial remission for a total overall response rate of 56%, 19 of the 20 complete response patients were reported to have ongoing complete responses beyond three years. The 5-year survival rate of 29% for all 93 patients was similar regardless of prior treatment, with the possible exception of the 5-year survival rate of 44% for the 11 patients who progressed after receiving prior anti-CTLA4 treatment.

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 providing research and development funding to the NCI for the development of TIL therapies for a variety of solid tumor indications, including cervical, head and neck, bladder, breast, and lung cancers. Depending on the data developed from these efforts, we expect to expand our product development efforts to develop TIL products for one or more of these other indications. In addition, at our research and development facility in Tampa, Florida, we are developing and evaluating a variety of technologies that can potentially improve the growth and potency of TIL.

LN-144

We are developing LN-144 to treat metastatic melanoma. Melanoma is a common type of skin cancer, accounting for approximately 76,800 patients diagnosed and 10,130 deaths each year in the United States according to the American Cancer Society, Cancer Facts and Figures estimates for 2015. 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.

The National Comprehensive Cancer Network (NCCN) has recently updated its recommendations for the treatment of patients with unresectable or metastatic melanoma. Initial therapy can include checkpoint inhibitors either alone or in combination (ipilimumab, nivolumab, pembrolimumab), targeted therapies for patients with BRAF mutations (dabrafenib/trametinib, vemurafenib/cobimetinib combinations or single agents) or a clinical trial. For patients not responding or progressing and having an adequate clinical status, agents selected from the previous list but of a different therapeutic class can be used as well as high dose IL-2 or a clinical trial. Patients who do not respond to the current second-line therapies have very few treatment options and typically have a very poor prognosis.

LN-145

We are developing LN-145 to treat cervical and head and neck cancers. In December 2015, we filed an IND application with the FDA to conduct clinical trials of LN-145 in these cancers, and in February, 2016 we announced that the IND was allowed thereby permitting us to begin clinical trials in these indications with our product. According to the American Cancer Society's Cancer Facts and Figures estimates for 2015, it is estimated that approximately 12,900 women are diagnosed in the United States every year with cervical cancer. If cervical cancer has spread to surrounding tissues or organs and/or the regional lymph nodes, the five-year survival rate is 57%. If the cancer has spread to a distant part of the body, the five-year survival rate is 16%. Head and neck cancer accounts for about 3% of all cancers in the United States. This year, an estimated 59,300 people (43,400 men and 15,900 women) will develop head and neck cancer. It is estimated that 12,300 deaths (8,900 men and 3,400 women) will occur in 2016.

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 20 patients with LN-144 for refractory metastatic melanoma. Patients with refractory disease are those who have not responded to other, non-TIL treatments. The trial's primary endpoints include safety, and feasibility of LN-144 production using our central manufacturing process. Secondary outcome measures include an additional feasibility measure of number of patients successfully infused with LN-144 and the best 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. At the end of 2015, we announced a collaboration to conduct clinical and preclinical research in immuno-oncology with MedImmune. Lion will fund and conduct two Phase 2a clinical trials combining MedImmune's investigational PD-L1 inhibitor durvalumab with LN-144 for the treatment of patients with metastatic melanoma, and LN-145 for head and neck cancer. These trials are expected to begin in 2016.

Additionally, at the end of 2015, we filed an Investigational New Drug (IND) application with the FDA to conduct clinical trials of LN-145 in the treatment of cervical cancer, and head and neck squamous cell carcinoma (HNSCC). In early 2016, the FDA allowed our IND application and we anticipate that we will begin enrolling a trial for at least one of these indications during 2016.

In addition to our company-sponsored and NCI-sponsored clinical trials, Moffitt is conducting a trial to evaluate TIL therapy in combination with ipilimumab or nivolumab in patients with metastatic melanoma.

Other TIL-based Product Candidates

Under our CRADA with the NCI, we are providing research and development and clinical funding for the development of TIL therapy for a variety of solid tumor indications, including cervical, head and neck, bladder, breast, and lung cancers. Some of the work being conducted by the NCI includes a clinical trial involving TIL therapy to treat advanced human papilloma virus (HPV)-positive cervical cancer. Data from this trial was published in the Journal of Clinical Oncology in April 2015. Out of 9 cervical cancer patients treated with HPV-TIL, two experienced complete remissions reported as ongoing at 22 and 15 months, respectively. Another patient experienced a three-month partial remission. Additionally, the NCI has an ongoing trial to treat patients using TIL within lung cancer; only a couple patients have been treated so far. Depending on results from the research and development and clinical trials conducted at the NCI, we will pursue the development and regulatory approval of TIL therapy for additional indications.

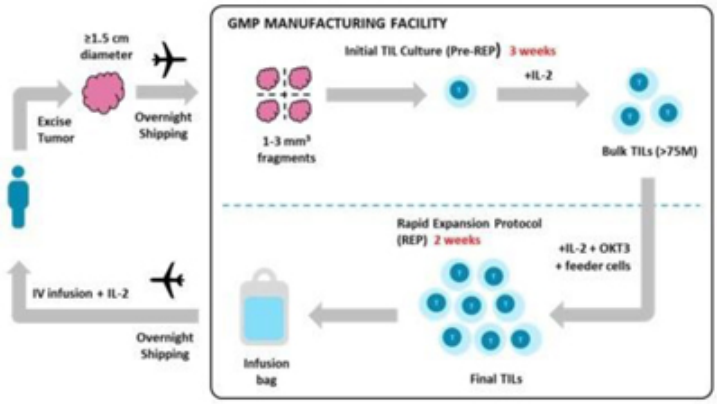
Selected TIL

The NCI also has a clinical trial ongoing to evaluate TIL selected for CD137 (also known as 4-1BB) expression to treat patients with metastatic melanoma. The NCI is working on a process to select TIL that express PD-1. This 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 the potential to reduce the time and cost of manufacturing.

Process development/manufacturing

Our manufacturing and processing of TIL-based product candidates is based on the NCI's original manufacturing and processing of TIL, which we have modified so that it can be reproduced in a Good Manufacturing Process (cGMP) environment. We believe we have streamlined and improved the NCI's original process to be able to produce TIL in a cGMP facility.

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 five to six 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 Manufacturing Services Agreements with Lonza Walkersville, Inc. (Lonza) and WuXi Apptech (WuXi) pursuant to which they have agreed to manufacture, package, ship and handle quality assurance and quality control of certain clinical trials for our TIL products. The production line for LN-144 is established at Lonza and is providing product for our Phase 2 trial in metastatic melanoma. We expect that the TIL production line at WuXi to be available to produce TIL product by the end of 2016. Cell processing activities will be conducted at both companies 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 and Wuxi to meet anticipated clinical trial demands. In the future, we may rely on them 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.

Commercialization plan

We currently have no sales, marketing or commercial product distribution capabilities and have limited experience as a company in marketing products. As we progress our clinical trials for our leading product candidates, we intend to further assess the costs and benefits associated with building our own sales and commercialization capabilities.

In the U.S., there are approximately 76,800 patients diagnosed with melanoma each year. About 4-7% 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.

Additionally, we are developing LN-145 to treat cervical and head and neck cancers. It is estimated that approximately 13,000 women are diagnosed in the U.S. every year with cervical cancer. If cervical cancer has spread to surrounding tissues or organs and/or the regional lymph nodes, the five-year survival rate is 57%. If the cancer has spread to a distant part of the body, the five-year survival rate is 16%. Head and neck cancer accounts for about 3% of all cancers in the U.S. This year, an estimated 59,000 people (43,000 men and 16,000 women) will develop head and neck cancer in this country. It is estimated that 12,000 deaths (9,000 men and 3,000 women) will occur in 2016 from this disease.

Outside the US, we have not yet defined our regulatory and commercial strategy for our TIL products. 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 infrastructure. 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, intellectual property protection and manufacturing needs may all influence our U.S., Europe and rest-of-world strategies.

Intellectual property

Intellectual property is of 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 an extensive freedom-to-operate (FTO) analysis of the current patent landscape with respect to our lead product candidate, and based on the analysis, 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.

Research, development and license agreements

Currently, our research and development is conducted with the NIH under the CRADA and at our own internal research and development laboratory in Tampa, Florida, near the H. Lee Moffitt Cancer & Research Institute (Moffitt) on the campus of the University of South Florida. See Part II—Item 7 —“Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this report for additional detail regarding our research and development activities.

National Institutes of Health and the National Cancer Institute Cooperative Research and Development Agreement

Effective August 5, 2011, we 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, we have been working with Dr. Steven A. Rosenberg, to develop adoptive cell immunotherapies that are designed to destroy metastatic melanoma cells using a patient’s tumor infiltrating lymphocytes.

On January 22, 2015, we entered into an amendment to the CRADA 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-up production and process development.

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 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. Although there can be no assurance, we anticipate that we will renew the agreement on similar terms. 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.

Development and Manufacture TIL

Effective October 5, 2011, we entered into a Patent 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”), which License Agreement was subsequently amended on February 9, 2015 and October 2, 2015. Pursuant to the License Agreement as amended, NIH granted to us an 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, bladder, lung, breast and HPV-associated cancers, including cervical and head and neck. The License Agreement requires us to pay royalties based on a percentage of net sales (which percentage is in the mid-single digits and 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 costs incurred by NIH pursuant to the agreement.

Exclusive Patent License Agreement

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 which was recognized as research and development expense during the year ended December 31, 2015. We also agreed 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 is a list of process and method patents and patent applications 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
9074185	Adoptive cell therapy with young T cells	US	Issued
14/771615	Methods of producing enriched populations of tumor-reactive t cells from tumor	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.

H. Lee Moffitt Cancer Center Research Collaboration Agreement

In September 2014, we entered into a two year research collaboration agreement with the H. Lee Moffitt Cancer Center and Research Institute, Inc ("Moffitt"). to jointly engage in transitional research and development of adoptive tumor-infiltrating lymphocyte cell therapy with improved anti-tumor properties and process. Total payments by us under the agreement approximate $1.5 million.

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 Moffitt under which we 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, we paid an upfront licensing fee which was recognized as research and development expense during 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, we 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 Moffitt and we agree to.

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 new 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.

Our current LN-144 and LN-145 product candidates do not involve genetically-engineered cell, but our future product may. 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.

Human immunotherapy products are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of immunotherapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval.

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 the 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 if the FDA requests 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.

A sponsor may seek approval of its product candidate under programs designed to accelerate the 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. However, the orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review or approval process.

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.

In 2015, we received orphan drug status for LN-144 in the treatment of patients with metastatic melanoma. We plan to seek orphan drug designation for some or all of our other 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 may 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, 2015, we had 20 employees, all of whom are full-time, six of whom hold Ph.D. or M.D. degrees, 14 of whom were engaged in research and development activities and 6 of whom were engaged in business development, finance, 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.

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 biotechnology 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. We do not have products approved for commercial sale and have not generated revenue. As of December 31, 2015, we had an accumulated deficit of $104.2 million. In addition, during the fiscal year ended December 31, 2015, we incurred a net loss of $27.7 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. We expect to incur significant additional operating losses in the future as we expand our development and clinical trial activities in support of demonstrating the effectiveness of our products.

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.

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

Although we entered into the License Agreement, the CRADA and the manufacturing services agreement with Lonza Walkersville, Inc. in 2011, our progress on developing our business and our product candidates was slow until 2014 because of a lack of financial resources and changes in our management. 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 technologies in an industry that is 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 rapidly evolving field of immunotherapy. 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 have limited experience as a company conducting clinical trials.

Prior to 2015, all of the preclinical and clinical trials relating to our product candidates had been conducted by the NCI. Although we have recruited a team that has significant experience with clinical trials prior to our commencing on current clinical level for LN-144, we have no experience as a company in conducting clinical trials. In part because of this lack of experience, we cannot be certain that planned clinical trials will begin or be completed on time, if at all. Large-scale trials would require significant additional financial and management resources, and reliance on third-party clinical investigators, contract research organizations, or CROs, or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays that are outside of our control.

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 initiated our first company sponsored clinical trial in 2015 and have secured with the FDA an IND for the use of LN-145 in cervical and head and neck cancers. Even after 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 our contract manufacturers 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, including any quality issues associated with the contract manufacturer.

We also may conduct clinical and preclinical research in collaboration with other biotechnology and biologics entities in which we combine our technologies with those of our collaborators. Such collaborations may be subject to additional delays as a result of the management of the trials and the necessity of obtaining additional approvals for therapeutics used in the combination trials. These combination therapies will require additional testing and clinical trials will require additional FDA regulatory approval and will increase our future cost of expenses.

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.

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.

During the second half of 2015, we began enrollment of our 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. However, we may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Accordingly, we cannot guarantee that the trial will progress as planned or as scheduled. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing clinical trial and planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

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 partners to manufacture our adoptive cell therapy products for clinical trials. If they fail 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.

Clinical trials are expensive, time-consuming and difficult to design and implement, and our clinical trial costs may be higher than for more conventional therapeutic technologies or drug products.

Clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates are based on new technologies and manufactured on a patient-by-patient basis, we expect that they will require extensive research and development and have substantial manufacturing costs. In addition, costs to treat patients with relapsed/refractory cancer and to treat potential side effects that may result from our product candidates can be significant. Some clinical trial sites may not bill, or obtain coverage from, Medicare, Medicaid, or other third-party payors for some or all of these costs for patients enrolled in our clinical trials, and we may be required by those trial sites to pay such costs. Accordingly, our clinical trial costs are likely to be significantly higher per patient than those of more conventional therapeutic technologies or drug products. In addition, our proposed personalized product candidates involve several complex and costly manufacturing and processing steps, the costs of which will be borne by us. Depending on the number of patients we ultimately enroll in our trials, and the number of trials we may need to conduct, our overall clinical trial costs may be higher than for more conventional treatments.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.

The clinical trials of our product candidates are, and the manufacturing and marketing of our products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also adequate duration of response, a delay in the progression of the disease, and/or an improvement in survival. For example, response rates from the use of our product candidates may not be sufficient to obtain regulatory approval unless we can also show an adequate duration of response. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of studies in one set of patients or line of treatment may not be predictive of those obtained in another. We expect there may be greater variability in results for products processed and administered on a patient-by-patient basis, as anticipated for our product candidates, than for “off-the-shelf” products, like many other drugs. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial’s primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics not involving cell based immunotherapy;
- clinicians’ and patients’ perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;

- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete a clinical trial.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and approved immunotherapies, rather than enroll patients in any future clinical trial. In addition, potential enrollees may opt to participate in alternate clinical trials because of the length of time between the time that their tumor is excised and the TIL is infused back into the patient.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If unacceptable toxicities arise in the development of our product candidates, we or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from personalized cell therapy are not normally encountered in the general patient population and by medical personnel. Any of these occurrences may harm our business, financial condition and prospects significantly.

The manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities. If we, or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Our product candidates are biologics and the process of manufacturing our products is complex, highly- regulated and subject to multiple risks. The manufacture of our product candidates involves complex processes, including harvesting tumor fragments from patients, genetically modifying the cells ex vivo, multiplying the cells to obtain the desired dose, and ultimately infusing the cells back into a patient. As a result of the complexities, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Our manufacturing process will be susceptible to product loss or failure due to logistical issues associated with the collection of tumor cells, or starting material, from the patient, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product, manufacturing issues associated with the differences in patient starting tumors, interruptions in the manufacturing process, contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If for any reason we lose a patient's tumor, or later-developed product at any point in the process, the manufacturing process for that patient will need to be restarted and the resulting delay may adversely affect that patient's outcome. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Because our product candidates are manufactured for each particular patient, we will be required to maintain a chain of identity with respect to the patient's tumor as it moves from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market. Further, as product candidates are developed through preclinical to late stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

Currently, our product candidates are manufactured using processes by our third-party research institution collaborators that we may not intend to use for more advanced clinical trials or commercialization. Although we are working to develop commercially viable processes, doing so is a difficult and an uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of raw materials. As a result of these challenges, we may experience delays in our clinical development and/or commercialization plans. We may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

We expect our manufacturing strategy will involve the use of one or more CMOs, or establishing our own capabilities and infrastructure, including a manufacturing facility. We would expect that development of our own manufacturing facility would provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long-term margins. However, we have no experience as a company in developing a manufacturing facility and may never be successful in developing our own manufacturing facility or capability. We may establish multiple manufacturing facilities as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we are successful, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures, and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

In addition, the manufacturing process for any products that we may develop is subject to FDA and foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

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 adoptive cell therapy (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 are developing new processes that we anticipate will enable more efficient manufacturing of our products. We may have difficulty demonstrating that the 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 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. These combination therapies will require additional testing and clinical trials will require additional FDA regulatory approval and will increase our future cost of development.

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 12 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.

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, it may take time to fully develop our research and development infrastructure. As a result, we conduct a 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, or that we will renew, the CRADA that expires in August 2016 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 research to support the filing with the FDA of investigational new drug applications, or INDs, to conduct more advanced clinical trials of our products. 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 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 LN-145 and our other product candidates. As of December 31, 2015, we had $103.7 million in cash, cash equivalents and short-term investments. We believe that this cash available to us will be sufficient to fund our operations for at least the next 12 months. However, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and 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 product candidates in markets where we may otherwise would seek to pursue our own development or commercialization.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

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.

We may not be able to license new TIL technology from the NIH and others.

An important element of our intellectual property portfolio is to license additional rights and technologies from the NIH. Our inability to license the rights and technologies that we 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 products or to develop additional products. No assurance can be given that we will be successful in licensing any additional rights or technologies from the NIH and others. Failure to obtain additional rights and licenses may 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.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

The FDA often approves new therapies initially only for use in patients with relapsed or refractory metastatic disease. We expect to initially seek approval of our product candidates in this setting. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval in earlier lines of treatment and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive second or third line therapy, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research by third parties, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates, and may also be limited by the cost of our treatments and the reimbursement of those treatment costs b third party payors. For instance, we expect our lead product candidate, LN-144, to initially target a small patient population that suffers from metastatic melanoma. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

We are required to pay substantial royalties and lump sum benchmark payments 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 both substantial benchmark payments and royalties to that institution based on our revenues from sales of our products utilizing the licensed technologies, and these 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 our current products represent, 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 our products 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. Our goal is to reduce the cost of manufacturing and providing our therapies. However, unless we are able to reduce those costs an acceptable amount, we may never be able to develop a commercially viable product. If we do not successfully develop and commercialize products based upon our approach, or find suitable and economical sources for materials used in the production of our products, we will not become profitable, which would materially and adversely affect the value of our common stock.

Our TIL therapy may be provided to patients in combination with other agents provided by third parties. The cost of such combination therapy may increase the overall cost of TIL therapy and may result in issues regarding the allocation of reimbursements between our therapy and the other agents, all of which may affect our ability to obtain reimbursement coverage for the combination therapy from third party medical insurers.

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

Pursuant to the CRADA, and in cooperation with our contract manufacturers and potentially other manufacturers, we are developing 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 cost effectively, 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 our partners. 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.

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;

- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. While we have obtained clinical trial insurance for our Phase 2 clinical trial of LN-144, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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 immunotherapies 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 are 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 engineered 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.

Our lead product candidate, LN-144, is a therapy for the treatment of refractory metastatic melanoma. Currently, there are numerous companies that are developing various alternate treatments for melanoma. Accordingly, LN-144 faces significant competition in the melanoma treatment space from multiple companies. Even if we obtain regulatory approval of LN-144, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our melanoma therapy. We may not be able to implement our business plan if the acceptance of our products is inhibited by price competition or the reluctance of physicians to switch from other methods of treatment to our product, or if physicians switch to other new therapies, drugs or biologic products or choose to reserve our product for use in limited circumstances.

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

As a result of our current strategy to outsource most of our manufacturing, we rely very heavily on third parties to perform for us the manufacturing of our products for our clinical trials. We also license a significant portion of our technology from others and, at this time, do not own any intellectual properties or technologies. We intend to rely upon our contract manufacturers to produce large quantities of materials needed for clinical trials and potentially 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.

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.

Our internal computer systems, or those used by our contract research organizations or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our contract research organizations and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our drug development programs. For example, the loss of clinical study data from completed or ongoing clinical studies for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of any product candidates could be delayed.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2015, we had 20 employees, 14 of whom are engaged in research and development. The loss of the services of any of executive officers or senior 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 research, manufacturing, clinical trials management and regulatory affairs. We have sufficient funds to hire what we believe are the necessary employees to support our planned operations in the near term. 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. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we must add a significant number of additional research and development, managerial, operational, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems, and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. Our efforts to manage our growth are complicated by the fact that nearly all of our executive officers have joined us since January 2014. This lack of long-term experience working together may adversely impact our senior management team’s ability to effectively manage our business and growth.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

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 information 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. We believe that the SEC is investigating improper conduct 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.

Although we are unaware of the exact scope or timing of the SEC's investigation, it is our understanding that the investigation is ongoing. We do not know when the investigation will be concluded or to what extent we will be further involved. If we receive additional subpoenas or other requests for documents from the SEC it is our intention to fully cooperate with 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 research and development programs. Furthermore, we and our former officers and directors may be the subject 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 and potential financial penalties required by the SEC.

Risks Related to Government Regulation

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of cell therapies for cancer. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent institutional review board, or IRB;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a subject by subject basis for use in clinical trials.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Healthcare Reform Act was enacted. The Healthcare Reform Act and its implementing regulations, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our product candidates, under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research.

Other legislative changes have been proposed and adopted in the United States since the Healthcare Reform Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect until 2024, unless additional congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our

results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Risks Related to Our Intellectual Property

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

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

We 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.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

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.

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 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. The issued or pending patents that the NIH licensed to us are exclusive, and specific with respect to melanoma, breast, HPV-associated, bladder and lung cancers. 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, one 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 on our entire product portfolio 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 will be sufficient to prevent others from competing with us and developing substantially similar products.

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.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Our Securities

Our existing directors and executive officers hold a substantial amount of our common stock and may be able to influence significant corporate decisions.

As of December 31, 2015, our officers and directors beneficially owned approximately 10% of our outstanding common stock. These stockholders, if they act together, may be able to materially affect the outcome of matters presented to our stockholders, including the election of our directors and other corporate actions such as:

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

Additionally, the decisions of these stockholders may conflict with our interests or those of our other stockholders and the market price of our stock may be adversely affected by market volatility.

Our stock price may be volatile, and our stockholders' investment in our stock could decline in value.

The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including but not limited to:

- 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, biotechnology and other industries;
- receipt, or lack of receipt, of funding in support of conducing our business;
- regulatory developments within, and outside of, the United States;
- litigation or arbitration;
- general volatility in the financial markets;
- 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 January 31, 2016, we had over 48 million shares of our common stock outstanding. However, we have registered 8,049,216 additional shares of our common stock that could be issued under outstanding common stock to 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.

If securities or industry analysts do not publish research or reports about our company, or if they issue adverse or misleading opinions regarding us or our stock, our stock price and trading volume could decline.

Although we have research coverage by securities and industry analysts, if coverage is not maintained, the market price for our stock may be adversely affected. Our stock price also may decline if any analyst who covers us issues an adverse or erroneous opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet analysts' expectations. If one or more analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline and possibly adversely affect our ability to engage in future financings

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. Until September 2015, we were a small company with few employees and we did not have sufficient personnel within our finance department 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. In June 2015 we hired a seasoned Chief Financial Officer to establish effective internal controls over our reporting. As of December 31, 2015, we believe we have remedied any material weaknesses and have sufficient controls in place to comply with the Sarbanes-Oxley Act of 2002. Nevertheless, in future years, our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls that we would be required to remediate in a timely manner so as to be able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act each year. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner each year, we could be subject to sanctions or investigations by the SEC, NASDAQ or other regulatory authorities which would require additional financial and management resources and could adversely affect the market price of our common stock. Material weaknesses in our internal controls could result in a loss of investor confidence in our financial reports.

Our board could issue one or more additional series preferred stock without stockholder approval with the effect of diluting existing stockholders and impairing their voting and other 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 July 1, 2015, our new corporate offices are located at 112 West 34th Street, 18th Floor, New York, New York 10120. We currently lease these offices under one year lease for a monthly rental of approximately $12,000.

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 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 was $10,443 for the first year, and increases 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 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 information from us. Nevertheless, the SEC may in the future require us to produce additional documents or other materials.

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. We believe that the SEC is investigating improper conduct 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.

Although we are unaware of the exact scope or timing of the SEC's investigation it is our understanding that the investigation is ongoing. We do not know when the investigation will be concluded or to what extent we will be further involved. If we receive additional subpoenas or other requests for documents from the SEC it is our intention to fully cooperate with 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 research and development programs. Furthermore, we and our former officers and directors, may be the subject 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 and potential financial penalties required by the SEC.

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.

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

Fiscal Year Ended December 31, 2015	**High**	**Low**
First Quarter	$ 15.03	$ 7.60
Second Quarter	$ 13.89	$ 8.02
Third Quarter	$ 10.29	$ 5.42
Fourth Quarter	$ 8.45	$ 5.27

Stockholders

As of December 31, 2015, there were approximately 78 holders of record of our common stock. Many of our shares are held by brokers and other institutions on behalf of an estimated 1,500 stockholders who are represented by these holders of record. In addition, we had three holders of record who owned shares of our Series A Convertible Preferred Stock. The transfer agent for our Common Stock is Continental Stock Transfer, 17 Battery Place, 8th Floor, New York, NY 10004.

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, 2015, one accredited investor who held warrants that we sold to him in the November 2013 private placement, exercised warrants to purchase 4,000 shares of common stock at an exercise price of $2.50 per share ($10,000 in the aggregate). These shares were issued pursuant to an exemption available under Section 4(a)(2) of the Securities Act of 1933, as amended. No commissions were paid with respect to these warrants exercises.

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 (in thousands, except per share information)

The statements of operations data for the years ended December 31, 2015, 2014 and 2013 and the balance sheet data as of December 31, 2015 and 2014 have been derived from our audited financial statements included elsewhere in this annual report on Form 10-K. The statements of operations data for the years ended December 31, 2012 and 2011 and the balance sheet data as of December 31, 2013, 2012 and 2011 have been derived from our audited financial statements not included in this annual report on Form 10-K. The following selected financial data should be read in conjunction with our “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and financial statements and related notes to those statements included elsewhere in this annual report on Form 10-K.

	Years Ended December 31,				
	2015	**2014**	**2013**	**2012**	**2011**
Net revenue	$ -	$ -	$ -	$ -	$ -
Operating expenses:					
Research and development	15,470	3,849	2,154	1,656	1,756
General and administrative	12,390	8,192	3,831	6,476	19,303
Cost of Lion transaction - related party	-	-	16,656	-	-
Other income (loss)	200	6	(2,741)	4,825	(4,476)
Net loss	$ (27,660)	$ (12,035)	$ (25,382)	$ (3,308)	$ (25,694)
Net loss per share	$ (0.62)	$ (0.48)	$ (3.47)	$ (0.04)	$ (0.34)

	As of December 31,				
	2015	**2014**	**2013**	**2012**	**2011**
Total assets	$ 105,653	$ 46,507	$ 19,877	$ 29	$ 568
Total liabilities	1,630	$ 1,662	$ 2,270	$ 11,349	$ 13,349
Derivative liabilities	-	-	-	-	$ 7,938
Total stockholders' equity	$ 104,023	$ 44,845	$ 17,604	$ (11,319)	$ (12,781)

See "Management's Discussion and Analysis of Financial Condition and Results of Operations" below, and the financial statements and accompanying notes and previously filed Annual Reports on Form 10-K for further information regarding our 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.

Overview

We are a clinical-stage biotechnology 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 along with other solid tumor cancer indications.

Although we were formed in 2007, we did not commence our current biotechnology business until 2011. In May 2013 we completed a restructuring of all 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 September 26, 2013, we amended and restated our Articles of Incorporation to, among other things, 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.

In November 2013, in order to fund our anticipated growth and expected research and development expenses, we raised a total of $23,290,600 in a private placement of shares of our common stock, shares of a new series of preferred stock designated as "Series A Convertible Preferred Stock," and warrants to purchase shares of common stock. Because of the capital raised in November 2013, in 2014 we were able to increase our operations, hire additional employees and consultants and, by the end of 2014, we were able to open our own research and development facilities in Tampa, Florida, near the H. Lee Moffitt Cancer & Research Institute (Moffitt) on the campus of the University of South Florida. 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. In 2015 we continued to increase our operations and hire additional employees and officer. On March 3, 2015 we closed a second 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 net proceeds to us from the second public offering were approximately $68.2 million. As a result of the financings effected in November 2013, December 2014 and March 2015, as of December 31, 2015 we had $103.2 million in cash, cash equivalents and short-term investments.

During the second half of 2015, we opened enrollment in a Phase 2 clinical trial of our lead product candidate, LN-144, for the treatment of refractory metastatic melanoma. The single-arm study is expected to enroll approximately 20 evaluable patients and will be conducted at up to ten sites. Additionally, at the end of 2015, we filed an Investigational New Drug (IND) application with the FDA to conduct clinical trials of LN-145 in the treatment of cervical cancer, and head and neck squamous cell carcinoma (HNSCC). In February, 2016 we announced that the FDA has allowed our IND application. We anticipate that we will begin enrolling for at least one of these trials during 2016.

Results of Operations for the Years Ended December 31, 2015, 2014 and 2013

Revenues

As a development stage company that is currently engaged in the development of novel cancer immunotherapy products, we have not yet generated any revenues from our biotechnology business or otherwise since our formation. We currently do not anticipate that we will generate any revenues during 2016 from the sale or licensing of our products. Our ability to generate revenues in the future will depend on our ability to complete the development of our product candidates and to obtain regulatory approval for them.

Costs and expenses

Research and Development Expense (in thousands)

	Year Ended December 31,			Aggregate Change	
	2015	2014	2013	2015 from 2014	2014 from 2013
Research and development expense	$ 15,470	$ 3,849	$ 2,154	$ 11,621	$ 1,695
Stock-based compensation expense included in research and development expense	$ 2,248	$ 1,144	$ 825	$ 1,104	$ 319

Research and development expense consists of costs incurred in performing research and development activities, clinical trials, personnel costs for research and development employees and consultants, rent at our research and development facility in Tampa, Florida, cost of laboratory supplies, manufacturing expenses, and fees paid to third parties, including the NCI and our third party contract manufacturer that will process and manufacture our products for our clinical trial. Research and development expenses also included amounts paid to the National Institutes of Health under terms of our license agreements, and to the NCI under the CRADA. During the year ended December 31, 2015, our research and development costs increased by $11.6 million when compared to the same period in 2014. The increase is mainly attributable to the expansion of our CRADA in 2015, the general expansion of our research and development efforts, the establishment of our Tampa, Florida, research facility in the fourth quarter of 2014 and the initiation of our Phase II clinical trial in September 2015. Research and development costs were $2.7 million in 2014 compared to $1.3 million for the year ended December 31, 2013. Research and development expenses in 2014 increased over 2013 as we expanded our research and development activities including: engaging Lonza to commence establishing a centralized TIL manufacturing center, entering into a clinical trial grant agreement with Moffitt Cancer Center, and opening our own research and development laboratory in Tampa.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase over the next several years as we continue to conduct our clinical trial for our products and as we increase our research and development efforts in other cancer indications. However, it is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates.

The duration, costs and timing of our clinical trials and development of our product candidates will depend on a number of factors that include, but are not limited to, the number of patients that enroll in the trial, per patient trial costs, number of sites included in the trial, discontinuation rates of patients, duration of patient follow-up, efficacy and safety profile of the product candidate, and the length of time required to enroll eligible patients. Additionally, the probability of success for our product candidate will depend on a number of factors, including competition, manufacturing capability and cost efficiency, and commercial viability.

For the years ended December 31, 2015, 2014 and 2013, we incurred $2.2 million, $1.1 million and $0.8 million, respectively, of non-cash stock-based compensation costs. The increases during the last three years are attributable to the increase in our hiring in support of our increased clinical development activities.

General and Administrative Expense (in thousands)

	Year Ended December 31,			Aggregate Change	
	2015	2014	2013	2015 from 2014	2014 from 2013
General and administrative expenses	$ 12,390	$ 8,192	$ 3,831	$ 4,198	$ 4,361
Stock-based compensation expense included in general and administrative expense	$ 6,275	$ 2,670	$ 1,925	$ 3,605	$ 745

General and administrative expenses include personnel costs for our employees engaged in general and administrative activities, legal fees, audit and tax fees, consultants and professional services, and general corporate expenses. For the year ended December 31, 2015 our general and administrative expenses increased by $4.2 million, or 51%, and for the year ended December 31, 2014 compared to the prior year comparable period, our general and administrative expenses increased by $4.4 million, or 114%. The increase in our general and administrative expenses during the years ended December 31, 2015 and 2014 is due to the increase in our overall corporate activities, including business development and increases in employment related expenses, insurance costs and legal fees. For the years ended December 31, 2015, 2014 and 2013, we incurred $6.3 million, $2.7 million, and $1.9 million, respectively, of non-cash stock-based compensation costs. Share based compensation includes stock and options granted to our executive officers, our employees, our directors, and our consultants and advisors. As a result of our increased operations and the additional employees, our general and administrative expenses in the future are expected to continue to increase.

Interest Income/(Expense) (in thousands)

	Year Ended December 31,			Aggregate Change	
	2015	2014	2013	2015 from 2014	2014 from 2013
Interest Income	$ 200	$ 6	$ (445)	$ 194	$ 6

Interest income results from our interest-bearing cash and investment balances. Interest income for the year ended December 31, 2015 increased over 2014 and 2013 due to the higher cash balances in 2015 as a result of the proceeds received from our equity financings in late 2014 and early 2015. In 2013, the Company incurred interest expense on its promissory notes which were restructured in late 2013.

Net Loss

We had a net loss of $27.7 million, $12.0 million, and $25.4 million for the years ended December 31, 2015, 2014 and 2013, respectively. The increase in our net loss during 2015 is due to an increase in general and administrative expenses, as described above, along with the expansion of our research and development activities. We anticipate that we will continue to incur net losses in the future as we further invest in our research and development activities, including our clinical development, and we do not expect to generate any revenues in the near term.

Liquidity and Capital Resources

As of December 31, 2015 we had cash, cash equivalents and short-term investments of $103.7 million. As of December 31, 2015, we had $102.3 million of working capital.

Cash Flows from Operating, Investing and Financing Activities (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Net cash provided by (used in):			
Operating activities	$ (18,381)	$ (8,633)	$ (3,661)
Investing activities	$ (91,153)	$ (1,592)	$ (13)
Financing activities	$ 78,267	$ 35,462	$ 23,346
Net (decrease) increase in cash and cash equivalents	$ (31,267)	$ 25,237	$ 19,672

Net cash used in operating activities was approximately $18.4 million in 2015 compared to approximately $8.6 million and $3.7 million in 2014 and 2013, respectively. Net cash used in operating activities primarily consisted of cash payments related to the increased spending within our research and development group in support of our clinical development programs as well as the increase in our administrative functions as we scale up our business to support of the clinical activities. The timing of cash requirements may vary from period to period depending on our research and development activities, including our planned clinical trials.

Net cash used in investing activities was approximately $91.2 million in 2015 compared to net cash used in investing activities of approximately $1.6 million and $13,000 in 2014 and 2013, respectively. The increase in investing activities in 2015 related to the investment of the approximately $100 million in proceeds we received from the 2014 and 2015 equity raises. Net cash used in investing activities in 2015 related to net purchases of short-term investments and capital expenditures. Capital expenditures were approximately $1.1 million, $1.6 million and $13,000 in 2015, 2014 and 2013, respectively. The objective of the company's investment policy is to ensure the safety and preservation of its capital while maximizing total return.

Net cash provided by financing activities was approximately $78.3 million in 2015 compared to approximately $35.5 million and $23.3 million in 2014 and 2013, respectively. Net cash provided by financing activities during the years reported related to the proceeds from the sale of our securities. Most recently, in the first quarter of 2015, we completed an underwritten public offering in which we received net proceeds of approximately $68.3 million. Net cash provided by financing activities in 2015 and 2014 also included proceeds from the exercise of outstanding warrants of approximately $9.7 million and $3.2 million, respectively.

During 2016, we expect to further ramp up our research and development activities, which will increase the amount of cash we will use in our operations. Our budget for 2016 includes significantly increased spending for clinical trials with LN-144 our lead product candidate and LN-145, and on research and development for other indications and TIL enhancements. In addition, we anticipate that we will have higher payroll expenses as we increase our professional staff. Based on the funds we had available on December 31, 2015 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 12 months.

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

Recent Accounting Pronouncements

See Note 2 of the financial statements for a discussion of recent accounting pronouncements.

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.

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, 2015 that will require future cash payments are as follows:

	Payments due by period (in thousands)				
Contractual obligations	**Total**	**Less than 1 Year**	**1-3 years**	**3-5 years**	**More than 5 years**
Long-Term Debt Obligations	-	-	-	-	-
Rent Obligations	$ 701	$ 215	$ 486	-	-
NIH minimum obligations	$ 630	$ 390	$ 120	$ 120	-
Moffitt obligations	$ 725	$ 725	-	-	-
CRADA minimum obligations	$ 8,000	$ 2,000	$ 6,000	$ -	-
Other Long-Term Liabilities Reflected on the Registrant's Balance Sheet under GAAP	-	-	-	-	-
Total	$ 10,056	$ 3,330	$ 6,606	$ 120	$ -

Each of the CRADA and certain of our license agreements under which we may be required to pay quarterly or annual fees is generally cancelable by us, given appropriate prior written notice and, as such, is excluded from the table above, unless the fees were already incurred at December 31, 2015. The annual amount payable by us to maintain the CRADA and certain of our license agreements is approximately $2 million. Our CRADA expires in August 2016, for the purposes of this table we assumed that the agreement will be renewed on equal terms and continued for another three years. Other than as disclosed in the table above, the payment obligations under the license agreements, as well as under the Moffitt Agreement, are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and we are required to make development milestone payments and royalty payments in connection with the sale of products developed under these agreements. As of December 31, 2015, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales and, therefore, any related payments are not included in the table above.

Off-Balance Sheet Arrangements

At December 31, 2015, we had no obligations that would require disclosure as off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our investments in marketable securities, which are composed primarily of corporate debt securities, are subject to default, changes in credit rating and changes in market value. The primary objective of our investment activities is to preserve principal. These investments are also subject to interest rate risk and will decrease in value if market rate interest rates increase. As of December 31, 2015, marketable securities we owned were $70.1 million. Due to the nature of these investments, if market interest rates were to increase immediately and uniformly by 10% from levels as of December 31, 2015, the decline in fair value would not be material. If interest rates had declined by 10% in the year ended December 31, 2015, the decrease in earned interest 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

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on our evaluation under the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2015.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect all 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 change over time.

The effectiveness of our internal control over financial reporting as of December 31, 2015 has been audited by Weinberg & Company. P.A., an independent registered public accounting firm, as stated in its attestation report which is set forth below in this Annual Report on Form 10-K.

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	Agreement and Plan of Merger, dated July 24, 2013, by and among Genesis Biopharma, Inc., Lion Biotechnologies, Inc., Genesis Biopharma Sub, Inc., Manish Singh and Sanford J. Hillsberg (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on July 25, 2013).
3.5	Bylaws (incorporated herein by reference to the Registrant's Registration Statement on Form SB-2 filed with the Commission on January 29, 2008).
3.6	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 Warrant (incorporated herein by reference to Registrant's Form 8-K filed with the Commission on October 31, 2013)
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 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).*
10.7	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).
10.8	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).#
10.9	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).

10.10	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).
10.11	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).
10.12	Executive Employment Agreement, dated July 24, 2013, between the Company and Manish Singh (incorporated herein by reference to the Registrant's Form 10-K filed with the Commission on March 28, 2014).#
10.13	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).
10.14	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).
10.15	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).#
1.016	Executive Employment Agreement, dated August 21, 2014, by and among Lion Biotechnologies, Inc. and Dr. Elma Hawkins (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on August 25, 2014).#
10.17	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).*
10.18	Patent License Agreement, dated February 9, 2015, by and between the Company and the National Institutes of Health. (incorporated herein by reference to the Registrant's Form 10-K filed with the Commission on March 16, 2015)*
10.19	Patent License Agreement, dated February 10, 2015, by and between the Company and the National Institutes of Health. (incorporated herein by reference to the Registrant's Form 10-K filed with the Commission on March 16, 2015)*
10.20	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)
10.21	Amendment No. 1, dated April 14, 2015, to Executive Employment Agreement by and among Lion Biotechnologies, Inc. and Dr. Elma Hawkins (incorporated herein by reference to the Registrant's Form 8-K filed with the Commission on April 14, 2015)#.
10.22	Employment Agreement, dated June 8, 2015, between Lion Biotechnologies, Inc. and Molly Henderson (incorporated herein by reference to the Registrant's Form 10-Q filed with the Commission on August 10, 2015)#
10.23	First Amendment to Patent License Agreement-Exclusive, effective October 2, 2015, between the Company and the National Institutes of Health (incorporated herein by reference to the Registrant's Form 10-Q filed with the Commission on November 6, 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, 2015, formatted in XBRL (eXtensible Business Reporting Language): (1) Balance Sheets as of December 31, 2015 and 2014; (2) Statements of Income for the years ended December 31, 2015, and 2014; (3) Statements of Shareholders' Equity for the years ended December 31, 2015, and 2014; (4) Consolidated Statements of Cash Flows for the years ended December 31, 2015, and 2014; 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.

# Indicates a management contract or compensatory plan or arrangement.

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 11, 2016

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 11, 2016
/s/ Molly Henderson Molly Henderson	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 11, 2016
/s/ Merrill A. McPeak Merrill A. McPeak	Director	March 11, 2016
/s/ Jay Venkatesan Jay Venkatesan	Director	March 11, 2016
/s/ Sanford J. Hillsberg Sanford J. Hillsberg	Director	March 11, 2016
/s/ Ryan D. Maynard Ryan D. Maynard	Director	March 11, 2016

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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, 2015 and 2014, and the related statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the three year period ended December 31, 2015. 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, 2015 and 2014, and the results of its operations and its cash flows for each of the years in the three year period ended December 31, 2015, 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, 2015, 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 11, 2016 expressed an unqualified opinion.

/s/Weinberg & Company, P.A.
Los Angeles, California
March 11, 2016

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.'s internal control over financial reporting as of December 31, 2015, 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 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, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and 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.

In our opinion, Lion Biotechnologies, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets and the related statements of operations, comprehensive loss, stockholders' equity, and cash flows of Lion Biotechnologies, Inc., and our report dated March 11, 2016 expressed an unqualified opinion.

/s/Weinberg & Company, P.A.
Los Angeles, California
March 11, 2016

LION BIOTECHNOLOGIES, INC.
Balance Sheets
(In thousands, except share information)

	December 31, 2015	December 31, 2014
ASSETS		
Current Assets		
Cash and cash equivalents	$ 13,642	$ 44,909
Money market funds	19,945	-
Short-term investments available for sale	70,113	-
Prepaid expenses and other current assets	277	66
Total Current Assets	103,977	44,975
Property and equipment, net of accumulated depreciation of $1,103 and $104, respectively	1,676	1,532
Total Assets	$ 105,653	$ 46,507
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 958	$ 1,248
Accrued expenses	586	328
Accrued payable to officers and former directors	86	86
Total Current Liabilities	1,630	1,662
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, $0.001 par value; 50,000,000 shares authorized, 1,694 and 5,694 shares issued and outstanding, respectively	-	-
Common stock, $0.000041666 par value; 150,000,000 shares authorized, 48,547,720 and 33,750,188 shares issued and outstanding, respectively	2	2
Common stock to be issued, 303,125 shares	245	245
Accumulated other comprehensive income	48	-
Additional paid-in capital	207,950	121,160
Accumulated deficit	(104,222)	(76,562)
Total Stockholders' Equity	104,023	44,845
Total Liabilities and Stockholders' Equity	$ 105,653	$ 46,507

See accompanying notes.

LION BIOTECHNOLOGIES, INC.
Statements of Operations
(In thousands, except per share information)

	For the Years Ended December 31,		
	2015	**2014**	**2013**
Revenues	**$ -**	**$ -**	**$ -**
Costs and expenses			
Research and development (including $2,248, $1,144 and $825 in share-based compensation costs)	15,470	3,849	2,154
General and administrative (including $6,275, $2,670 and $1,925 in share-based compensation costs)	12,390	8,192	3,831
Cost of Lion transaction	-	-	16,656
Total costs and expenses	27,860	12,041	22,641
Loss from operations	(27,860)	(12,041)	(22,641)
Other income (expense)			
Interest income (expense)	200	6	(445)
Cost to induce exchange transaction	-	-	(2,296)
Total other income (expense)	200	6	(2,741)
Net Loss	(27,660)	(12,035)	(25,382)
Deemed dividend related to beneficial conversion feature of convertible preferred stock	-	-	(8,462)
Net Loss Attributable to common Stockholders	$ (27,660)	$ (12,035)	$ (33,844)
Net Loss Per Share Attributable to common Stockholders, Basic and Diluted	$ (0.62)	$ (0.48)	$ (3.47)
Weighted-Average Common Shares Outstanding, Basic and Diluted	44,410,036	24,985,542	9,762,513

See accompanying notes.

LION BIOTECHNOLOGIES, INC.
Condensed Statements of Comprehensive Loss
(in thousands, except share information)

	For the Years Ended December 31,		
	2015	**2014**	**2013**
Net Loss	$ (27,660)	$ (12,035)	$ (25,382)
Other comprehensive income:			
Unrealized gain on short-term investments	48	-	-
Comprehensive Loss	$ (27,612)	$ (12,035)	$ (25,382)

See accompanying notes.

LION BIOTECHNOLOGIES, INC.
Statements of Stockholders' Equity
(In thousands, except share information)

	Preferred Stock		Common Stock		Common Stock to	Additional Paid-In	Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Be Issued	Capital	Income	Deficit	Equity
Balance - January 1, 2013	-	$ -	818,806	$ -	245	$ 19,119	$ -	$ (30,683)	$ (11,319)
Common stock issued in settlement of notes payable and accrued interest and penalty			9,267,641	1		9,267			9,268
Common stock issued for cash under the restructuring, net of offering costs of $109			1,350,000			1,239			1,239
Common stock issued to induce exchange transaction			2,295,868			2,296			2,296
Fair value of vested stock options and warrants						747			747
Common stock Issued for Lion transactions			2,690,000			16,656			16,656
Common stock issued for services			50,000			274			274
Common stock issued to directors			400,596			2003			2,003
Common stock sold in private placement			3,145,300			5,887			5,887
Preferred stock sold in private placement	17,000					15,909			15,909
Common stock issued for settlement of payable			5,747			25			25
Deemed dividend on beneficial conversion feature of preferred stock						8,462		(8,462)	-
Net loss								(25,382)	(25,382)
Balance - December 31, 2013	17,000	-	20,023,958	1	245	81,884	-	(64,527)	17,603
Fair value of vested stock options						2,559			2,559
Common stock issued upon exercise of warrants			1,288,730			3,222			3,222
Common stock issued upon conversion of preferred shares	(11,306)		5,653,000						-
Common stock issued for services			784,500			1,255			1,255
Common stock sold in private placement			6,000,000	1		32,240			32,241
Net loss								(12,035)	(12,035)
Balance - December 31, 2014	5,694	-	33,750,188	2	245	121,160	-	(76,562)	44,845
Fair value of vested stock options						6,752			6,752
Common stock issued upon exercise of warrants, net of cancellation			3,880,210			9,705			9,705
Common stock issued upon exercise of options			42,387			255			255
Common stock issued upon conversion of preferred shares	(4,000)		2,000,000						-
Common stock sold in public offering, net of offering costs			9,200,000			68,307			68,307
Common stock issued for services			15,000			1,771			1,771
Forfeiture and cancellation of restricted shares issued for services			(340,065)						-
Unrealized gain on short- term investments							48		48
Net loss								(27,660)	(27,660)
Balance - December 31, 2015	1,694	$ -	48,547,720	$ 2	245	$ 207,950	$ 48	$ (104,222)	$ 104,023

See accompanying notes.

LION BIOTECHNOLOGIES, INC.
Statements of Cash Flows
(In thousands)

	For the Years Ended December 31,		
	2015	**2014**	**2013**
Cash Flows From Operating Activities			
Net loss	$ (27,660)	$ (12,035)	$ (25,382)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	999	88	7
Fair value of vested stock options	6,752	2,559	747
Common stock issued for services	1,771	1,255	274
Common stock issued to induce exchange transaction	-	-	2,296
Common stock issued for Lion transaction	-	-	16,656
Common stock issued to directors	-	-	2,003
Changes in assets and liabilities:			
Prepaid expenses and other current assets	(211)	108	(164)
Accounts payable and accrued expenses	(32)	(608)	(98)
Net cash used in operating activities	(18,381)	(8,633)	(3,661)
Cash Flows From Investing Activities			
Increase in money market funds	(19,945)	-	-
Purchase of short- term investments	(140,665)	-	-
Maturities of short- term investments	70,600	-	-
Purchases of property and computer equipment	(1,143)	(1,592)	(13)
Net cash used in investing activities	(91,153)	(1,592)	(13)
Cash Flows From Financing Activities			
Proceeds from the issuance of common stock upon exercise of warrants	9,705	3,222	-
Proceeds from the issuance of common stock upon exercise of options	255	-	-
Proceeds from the issuance of common stock, net	68,307	32,240	7,126
Proceeds from the issuance of convertible notes, net	-	-	311
Proceeds from the issuance of preferred stock, net	-	-	15,909
Net cash provided by financing activities	78,267	35,462	23,346
Net (decrease) increase in cash and cash equivalents	(31,267)	25,237	19,672
Cash and cash equivalents, beginning of period	44,909	19,672	-
Cash and cash equivalents, end of period	$ 13,642	$ 44,909	$ 19,672
Supplemental Disclosures of Cash Flow Information:			
Unrealized gain on short-term investments	$ 48	$ -	$ -
Common stock issued upon conversion of convertible notes	$ -	$ -	$ 6,793
Common stock issued upon conversion of accrued interest and penalty	$ -	$ -	$ 2,475

See accompanying notes.

NOTE 1. GENERAL ORGANIZATION AND BUSINESS

Lion Biotechnologies, Inc. (the "Company," "we," "us" or "our") is a 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, increase (after the reverse stock split) the number of our authorized number of shares of common stock to 150,000 shares, and authorize the issuance of 50,000,000 shares of "blank check" preferred stock, $0.001 par value per share. All references herein to the number of shares issued or outstanding, and all per share and other similar data, reflect a 1-for-100 reverse stock split effected on September 26, 2013.

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 2016 from the sale or licensing of any products. As shown in the accompanying financial statements, we have incurred a net loss of $27.7 million for the year ended December 31, 2015 and used $18.4 million of cash in our operating activities during the year ended December 31, 2015. As of December 31, 2015, we had $103.7 million of cash and cash equivalents, money market funds, and short-term investments on hand, stockholders' equity of $104.0 million and had working capital of $102.3 million.

During 2016, we expect to further ramp up our clinical operations which will increase the amount of cash we will use in our operations. Our budget for 2016 includes increased spending on Phase II clinical trials, research and development activities, higher payroll expenses as we increase our professional and scientific staff, as well as ongoing payments under our Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI). Based on the funds we had available on December 31, 2015, we believe that we have sufficient capital to fund our anticipated operating expenses for at least 12 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 $68.3 million, after deducting expenses of the offering. 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. In November 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 12 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

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of 90 days or less when purchased to be cash equivalents. The carrying amounts reported in the Balance Sheets for cash and cash equivalents are valued at cost, which approximates their fair value.

Short-term Investments

The Company's short-term investments represent available for sale securities and are recorded at fair value and unrealized gains and losses are recorded within accumulated other comprehensive income (loss). The estimated fair value of the available for sale securities is determined based on quoted market prices or rates for similar instruments. In addition, the cost of debt securities in this category is adjusted for amortization of premium and accretion of discount to maturity. The Company evaluates securities with unrealized losses to determine whether such losses, if any, are other than temporary.

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. Expenditures for maintenance and repairs are charged to operations as incurred while renewals and betterments are capitalized. Gains and losses on disposals are included in the consolidated statements of operations.

Management assesses the carrying value of property and equipment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If there is indication of impairment, management prepares an estimate of future cash flows expected to result from the use of the asset and its eventual disposition. If these cash flows are less than the carrying amount of the asset, an impairment loss is recognized to write down the asset to its estimated fair value. For the years ended December 31, 2015 2014 and 2013, the Company did not recognize any impairments for its property and equipment.

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. Shares of restricted stock are included in the basic weighted average number of common shares outstanding from the time they vest. 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. Shares of restricted stock are included in the diluted weighted average number of common shares outstanding from the date they are granted unless they are antidilutive. For the years ended December 31, 2015, 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.

At December 31, 2015, 2014 and 2013, the dilutive impact of outstanding stock options for 2,693,237, 1,857,877, and 278,750 shares, respectively; outstanding warrants for 7,202,216, 11,084,426, and 12,373,156 shares, respectively; and preferred stock that can convert into 847,000, 2,847,000, and -0- shares of our common stock, respectively, have been excluded because their impact on the loss per share is anti-dilutive.

Fair Value Measurements

Under FASB ASC 820, *Fair Value Measurements and Disclosures*, fair value is defined as the price at which an asset could be exchanged or a liability transferred in a transaction between knowledgeable, willing parties in the principal or most advantageous market for the asset or liability. Where available, fair value is based on observable market prices or parameters or derived from such prices or parameters. Where observable prices or parameters are not available, valuation models are applied.

Assets and liabilities recorded at fair value in our financial statements are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels directly related to the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities, are as follows:

Level 1—Inputs are unadjusted, quoted prices in active markets for identical assets at the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

The fair valued assets we hold that are generally included under this Level 1 are money market securities where fair value is based on publicly quoted prices.

Level 2—Are inputs, other than quoted prices included in Level 1, that are either directly or indirectly observable for the asset or liability through correlation with market data at the reporting date and for the duration of the instrument's anticipated life.

The fair valued assets we hold that are generally assessed under Level 2 are corporate bonds and commercial paper. We utilize third party pricing services in developing fair value measurements where fair value is based on valuation methodologies such as models using observable market inputs, including benchmark yields, reported trades, broker/dealer quotes, bids, offers and other reference data. We use quotes from external pricing service providers and other on-line quotation systems to verify the fair value of investments provided by our third party pricing service providers. We review independent auditor's reports from our third party pricing service providers particularly regarding the controls over pricing and valuation of financial instruments and ensure that our internal controls address certain control deficiencies, if any, and complementary user entity controls are in place.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities and which reflect management's best estimate of what market participants would use in pricing the asset or liability at the reporting date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

We do not have fair valued assets classified under Level 3.

The Company believes the carrying amount of its financial instruments (consisting of cash and cash equivalents, and accounts payable and accrued expenses) approximates fair value due to the short-term nature of such instruments.

Fair Value on a Recurring Basis

Financial assets measured at fair value on a recurring basis are categorized in the tables below based upon the lowest level of significant input to the valuations (in thousands):

	Assets at Fair Value as of December 31, 2015			
	Level 1	**Level 2**	**Level 3**	**Total**
Money market funds	$ 19,945	$	$ -	$ 19,945
Corporate debt securities		70,113	-	70,113
Total	$ 19,945	$ 70,113	$ -	$ 90,058

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 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 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 is 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.

The Company issues restricted shares of its common stock for share-based compensation programs. The Company measures the compensation cost with respect to restricted shares to employees based upon the estimated fair value of the equity instruments at the date of the grant, and is recognized as expense over the period which an employee is required to provide services in exchange for the award.

Total stock-based compensation expense related to all of our stock-based awards was as follows (in thousands):

	For the Years Ended December 31,		
	2015	2014	2013
Research and development	$ 2,248	$ 1,144	$ 825
General and administrative	6,275	2,670	1,925
Total stock-based compensation expense	$ 8,523	$ 3,814	$ 2,750

Research and Development

Research and development costs consist primarily of compensation paid to employees engaged in research and development activities, 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, or if applicable, 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.

Income taxes

The Company accounts for income taxes using the asset and liability method whereby deferred tax assets are recognized for deductible temporary differences, and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

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, 2015 and 2014, the Company's cash balances were in excess of insured limits maintained at the bank.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-02, Leases. ASU 2016-02 requires a lessee to record a right of use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. ASU 2016-02 is effective for all interim and annual reporting periods beginning after December 15, 2018. Early adoption is permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is in the process of evaluating the impact of ASU 2016-02 on the Company's financial statements and disclosures.

In January 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. The new guidance will impact the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. All equity investments in unconsolidated entities (other than those accounted for under the equity method of accounting) will generally be measured at fair value with changes in fair value recognized through earnings. There will no longer be an available-for-sale classification for equity securities with readily determinable fair values in which changes in fair value are currently reported in other comprehensive income. In addition, the FASB clarified the need for a valuation allowance on deferred tax assets resulting from unrealized losses on available-for-sale debt securities. In general, the new guidance will require modified retrospective application to all outstanding instruments, with a cumulative effect adjustment recorded to opening retained earnings. This guidance will be effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. We are currently evaluating the expected impact that the standard could have on our financial statements and related disclosures.

In November 2015, the FASB issued Accounting Standards Update No. 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*. The update simplifies the presentation of deferred income taxes by requiring that deferred tax liabilities and assets be classified as noncurrent in the balance sheet. The update is effective for public companies for annual reporting periods beginning after December 15, 2016, and interim periods within those fiscal years. The guidance may be adopted prospectively or retrospectively and early adoption is permitted. As of December 31, 2015, the Company has elected to early adopt this ASU on a prospective basis and therefore, prior years were not retrospectively adjusted.

In June 2014, the FASB issued Accounting Standards Update No. 2014-12, *Compensation – Stock Compensation (Topic 718).* The pronouncement was issued to clarify the accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. The pronouncement is effective for reporting periods beginning after December 15, 2015. The adoption of ASU 2014-12 will not have a significant impact on the Company's financial position or results of operations.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers.* ASU 2014-09 is a comprehensive revenue recognition standard that will supersede nearly all existing 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 interim and annual periods beginning after December 15, 2017. Early adoption is permitted in annual reporting periods beginning after December 15, 2016, and the interim periods within that year, and either full retrospective adoption or modified retrospective adoption is permitted. The Company is in the process of evaluating the impact of ASU 2014-09 on the Company's financial statements and disclosures.

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 did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statements.

Reclassifications

In presenting the Company's statement of operations for the years ended December 31, 2014 and 2013, the Company has reclassified $1.1 million and $0.8 million, respectively, of stock-based compensation that was previously reflected as general and administrative expenses to research and development expenses. The reclassification relates to stock-based compensation attributable to individuals working in the Company's research and development activities, and had no impact on total costs and expenses, or on net loss.

NOTE 3. CASH, MONEY MARKET FUNDS, AND SHORT-TERM INVESTMENTS

Cash, money market funds, and short-term investments consist of the following (in thousands):

	December 31,	
	2015	2014
Checking and savings accounts (reported as cash and cash equivalents)	$ 13,642	$ 44,909
Money market funds	19,945	-
Corporate debt securities (reported as short-term investments)	70,113	-
	$ 103,700	$ 44,909

Money market funds and short-term investments include the following securities with gross unrealized gains and losses (in thousands):

December 31, 2015	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 19,945	$ -	$ -	$ 19,945
Corporate debt securities	70,065	48	-	70,113
Total	$ 90,010	$ 48	$ -	$ 90,058

As of December 31, 2015, the contractual maturities of our money market funds and short-term investments were (in thousands):

	Within One Year
Money market funds	$ 19,945
Corporate debt securities	70,113
	$ 90,058

At December 31, 2015, the Company's short-term investments were invested in short-term fixed income debt securities and notes of domestic and foreign high credit issuers and in money market funds. The Company's investment policy limits investments to certain types of instruments such as certificates of deposit, money market instruments, obligations issued by the U.S. government and U.S. government agencies as well as corporate debt securities, and places restrictions on maturities and concentration by type and issuer. At December 31, 2015, the Company's short-term investments totaled $70.1 million, of which 43% were invested in notes of five companies, 37% were invested in notes of other domestic issuers, and 20% were invested in notes of foreign issuers. The average maturity of these notes was 66 days. At December 31, 2015 the Company's money-market funds totaled $19.9 million and were invested in a single, no-load money market fund.

NOTE 4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following (in thousands):

	December 31, 2015	December 31, 2014
Lab equipment	$ 1,703	$ 689
Computer equipment	85	72
Office furniture and equipment	138	113
Leasehold improvements	853	762
Total Property and equipment, cost	2,779	1,636
Less: Accumulated depreciation and amortization	(1,103)	(104)
Property and equipment, net	$ 1,676	$ 1,532

Depreciation expense for the years ended December 31, 2015, 2014 and 2013 was $999, $88 and $7, respectively.

NOTE 5. STOCKHOLDERS' EQUITY

On March 3, 2015, the Company completed an underwritten public offering of 9,200,000 shares of its common stock at a price of $8.00 per share of common stock. The net proceeds to the Company from the offering were $68.3 million, after deducting underwriting discounts and commissions and offering expenses. The offering was made pursuant to the Company's 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.

On May 6, 2015, certain stockholders of the Company, including certain members of Board of Directors of the Company and their affiliates, sold 4,750,000 shares of the Company's common stock in an underwritten secondary offering at a price of $10.00 per share. The Company did not sell any shares in the offering and did not receive any of the proceeds from the offering.

On December 22, 2014 the Company 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 $32.2 million, 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.

During 2015 and 2014, the Company granted 15,000 and 782,500 shares, respectively, of its restricted common stock to certain of its employees in accordance with the terms of their employment agreements. The total of 797,500 shares vest over a period of three years. As these shares were granted to employees, the Company calculated the aggregate fair value of the 797,500 shares to be $4.3 million based on the trading prices of the Company's stock at their grant dates. The allocable portion of the fair value of the stock that vested during the years ended December 31, 2015 and 2014 totaled $1.7 million and $1.3 million, respectively, and is recognized as expense in the accompanying statements of operations. As of December 31, 2015, the amount of unvested compensation related to the unvested outstanding shares of restricted common stock was $1.3 million, which will be recorded as expense in over a weighted average life of 2.25 years as the shares vest.

During 2015, certain employees authorized the Company to cancel 148,565 vested shares to satisfy withholding requirements related to such vesting. The cancellation is recorded as a reduction to shares outstanding. Additionally, 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.

The following table summarizes restricted common stock activity:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested shares, January 1, 2014	-	$ -
Granted	782,500	7.04
Vested	-	-
Forfeited	-	-
Non-vested shares, December 31, 2014	782,500	7.04
Granted	15,000	8.44
Vested	(284,748)	4.31
Forfeited	(191,500)	6.81
Non-vested shares, December 31, 2015	321,252	$ 6.96

In May 2013, the Company completed a transaction in which it cancelled certain debt and sold shares of common stock. As part of the transaction, certain investors purchasing common stock received as an inducement of 2,173,134 shares of common stock with a fair value of $2.1 million for no consideration. In addition, certain creditors received 122,734 shares of common stock valued at $0.1 million to cancel warrants to acquire 122,734 shares of common stock. The aggregate fair value of $2.2 million is reflected as cost to induce exchange transaction in the accompanying statement of operations for the year ended December 31, 2013.

In July 2013, the Company issued 1,340,000 shares of common stock with a fair value of $6.7 million to the two owners of Lion Biotechnologies, then a privately owned Delaware corporation, for all of their issued and outstanding shares of common stock. In the fourth quarter of 2013, the Company issued an additional 1,350,000 shares of common stock with a fair value of $9.9 million to the two owners. The aggregate fair value of all shares issued in the transaction was $16.6 million and is reflected as cost of Lion transaction in the accompanying statement of operations for the year ended December 31, 2013.

Series A Convertible Preferred Stock

A total of 17,000 shares of Series A Convertible Preferred Stock have been authorized for issuance under the Certificate of Designation of Preferences and Rights of Series A Convertible Preferred Stock. 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.

The Series A Preferred Stock may, at the option of the investor, be converted into fully paid and non-assessable shares of common stock. The holders of shares of Series A Preferred Stock shall not have the right to vote on matters that come before stockholders. In the event of any dissolution or winding up of the Company, 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 holder. The Company may not declare, pay or set aside any dividends on shares 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 an equal dividend on each outstanding share of Series A Preferred Stock.

During the years ended December 31, 2015 and 2014, 4,000 shares and 11,306 shares, respectively, of Series A Convertible Preferred Stock were converted into 2,000,000 and 5,653,000 shares of common stock, respectively. The common shares issued were determined on a formula basis of 500 common shares for each share of Series A Convertible Preferred Stock converted.

NOTE 6. STOCK OPTIONS AND WARRANTS

Stock Options

A summary of the status of stock options at December 31, 2015, and the changes during the year ended, is presented in the following table:

	Shares Under Option	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2013	93,750	$ 109.00	8.5	$ 217
Granted	225,000	104.00		
Exercised	-			
Expired/Forfeited	(40,000)	92.00		
Outstanding at December 31, 2013	278,750	23.10	9.1	1,176
Granted	1,604,127	6.58		
Exercised	-	-		
Expired/Forfeited	(25,000)	125.00		
Outstanding at December 31, 2014	1,857,877	7.31	8.5	2,874
Granted	1,171,984	8.12		
Exercised	(42,387)	-		
Expired/Forfeited	(294,237)	2.88		
Outstanding at December 31, 2015	2,693,237	$ 8.12	8.02	$ 2,347
Exercisable at December 31, 2015	1,099,043	$ 8.38	6.93	$ 1,487

During the year ended December 31, 2015, the Company granted options to purchase 1,171,984 shares of common stock to employees and directors of the Company. The stock options generally vest between one and three years. The fair value of these options was determined to be $10.1 million using the Black-Scholes option pricing model based on the following assumptions: (i) volatility rate ranging from 207% to 218%, (ii) discount rate of 1.57%, (iii) zero expected dividend yield, and (iv)expected life of 6 years.

During the years ended December 31, 2015, 2014, and 2013, the Company recorded compensation costs of $6.7 million, $2.6 million, and $0.7 million, respectively, relating to the vesting of stock options. As of December 31, 2015, the aggregate value of unvested options was $11.1 million, which will continue to be amortized as compensation cost as the options vest over terms ranging from nine months to three years, as applicable.

On September 19, 2014, the Company's Board of Directors adopted the Lion Biotechnologies, Inc. 2014 Equity Incentive Plan (the "2014 Plan"). The 2014 Plan was approved by our stockholders at the annual meeting of stockholders held in November 2014. The 2014 Plan as approved by the stockholders authorized the issuance up to an aggregate of 2,350,000 shares of common stock. On April 10, 2015 the Board amended the 2014 Plan to increase the total number of shares that can be issued under the 2014 Plan by 1,650,000 from 2,350,000 shares to 4,000,000 shares. The increase in shares available for issuance under the 2014 Plan was approved by stockholders on June 12, 2015.

Warrants

A summary of the status of stock warrants at December 31, 2015, 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 (in thousands)
Outstanding at January 1, 2013	108,734	$ 123.00	3.5	$ -
Issued	12,387,156	2.50		
Exercised	-	-		
Expired	(122,734)			
Outstanding at December 31,2013	12,373,156	2.51	4.1	$ 31,056
Issued	-			
Exercised	(1,288,730)	2.50		
Expired	-			
Outstanding at December 31, 2014	11,084,426	2.51	3.9	59,518
Issued	-	-		
Exercised	(3,882,210)	2.50		
Expired	-	-		
Outstanding and exercisable at December 31, 2015	7,202,216	$ 2.51	3.3	$ 37,596

During the year ended December 31, 2015, the Company received $9.7 million in cash from the exercise of 3,882,210 warrants for the purchase of an equal number of shares of its common stock.

NOTE 7. INCOME TAXES

The Company has no tax provision for any period presented due to our history of operating losses. As of December 31, 2015, the Company had state and federal net operating loss carry forwards of approximately $45 million that may be available to reduce future years' taxable income through 2035. 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 (in thousands):

	December 31, 2015	2014
Deferred income tax asset:		
Net operating loss carry forward	$ 15,300	$ 8,428
Valuation allowance	(15,300)	(8,428)
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,		
	2015	2014	2013
Federal Statutory tax rate	(34)%	(34)%	(34)%
State tax, net of federal benefit	(5)%	(5)%	(5)%
	(39)%	(39)%	(39)%
Valuation allowance	39%	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, 2015, no liability for unrecognized tax benefits was required to be recorded.

NOTE 8. LICENSES AND COMMITMENTS

National Institutes of Health and the National Cancer Institute

Cooperative Research and Development Agreement

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 Dr. 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.

On January 22, 2015, the Company executed an amendment (the "Amendment") to the CRADA 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 the Company 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. 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.

Development and Manufacture TIL

Effective October 5, 2011, the Company entered into a Patent 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"), which License Agreement was subsequently amended on February 9, 2015 and October 2, 2015. Pursuant to the License Agreement as amended, NIH granted to the Company an 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 requires the Company to pay royalties based on a percentage of net sales (which percentage is in the mid-single digits and 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 costs incurred by NIH pursuant to the agreement.

Exclusive Patent License Agreement
On February 10, 2015, the Company entered into an exclusive Patent License Agreement with the NIH under which the Company 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, the Company agreed to pay the NIH a non-refundable upfront licensing fee which was recognized as research and development expense during the year ended December 31, 2015. The Company also agreed 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 the Company's first Phase 2 clinical study, the successful completion of the Company's 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 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 License.

H. Lee Moffitt Cancer Center

Research Collaboration Agreement
In September 2014, the Company 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.

Exclusive License Agreement
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 which was recognized as research and development expense during 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.

During the year ended December 31, 2015 and 2014, the Company recognized $3.8 million and $1.4 million respectively, of expenses related to its license agreements. The amounts were recorded as part of research and development expenses in the statement of operations. Additionally, during the years ended December 31, 2015, 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 regulatory milestones for each of the various indications.

Aggregate guaranteed commitments for 2016, under all of the Company's license and research agreements, are approximately $2.1 million.

Tampa Lease

In July 2014, the Company entered into a five-year non-cancellable operating lease with the University of South Florida Research Foundation for an approximately 5,200 square foot facility located in Tampa, Florida. The facility is part of the University of South Florida research park and is used as the Company's research and development facilities. The monthly base rent for this facility during the first year of the lease was $10,443 and 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 (in thousands):

Year	Amount
2016	$ 152
2017	157
2018	162
2019	167
	$ 638

NOTE 9. QUARTERLY UNAUDITED RESULTS

The results of operations by quarter for the years ended December 31, 2015 and 2014 are as follow:

	2015				2014			
	(in thousands, except per share information)							
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenue	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Net loss	$ (5,298)	$ (6,367)	$ (7,635)	$ (8,360)	$ (2,260)	$ (2,110)	$ (3,014)	$ (4,651)
Net loss per share, basic and diluted	$ (0.14)	$ (0.14)	$ (0.16)	$ (0.18)	$ (0.11)	$ (0.09)	$ (0.11)	$ (0.17)
Weighted average shares used in computing net loss per share, basic and diluted	37,679	45,082	47,272	47,912	20,798	24,138	26,633	28,271

NOTE 10. 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 did not indicate whether the Company is, or is 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 information from us. Nevertheless, the SEC may in the future require us to produce additional documents or other materials.

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. We believe that the SEC is investigating improper conduct 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.

Although we are unaware of the exact scope or timing of the SEC's investigation, it is our understanding that the investigation is ongoing. We do not know when the investigation will be concluded or to what extent we will be further involved. If we receive additional subpoenas or other requests for documents from the SEC it is our intention to fully cooperate with 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 research and development programs. Furthermore, we, and our former officers and directors, may be the subject 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 and potential financial penalties required by the SEC.

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Registration Statements on From S-8 (File No. 333-205097) and on form S-3 (File Nos. 333-192649 and 333-203284) of Lion Biotechnologies, Inc. of our reports dated March 11, 2016, 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 11, 2016

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 11, 2016

/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, Molly Henderson, 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 11, 2016

/s/ Molly Henderson
Molly Henderson
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, 2015 (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 11, 2016

/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, Molly Henderson, 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, 2015 (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 11, 2016

/s/ Molly Henderson
Molly Henderson
Chief Financial Officer
(Principal Financial Officer)