

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

FORM 8-K

Current Report
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): December 16, 2014

LION BIOTECHNOLOGIES, INC.
(Exact Name of Registrant as Specified in Charter)

NEVADA
(State of Incorporation)

000-53127
(Commission File Number)

75-3254381
(I.R.S. Employer Identification No.)

21900 Burbank Blvd., Third Floor, Woodland Hills, California
(Address of Principal Executive Offices)

91367
(Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).

Forward-Looking Statements

This Form 8-K and the exhibit attached hereto contain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts, including statements regarding our future results of operations and financial position, business strategy, prospective products, regulatory filings and initiation of clinical trials and other research and development activities, intellectual property rights and license agreements, and other future events, are forward-looking statements. You can generally identify these forward-looking statements by forward-looking words such as “anticipates,” “believes,” “expects,” “intends,” “future,” “could,” “estimates,” “plans,” “would,” “should,” “potential,” “continues” and similar words or expressions (as well as other words or expressions referencing future events, conditions or circumstances). These forward-looking statements involve risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to:

- our current unprofitability and the risk that we may never become profitable;
 - our limited operating history;
 - our lack of revenue and our need for additional funding, which may not be available, and the risks associated with raising additional capital;
 - risks related to our clinical trials, including the uncertainty that results will support our product candidate claims;
 - our plans and timing with respect to seeking regulatory approvals and uncertainties regarding the regulatory process;
 - risks associated with litigation or regulatory investigations, including expending substantial resources and distracting personnel from their normal responsibilities;
 - delays in enrollment of patients in our clinical trials, which could delay or prevent regulatory approvals;
 - the dependence of our development program upon third parties who are outside our control;
 - failure to compete successfully against other actual and potential future competitors;
 - developments by competitors that may render our products or technologies obsolete or non-competitive;
 - failure to comply with obligations of our intellectual property licenses;
 - our or our licensors’ inability to obtain and maintain patent protection for technology and products;
 - the risk that other companies may license the same intellectual properties that we have licensed, including as a result of our inability to obtain exclusive rights from the NIH or NCI, or that other companies may otherwise duplicating our business model and operations;
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- risks related to our dependence on third party vendors to design, build, maintain and support our manufacturing and cell processing facilities and our information technology infrastructure and systems;
- risks related to our compliance with patent application requirements;
- risks related to our infringement of third parties' rights;
- risks associated with intellectual property litigation;
- risks associated with healthcare reform;
- our reliance on key executive officers and advisors;
- our inability to hire additional qualified personnel;
- volatility in the price of our common stock; and
- capital appreciation being the only source of gain for our common stock.

All forward-looking statements contained in this Form 8-K are expressly qualified in their entirety by this cautionary statement, the risk factors set forth under the heading "Risk Factors" in our most recent Annual Report on Form 10-K, as updated by our subsequent filings under the Exchange Act. These forward-looking statements speak only as of the date of hereof. Except to the extent required by applicable laws and regulations, we undertake no obligation to update these forward-looking statements to reflect new information, events or circumstances after the date of this prospectus supplement or to reflect the occurrence of unanticipated events. In light of these risks and uncertainties, the forward-looking events and circumstances described in this Form 8-K may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements.

Item 8.01. Other Events.

We are filing certain information for the purpose of updating various aspects of the descriptions of our business and risk factors contained in our other filings with the Securities and Exchange Commission. A copy of this additional disclosure is attached as Exhibit 99.1 to this Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

99.1 Company Disclosure

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

LION BIOTECHNOLOGIES, INC.

Date: December 16, 2014

By: /s/ Michael Handelman
Michael Handelman, Chief Financial Officer

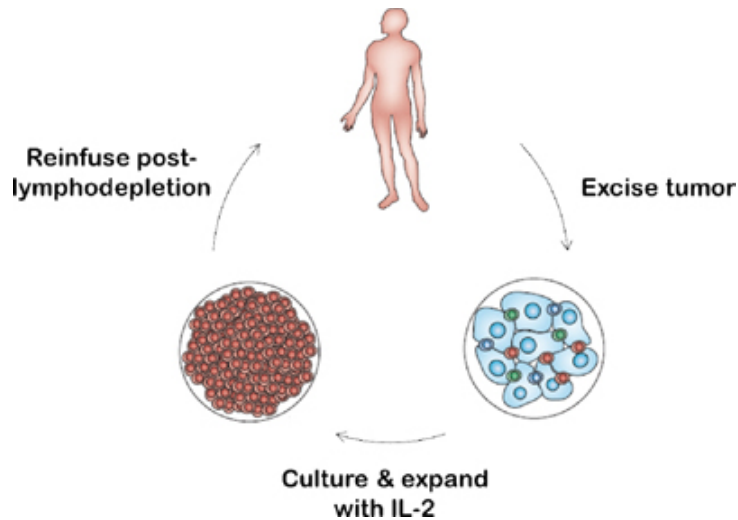
BUSINESS

Overview

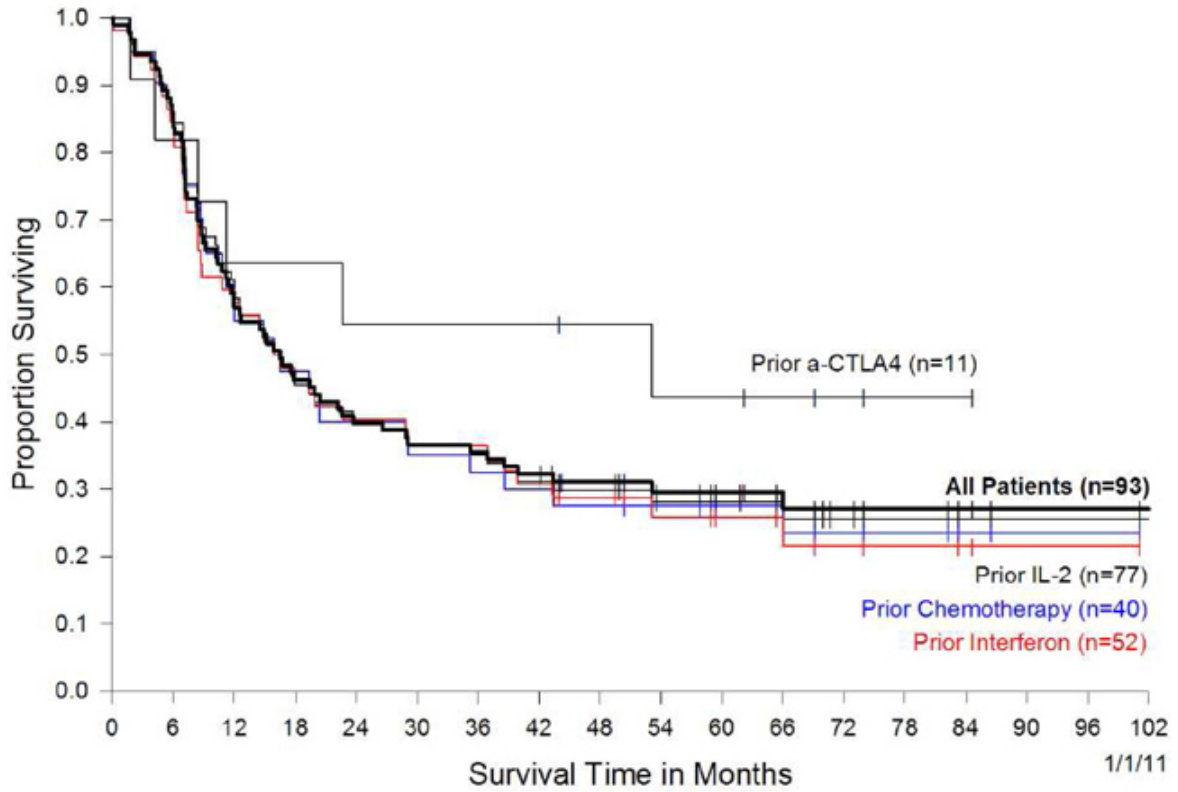
Lion Biotechnologies, Inc. is an emerging biotechnology company focused on developing and commercializing adoptive cell therapy (ACT) using autologous tumor infiltrating lymphocytes (TIL) for the treatment of metastatic melanoma and other solid cancers. ACT using TIL was developed by Dr. Steven Rosenberg, Chief of Surgery at the National Cancer Institute (NCI), who is a recognized pioneer in immuno-oncology. ACT utilizes the patient's own immune system (T-cells harvested from a patient) to treat cancer in that patient. TIL are anti-tumor T-cells that are naturally present in a patient's tumors and are collected from individual patients' tumor samples. The TIL are then activated and expanded *ex vivo* and then infused back into the patient to eliminate tumor cells.

Adoptive cell therapy using tumor infiltrating lymphocytes

Patients undergoing TIL therapy must have their tumors surgically resected. The TIL are then isolated, activated, and expanded to billions *in vitro*, away from cancer's immune-suppressing effects. These highly activated, potent TIL are then infused back into the patient, who has been preconditioned to remove all suppressive influences.

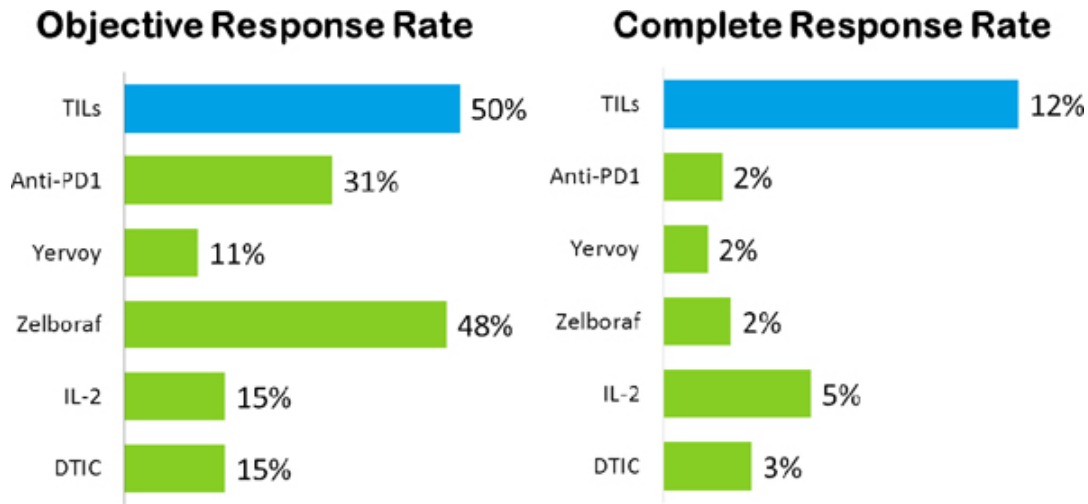


Our lead product candidate, TIL for the treatment of melanoma, is based on the clinical development and trials conducted by Dr. Steven A. Rosenberg at the NCI. For more than a decade, clinical development and trials have been conducted by the NCI, MD Anderson Cancer Center (MD Anderson), the H. Lee Moffitt Cancer & Research Institute (Moffitt) and Sheba Hospital in Israel. We are also aware of other on-going clinical trials, including on-going work by other non-profit institutions, hospitals and academic institutions in the U.S. and Europe. Although we are funding development of TIL at NCI and work closely with some of the physicians involved in developing these technologies at Moffitt and MD Anderson, to date we have not been the sponsors of these clinical trials. Our goal is to initially focus on metastatic melanoma, but to also expand the development of TIL therapy to treat other solid tumors. Results from Phase 1 and Phase 2 clinical trials conducted in small patient populations at these four institutions show that between 46% and 49% of stage IV metastatic melanoma patients refractory to other treatments and treated with TIL experienced an objective response, showing greater than 50% tumor shrinkage. Complete responses, where all of the tumor was eradicated, occurred between 7% and 13% of patients. Of 20 refractory metastatic melanoma patients treated with TIL therapy at the NCI who had complete responses, 19 are ongoing from seven to more than ten years. The graph below shows the long term survival of this 93 patient NCI study showing more than 25% long term survivors over 8 years.



In a recent two-arm randomized trial of 101 patients at the NCI to determine the effect of improved lymphodepletion on the clinical outcomes, an objective response rate of 54% was achieved. There were 14 complete responders, 13 of which are ongoing beyond two years. Of the 41 partial responders, 22 are ongoing beyond a year and 15 ongoing beyond two years.

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



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

Intellectual Property

Under a patent license agreement (the NIH License Agreement) with the National Institutes of Health (NIH), an agency of the United States Public Health Service within the Department of Health and Human Services, we have acquired a non-exclusive, worldwide right and license to develop and manufacture autologous TIL for the treatment of metastatic melanoma, ovarian, breast and colorectal cancers. The intellectual property subject to the NIH License Agreement is covered by patents and patent applications, consisting of issued and pending patent applications in the United States, as well as foreign patents and pending patent applications as counterparts of U.S. patents and patent applications, including Europe, Australia, and Canada. The NIH License Agreement will expire on a product-by-product basis upon the expiration of the subject patent rights. The subject matter claimed in the patents and patent applications that were licensed by us under the NIH License Agreement generally relates to:

- *Ex vivo* methods to grow T-cells and TIL in particular; and
- Methods to use T-cells and TIL in particular as therapeutic agents for the treatment of metastatic cancers, including but not limited to metastatic melanoma.

We recently surrendered to the NIH some of the unnecessary patents/patent applications included in the NIH License Agreement. The patents and patent applications currently covered by the NIH License Agreement include non-exclusive licenses to (i) adoptive immunotherapy with enhanced T lymphocyte survival (using T lymphocytes genetically modified to express IL-15) (issued U.S. patent no. 7,998,736), (ii) immunotherapy with in vitro-selected antigen-specific lymphocytes after non-myeloablative lymphodepleting chemotherapy (issued U.S. patent nos. 8,034,334 and 8,287,857), (iii) methods of growing TIL in gas-permeable containers (pending), and (iv) adoptive cell therapy with young T-cells (issued U.S. patent no. 8,383,099 and a pending U.S. continuation application). We also have the right to issued patents, or patent applications, for certain of the issued patents filed in Australia, Canada, and Europe. The issued U.S. patents will expire at various times through 2030, assuming that all maintenance fees are timely paid. We have conducted freedom-to-operate analyses of the current patent landscape with respect to our lead product candidate, and based on these analyses we believe that we have the freedom to operate for metastatic melanoma. However, the area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties.

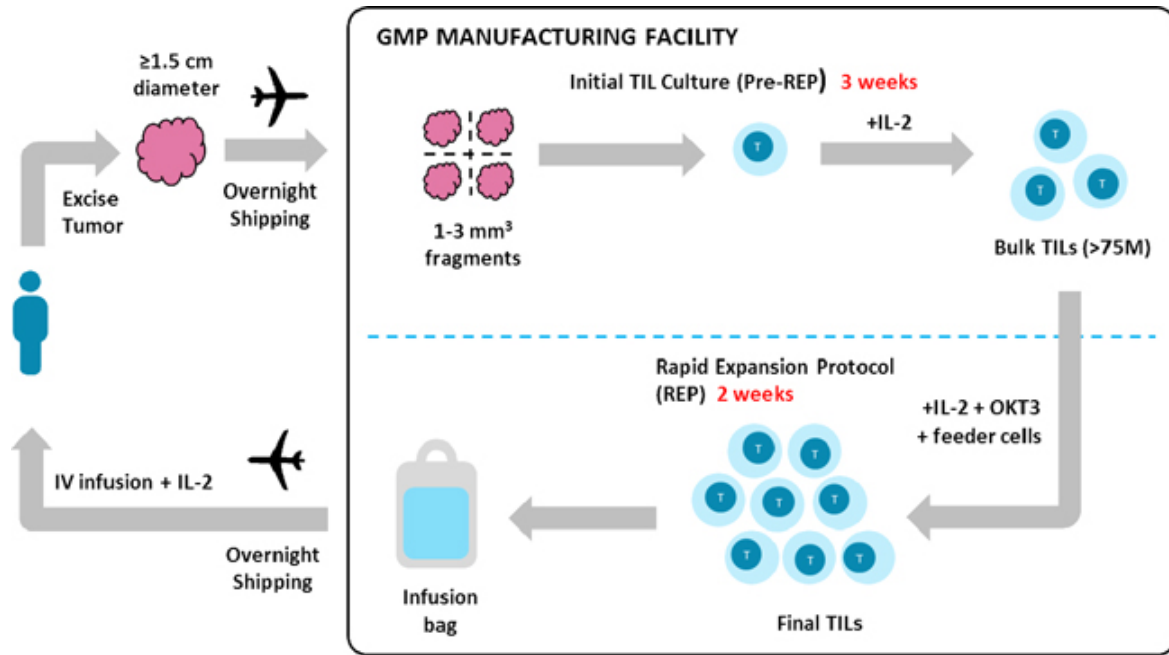
On July 21, 2014, we entered into an exclusive license agreement with Moffitt (Moffitt License Agreement) under which we received an exclusive, worldwide license to Moffitt's rights in and to two technologies. For each of the technologies covered under the Moffitt License Agreement, there is a U.S. provisional application pending, which technologies are related to methods for improving tumor-infiltrating lymphocytes for adoptive cell therapy. The license covers the application of this technology to metastatic melanoma and other solid tumor types, including triple-negative breast cancer, non-small cell lung cancer and other tumors that historically have been difficult to treat. However, no assurance can be given that any patent will issue in the United States or any other country from these licensed patent applications.

Currently, we are also in discussions with the NIH to license additional exclusive rights to genetic engineering of T-cells. These next generation T-cell technologies include designer T-cells to incorporate cytokines to enhance activity and checkpoint inhibition to control the tumor microenvironment. Next generation T-cell technologies include TIL enriched for higher potency that have a lower cost of goods and a shorter manufacturing process. However, no assurance can be given that we will be able to license these additional rights, or that any patent will issue in the United States or in any other country from any of such additional licensed patent applications.

In 2011 we entered into a Cooperative Research and Development Agreement (CRADA) with the NCI, pursuant to which we support the *in vitro* development of improved methods for the generation and selection of TIL, develop approaches for large-scale production of TIL, and conduct clinical trials using these improved methods of generating TIL for the treatment of metastatic melanoma. The CRADA provides that we are entitled to obtain exclusive rights to the technologies developed thereunder. We have elected to exercise our option to negotiate an exclusive license to new adoptive cell therapy technologies for the treatment of metastatic melanoma. However, no assurance can be given that we will receive these rights from the NCI. The CRADA also provides us with access to important clinical data, manufacturing data and to operating procedures.

Manufacturing

TIL therapy to date has been limited because manufacturing of TIL is currently labor intensive, costly, and time-consuming. We have entered into a Manufacturing Services Agreement with Lonza Walkersville, Inc. (Lonza) pursuant to which Lonza has agreed to manufacture, package, ship and handle quality assurance and quality control of our TIL. Lonza has commenced developing a commercial-scale manufacturing process for the TIL therapy. Our goal is to develop and establish a manufacturing process for the large-scale production of TIL that is in accord with current Good Manufacturing Practices (cGMP). By providing centralized manufacturing, we believe TIL therapy can be made more widely available to a larger number of cancer patients. Since 2011 we have worked with NCI to develop new systems for large scale manufacturing of TIL and to transfer the manufacturing process to Lonza for further development. The following diagram illustrates our proposed TIL manufacturing process.

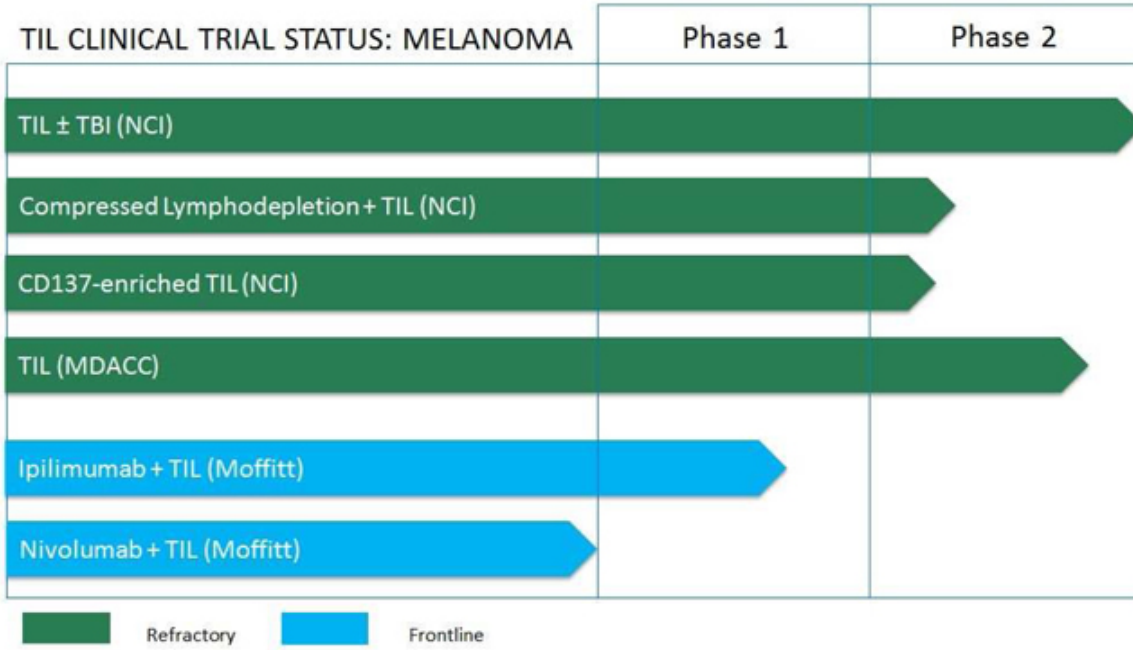


Development Plans and Goals

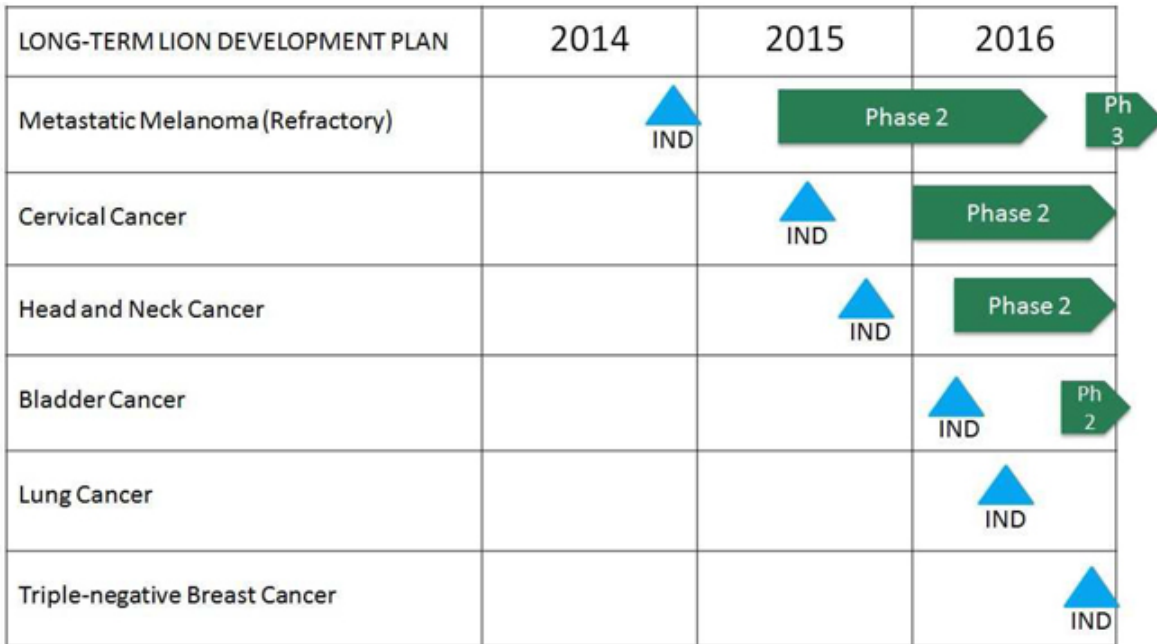
In addition, the NCI, under our CRADA, is currently continuing to test TIL in metastatic melanoma patients either alone, or in combination with other therapeutic agents. We intend to supplement the research being conducted under the CRADA with research to be conducted at our research facility recently established in Tampa, Florida, near Moffitt on the campus of the University of South Florida, and through a clinical trial grant agreement we entered into with Moffitt in July 2014 to expand an ongoing Phase 1 study of TIL combined with the checkpoint inhibitor ipilimumab in patients with metastatic melanoma.

We plan to file an investigational new drug application (IND) with the U.S. Food & Drug Administration (FDA) by the end of 2014 and to initiate a Phase 2 clinical trial early in 2015 in order to evaluate Lonza’s manufacturing process and to determine whether clinical responses can be observed. Thereafter, our goal is to initiate a Phase 3 trial in 2016 in refractory metastatic melanoma patients. Our target milestones for 2015 include amending the NIH License Agreement to obtain exclusive rights to metastatic melanoma, receiving the exclusive rights to the next generation T-cell technologies that we applied for under the CRADA, potentially receiving the exclusive rights from the NCI to the use of the licensed technologies for other tumors, filing INDs for cervical cancer and head and neck cancer and initiating a Phase 1 combination trial at Moffitt to treat metastatic melanoma in the frontline setting by combining TIL with PD-1/PD-L1 antibodies.

The status of various TIL clinical trials using the TIL technology developed by the NCI and licensed to us under the NIH License Agreement is set forth below in the following chart. The NCI trials are under the CRADA; we are partially funding the Ipilimumab and TIL trial at Moffitt and will partially fund Moffitt’s proposed Nivolumab and TIL trial.



Our long term development plan is summarized in the following chart.



RISK FACTORS

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

The intellectual properties that we are currently using to develop TIL-based cancer therapy products were licensed to us 1) by the NIH under the License Agreement and 2) by the H. Lee Moffitt Cancer & Research Institute under the Moffitt License Agreement. However, the License Agreement from the NIH is non-exclusive, and any other party could obtain a license for some or all of the licensed intellectual properties that we currently use. No assurance can be given that the NIH has not previously licensed, or that the NIH hereafter will not license to other biotechnology companies some or all of the technologies available to us under the License Agreement. In addition, a certain pending U.S. patent application in the 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. In addition, 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.

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

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

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

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

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

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

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

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

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

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

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