CLEVELAND BIOLABS INC
Form 10-K
March 17, 2014
Table of Contents

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, 2013

or

¨ **Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the transition period from _____ to _____

Commission file number 001-32954

CLEVELAND BIOLABS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	20-0077155
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
73 High Street, Buffalo, NY 14203	(716) 849-6810
(Address of principal executive offices)	Telephone No.

Securities Registered Pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange which registered
Common Stock, par value $0.005 per share	NASDAQ Capital 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 x

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 x

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 x 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 x No ¨

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition 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 x
Non-accelerated filer ¨	Smaller reporting company ¨

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates, computed by reference to the price at which the common equity was last sold or the average bid and asked price of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter was $65,171,586. There were 50,919,820 shares of common stock outstanding as of March 14, 2014.

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant s 2014 Annual Meeting of Stockholders is incorporated by reference in Part III to the extent described therein.

Table of Contents

Cleveland BioLabs, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2013

INDEX

Table of Contents

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. Forward-looking statements give our current expectations of forecasts of future events. All statements other than statements of current or historical fact contained in this annual report, including statements regarding our future financial position, business strategy, new products, budgets, liquidity, cash flows, projected costs, regulatory approvals or the impact of any laws or regulations applicable to us, and plans and objectives of management for future operations, are forward-looking statements. The words anticipate, believe, continue, should, estimate, expect, intend, may, plan, project, will, and similar expressions, as they relate to us, are intended to identify forward-looking statements.

We have based these forward-looking statements on our current expectations about future events. While we believe these expectations are reasonable, such forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. Our actual future results may differ materially from those discussed here for various reasons. When you consider these forward-looking statements, you should keep in mind these risk factors and other cautionary statements in this annual report including in Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations and in Item 1A Risk Factors.

Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. We do not undertake any obligation to update any such statements or to publicly announce the results of any revisions to any of such statements to reflect future events or developments. When used in the report, unless otherwise stated or the context otherwise requires, the terms Cleveland BioLabs and CBLI refer to Cleveland BioLabs, Inc., but not its consolidated subsidiaries and the Company, we, us and our refer to Cleveland BioLabs, Inc. together with its consolidated subsidiaries.

Table of Contents

PART I

Item 1. Business

GENERAL OVERVIEW

We are an innovative drug development company seeking to develop first-in-class pharmaceuticals designed to address diseases with significant unmet medical need. We combine our proven scientific expertise and our depth of knowledge about our products mechanisms of action into a passion for developing drugs to save lives. Our programs are focused on the implementation of novel pharmacological approaches to control cell death. Our proprietary drug candidates act via unique mechanisms and targets to kill cancer and protect healthy cells. We conduct business in the United States and the Russian Federation and have worldwide development and commercialization rights to all of our product candidates, subject to certain financial obligations to our current licensors. Our lead product candidates are Entolimod, which we are developing as a radiation countermeasure and an oncology drug, and Curaxin CBL0137, our lead oncology product candidate. We also have an additional clinical stage program and multiple innovative projects in different stages of preclinical drug development (see Product Development Pipeline Other Compounds).

Entolimod, our most advanced product candidate, is a Toll-like receptor 5, or TLR5, agonist, which we are developing as a radiation countermeasure for prevention of death from Acute Radiation Syndrome, or ARS, and as an oncology drug. We believe that Entolimod is the most efficacious radiation countermeasure currently in development. Following is a summary of the clinical development of Entolimod to date and regulatory status:

Entolimod is being developed under the U.S. Food & Drug Administration s, or FDA s, Animal Efficacy Rule, or the Animal Rule, for the indication of reducing the risk of death following total body irradiation (see Government Regulation Animal Rule). We have completed two dose escalation clinical studies designed to evaluate the safety, pharmacokinetics and pharmacodynamics in a total of 150 healthy volunteers. Administration of Entolimod was not associated with irreversible harm at any of the doses evaluated in these two studies. We have completed a Good Laboratory Practices, or GLP, randomized, blinded, placebo-controlled, pivotal study designed to evaluate the dose-dependent effect of Entolimod on survival and biomarker induction in 179 non-human primates exposed to 7.2 Gy total body irradiation when Entolimod or placebo were administered at 25 hours after radiation exposure. We have completed a GLP, randomized, open-label, placebo-controlled, pivotal study designed to evaluate the dose-dependent effect of Entolimod on biomarker induction in 160 non-irradiated non-human primates. We were granted Fast Track and Orphan Drug designations by the FDA. We plan to meet with the FDA regarding our human dose-conversion and our intent to submit a pre-Emergency Use Application, or pre-EUA, and, if appropriate after such meeting, plan to submit a pre-EUA in 2014.

Additionally, we are conducting a Phase 1 open-label, dose-escalation trial of Entolimod in patients with advanced cancer in the United States. In 2014, we plan to initiate, in the Russian Federation, a placebo-controlled, randomized trial of Entolimod in healthy volunteers to define optimal innate stimulatory dose and to support the safety database for our radiation countermeasure development program.

Curaxin CBL0137, our lead oncology product candidate, acts through a novel mechanism enabling this compound to simultaneously target three molecular pathways within cancer cells. We believe that CBL0137 has the potential to be a broadly-marketed cancer treatment that will address the unmet needs of treating diseases such as glioblastoma, lymphoma and treatment resistant neuroblastoma in children. CBL0137 inhibits Nuclear Factor kappa-B, or NF-kB, and Heat Shock Factor Protein-1, or HSF-1, transcription factors that are essential for viability of many types of tumors and activates tumor suppressor protein p53 by modulating intracellular localization and activity of chromatin remodeling complex Facilitates Chromatin Transcription, or FACT. CBL0137 has demonstrated reproducible

anti-tumor effects in animal models of colon, breast, renal, pancreatic, head and neck and prostate cancers, melanoma, non-small cell lung cancer, glioblastoma, lymphoma, leukemia and neuroblastoma. We are currently enrolling two Phase 1 trials of CBL0137: (i) a multi-center, single agent, dose escalation study evaluating oral administration of CBL0137 in subjects with advanced solid tumors that are

Table of Contents

resistant or refractory to standard of care treatment in the Russian Federation; and (ii) a multi-center, single agent dose escalation study in the United States, evaluating intravenous administration of CBL0137 in patients with metastatic or unresectable advanced solid cancers and lymphomas in the United States. We are conducting parallel evaluation of oral and intravenous routes of administration and continuous low-dose versus interrupted high-dose schedules to reduce our developmental risk by fully characterizing the clinical pharmacology of CBL0137.

CORPORATE INFORMATION

We were incorporated in Delaware in June 2003 as a spin-off company from the Cleveland Clinic Foundation, or CCF. We exclusively license our founding intellectual property from CCF. In 2007, we relocated the company to Buffalo, New York and became affiliated with Roswell Park Cancer Institute, or RPCI, through technology licensing and research collaboration relationships. Our common stock is listed on the NASDAQ Capital Market under the symbol CBLI.

Our principal executive offices are located at 73 High Street, Buffalo, New York 14203, and our telephone number at that address is (716) 849-6810.

The CBLI logo and CBLI product names are proprietary trade names of CBLI or its subsidiaries. We may indicate U.S. trademark registrations and U.S. trademarks with the symbols ® and™, respectively. Other third-party logos and product/trade names are registered trademarks or trade names of their respective owners.

PRODUCT DEVELOPMENT PIPELINE

Our product development programs arise from internally developed and in-licensed intellectual property from our innovation partners, CCF and RPCI. For instance, Entolimod emerged from our strategic licensing arrangement with CCF and CBL0137 emerged from our internal research efforts. In building our product development pipeline, we have intentionally pursued drug targets with applicability across multiple therapeutic areas and indications. This approach gives us multiple product opportunities and ensures that our success is not dependent on any single product or indication.

Our primary product development programs and their respective development stages are illustrated below:

* *Lead product development program*
** *HSCT means hematopoietic stem cell transplant*

Table of Contents

Our product development efforts were initiated by discoveries related to apoptosis, a tightly regulated form of cell death that can occur in response to internal stresses or external events such as exposure to radiation or toxic chemicals. Apoptosis is a major determinant of the tissue damage that occurs in a variety of medical conditions involving ischemia, or temporary loss of blood flow, such as cerebral stroke, heart attack and acute renal failure. In addition, apoptotic loss of cells of the hematopoietic, or HP, system and gastrointestinal, or GI, tract is largely responsible for the acute lethality of high-dose radiation exposure. On the other hand, apoptosis is also an important protective mechanism that allows the body to eliminate defective cells such as those with cancer-forming potential.

We have developed novel strategies to target the molecular mechanisms controlling apoptotic cell death for therapeutic benefit. These strategies take advantage of the fact that tumor and normal cells respond to apoptosis-inducing stresses differently due to tumor-specific defects in cellular signaling pathways such as inactivation of p53 (a pro-apoptosis regulator) and constitutive activation of NF-kB (a pro-survival regulator).

Thus, we designed two oppositely-directed general therapeutic concepts:

(a) Temporary and reversible suppression of apoptosis in normal cells to protect healthy tissues from stress-induced damage using compounds we categorize as Protectans, which include Entolimod and CBLB612; and

(b) Reactivation of apoptosis in tumor cells to eliminate cancer using compounds we categorize as Curaxins, which include CBL0137 and CBL0102.

Entolimod Biodefense Indication

Our lead Protectan product candidate is Entolimod, an engineered derivative of the *Salmonella* flagellin protein that was designed to retain its specific TLR5-activating capacity while increasing its stability, reducing its immunogenicity and enabling high-yield production. We are developing Entolimod for dual indications: (i) as a radiation countermeasure for prevention of death from ARS, which we refer to as a Biodefense Indication; and (ii) as an oncology drug (discussed in Product Development Pipeline Other Programs).

The market for radiation countermeasures grew dramatically following the September 11, 2001 terrorist attacks and the subsequent use of anthrax in a biological attack in the United States. Terrorist activities worldwide have continued in the intervening years and the possibility of chemical, biological, radiation and nuclear attacks continues to represent a perceived threat for governments world-wide. In addition to the U.S. government, we believe the potential markets for the sale of radiation countermeasures include U.S. and foreign state and local governments, including both defense and public health agencies, non-governmental organizations and multinational companies, transportation and security companies, healthcare providers, hospitals and clinics, and nuclear power facilities.

Acute high-dose whole body or significant partial body radiation exposure induces massive apoptosis of cells of the HP system and GI tract, which leads to ARS, a potentially fatal condition for which there are currently no FDA-approved treatments. The threat of ARS is primarily limited to emergency/defense scenarios and is significant given the possibility of nuclear/radiological accidents, warfare or terrorist incidents. The scale of possible exposure (number of people affected) has been estimated by the U.S. government to be in the range of 500,000 based on a modeled 10-kiloton device detonation in New York City. And we believe the current lack of approved efficacious treatments to deal with such an event makes Entolimod a compelling product candidate. It is not feasible or ethical to test the efficacy of Entolimod as a radiation countermeasure in humans. Therefore, we are developing Entolimod

under the FDA s Animal Rule guidance (see Government Regulation Animal Rule). The Animal Rule authorizes the FDA to rely on data from animal studies to provide evidence of a product s effectiveness under circumstances where there is a reasonably well-understood mechanism for the activity of the product. Under these requirements, and with the FDA s prior agreement, medical countermeasures, like Entolimod, may be approved for use in humans based on evidence of effectiveness derived from appropriate animal studies, evidence of safety derived from studies in humans and any additional supporting data.

Table of Contents

In 2014, we plan to meet with the FDA regarding human dose-conversion and our intent to file a pre-EUA. If appropriate after such meeting, we will submit a pre-EUA using the human dose of Entolimod that we determined through our proprietary dose conversion methodology, which utilizes the data from our pivotal non-human primate studies and our clinical studies of Entolimod in healthy volunteers. If authorized, pre-EUA status will allow Entolimod to be sold into the National Stockpile and used under a state of emergency. Such authorization is not equivalent to full licensure through approval of a biologic license application, or BLA, but precedes full licensure, and, importantly, would position Entolimod for potential sales in advance of full licensure in the United States. We further believe pre-EUA status will position us to explore sales opportunities with foreign governments.

Our pivotal efficacy study conducted in 179 non-human primates demonstrated with a high degree of statistical significance that injection of a single dose of Entolimod given to rhesus macaques 25 hours after exposure to a 70% lethal dose of total body irradiation improved animal survival by nearly three-fold compared to the control group. Dose-dependence of Entolimod s efficacy was demonstrated with doses above the minimal efficacious dose establishing a plateau at approximately 75% survival at 60 days after irradiation, as compared to 27.5% survival in the placebo-treated group.

Our pivotal study conducted in 160 non-human primates established the dose-dependent effect of Entolimod on biomarkers for efficacy in non-irradiated non-human primates.

Our clinical studies of Entolimod in 150 healthy human subjects demonstrated the safety profile of Entolimod and established the dose-dependent effect of Entolimod on efficacy biomarkers in humans. In these studies, and in our currently ongoing Phase 1 oncology study, transient decrease in blood pressure and elevation of liver enzymes were observed along with transient mild to moderate flu-like syndrome. Such effects are the most common adverse events and they are linked to up-regulation of cytokines that are also biomarkers for efficacy.

The FDA has granted Fast Track status to Entolimod (see Government Regulation Fast Track Designation) and Orphan Drug status for prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster (see Government Regulation Orphan Drug Designation).

We have worldwide development and commercialization rights to Entolimod.

Curaxin CBL0137

Our lead Curaxin product candidate is CBL0137, a small molecule with a multi-targeted mechanism of action that may be broadly useful for treatment of many different types of cancer with greater efficacy and substantially lower risk for patients developing drug resistance than conventional chemotherapeutic agents. CBL0137 inhibits NF-kB and HSF-1 transcription factors that are essential for viability of many tumor types of tumors and activates tumor suppressor protein p53 by modulating intracellular localization and activity of chromatin remodeling complex FACT. CBL0137 has been shown to be efficacious in pre-clinical models of colon, breast, renal, pancreatic, head and neck and prostate cancers, melanoma, non-small cell lung cancer, glioblastoma, lymphoma, leukemia and neuroblastoma.

We are currently enrolling patients in a Phase 1 multi-center, single agent, dose escalation study of an oral administration of CBL0137 in subjects with advanced solid tumors that are resistant or refractory to the standard of care in the Russian Federation. We are also currently enrolling patients in a Phase 1 multi-center, single agent, dose escalation study of an intravenous administration of CBL0137 in subjects with metastatic or unresectable advanced solid cancers and lymphomas in the United States. These studies are designed to evaluate safety, pharmacokinetics, and document any objective tumor response. The exploratory objectives of these trials are to examine (i) the relationship between tumor expression of FACT and response to CBL0137, and (ii) the effect of CBL0137 on the

expression of biomarkers in peripheral blood mononuclear cells, or PBMCs, and on soluble

Table of Contents

factors in serum. We are conducting parallel evaluation of oral and intravenous routes of administration and continuous low-dose versus interrupted high-dose schedules to reduce our developmental risk by fully characterizing the clinical pharmacology of CBL0137.

Our majority-owned subsidiary, Incuron, holds worldwide development and commercialization rights to CBL0137.

Other Programs

In addition to our Entolimod and CBL0137 development programs, we have an additional clinical stage program and multiple earlier stage development programs. The most advanced of these programs and projects are described below.

Curaxin CBL0102, a non-proprietary molecule that is a relative of 9-aminoacridine, a compound that is the core structure of many existing drugs. CBL0102 is a Quinacrine, a compound with a long history of use in humans as a treatment for malaria, osteoarthritis and autoimmune disorders. Quinacrine was not, however, previously used as an anti-cancer agent. In 2008, we completed a Phase 2 study in 31 patients with late stage, hormone refractory (androgen-independent) prostate cancer that had not responded to or relapsed following previous hormonal therapy and/or chemotherapy. The study results showed that one patient had a partial response, while 50% of the patients exhibited a decrease or stabilization in the rate of prostate cancer progression. CBL0102 was well-tolerated and there were no serious adverse events attributed to the drug. Therefore, the trial provided indications of anti-cancer activity and demonstrated safety for CBL0102 treatment for the cancer patients who were in the trial. In late 2013, we completed a Phase 1 safety and tolerability study of CBL0102 in patients with liver metastases from solid tumors of epithelial origin or primary advanced hepatic carcinoma for which standard therapy had failed or did not exist in the Russian Federation and we are in the process of finalizing the reports for this study. An investigator-initiated Phase 1/2 trial evaluating the tolerability of CBL0102 in combination with erlotinib in patients with stage 3B-4 non-small cell lung cancer is currently enrolling patients at the Case Comprehensive Cancer Center. The FDA has granted CBL0102 Orphan Drug status for treatment of hepatocellular carcinoma. Our majority owned subsidiary, Incuron, holds worldwide development and commercialization rights to CBL0102.

Entolimod is an engineered derivative of the *Salmonella* flagellin protein that was designed to retain its specific TLR5-activating capacity while increasing its stability, reducing its immunogenicity and enabling high-yield production. In addition to developing Entolimod as a radiation countermeasure for prevention of death from ARS, we are also developing Entolimod as an oncology drug. We believe that Entolimod has the potential to treat cancer by activating the innate and adaptive immune response in patients. In preclinical studies, Entolimod produced tissue-specific activation of innate immune responses via interaction with its receptor, TLR5, and the liver was identified as a primary mediator of Entolimod activity. Entolimod has also been shown to have a direct cytotoxic effect on tumors expressing TLR5 in animal models. Evaluations of local administration of Entolimod in organs expressing TLR5, such as the bladder, have also been performed in pre-clinical models. We are currently enrolling patients in a Phase 1, open-label, dose-escalation study designed to evaluate the safety, pharmacokinetics, pharmacodynamics and clinical activity of Entolimod in advanced cancer patients. In the second half of 2014 we plan to initiate a placebo-controlled, randomized trial of Entolimod in healthy subjects to define an optimal immunostimulatory dose. The study will be performed in the Russian Federation as the first of two planned studies under a 149 million ruble matching funds development contract that we received in October 2013 from the Ministry of Industry and Trade of the Russian Federation, or MPT (see Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations).

Protectan CBLB612 is a proprietary compound based upon a natural activator of another tissue-specific component of the innate immune system, the TLR2/TLR6 heterodimeric receptor. CBLB612 is a pharmacologically optimized synthetic molecule that structurally mimics naturally occurring lipopeptides of Mycoplasma (a genus of parasitic

bacteria) and activates NF-kB pro-survival and immunoregulatory signaling

Table of Contents

pathways via specific binding to TLR2 on a subset of body tissues and cell types that express this receptor. Preclinical studies have shown that the efficacy of CBLB612 exceeds that of granulocyte colony-stimulating factor, or G-CSF (Amgen s Neupogen®), the market-leading drug used for stimulation of white blood cell regeneration. CBLB612 s hematopoietic stem cell, or HSC, stimulatory activity outweighed that of G-CSF when the drugs were administered either as monotherapies, in either mice or non-human primates, or in combination with Plerixafor (Genzyme s Mozobil®, a chemokine receptor antagonist approved by the FDA as an HSC mobilizer). However, the highest degree of HSC mobilization, 12-fold greater than that induced by the current clinical standard of G-CSF+Plerixafor, was observed when CBLB612 was added to that combination. The strong synergistic effect of this triple drug combination provides further support for development of CBLB612 as a valuable stem cell mobilizing agent. In 2014, we plan to initiate a Phase 1, single-center, blind, placebo-controlled, single ascending dose study in the Russian Federation to evaluate the safety and tolerability of CBLB612 in healthy volunteers and measure response of various HP stem and progenitor cell types in order to gain a preliminary estimate of the drug s HSC stimulatory efficacy under a 139 million ruble matching funds development contract that we received in July 2012 from MPT (see Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations). We have licensed CBLB612 to Zhejiang Hisun Pharmaceutical Co., Ltd. for the territories of China, Taiwan, Hong Kong and Macau. We have rest-of-world development and commercialization rights to CBLB612.

Mobilan is our most advanced discovery/pre-clinical stage program. Mobilan is a nanoparticle-formulated recombinant non-replicating adenovirus that directs expression of TLR5 and its agonistic ligand, flagellin. In pre-clinical studies, delivery of Mobilan to tumor cells results in constitutive autocrine TLR5 signaling and strong activation of the innate immune system with subsequent development of adaptive anti-tumor immune responses. Mobilan is in the pre-clinical stage of development as a universal anti-cancer therapy. In 2014, we plan to file an IND in the Russian Federation under a 149 million ruble matching funds development contract that we received in October 2013 from MPT (see Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations). Our majority owned subsidiary, Panacela, holds worldwide development and commercialization rights to Mobilan.

STRATEGIC PARTNERSHIPS

Since our inception, strategic alliances and collaborations have been integral to our business. We have leveraged the experience, contacts and knowledge of our founders to engage funding partners in the Russian Federation and to develop and maintain academic-corporate innovation partnerships with CCF and RPCI. Through these partnerships we have collaborated with world-class scientists to develop our novel technologies and accessed non-traditional funding sources, including federal and foreign government contracts and project-oriented funding to support the development of certain of our technologies. We have received project-oriented funding from Russian Federation based venture funds BioProcess Capital Partners, or BCP, and Open Joint Stock Company Rusnano , or Rusnano, through the formation of our majority owned subsidiaries, Incuron and Panacela, both of which are co-located in the Russian Federation and the United States. We believe that these companies, as well as our wholly-owned subsidiary BioLab 612, may benefit from programs supporting domestic pharmaceutical industry development in the Russian Federation as well as the relative ease of enrolling patients as compared to western markets. We have negotiated exclusive licenses to rights in each of our technologies from CCF and RPCI.

BioProcess Capital Partners

In December 2009, we entered into our Incuron joint venture with BCP to develop Curaxin compounds for treatment of oncological diseases. According to the terms of the agreement, we transferred rights in the Curaxin molecules to the new joint venture company, Incuron, in which BCP agreed to contribute an aggregate of 549,497,000 Russian rubles (approximately $17.2 million as noted below) to support development of the compounds. As of December 31, 2013,

Incuron had received from BCP payments of 369,570,000 Russian rubles (approximately $11.7 million) and BCP will make the balance of its contribution of 179,927,000 Russian rubles

Table of Contents

(approximately $4.9 million, based on the March 11, 2014 exchange rate) upon the achievement of predetermined development milestones, which are expected in early 2014. As of December 31, 2013, we had a 59.2% ownership interest in Incuron. After the remaining contractual investments, CBLI expects to own approximately 47% of Incuron. CBLI has an option to maintain a majority ownership stake by investing $3.0 million in Incuron within 60 days of the last contribution by BCP.

Rusnano

In October 2011, we entered into our Panacela joint venture with Rusnano to carry out a complete cycle of development and commercialization in the Russian Federation for the treatment of oncological, infectious or other diseases. We invested $3.0 million in Panacela preferred shares and warrants, and, together with certain third-party owners, assigned and/or provided exclusive licenses, as applicable, to Panacela to provide Panacela with worldwide development and commercialization rights to five preclinical product candidates in exchange for Panacela common shares. Rusnano invested $9.0 million in Panacela preferred shares and warrants. In 2013, Rusnano loaned Panacela $1.5 million through a convertible term loan, or the Panacela Loan, and revised their original investment agreement to provide that Rusnano may invest an additional $15.5 million at their option and to remove the predetermined development milestones and timelines for further investment. As of December 31, 2013, we had an ownership stake of approximately 54.6% in Panacela. However, we may have a less than majority ownership interest in Panacela if Panacela raises additional capital through dilutive financing with a third-party or by Rusnano exercising their options to invest an additional $15.5 million, exercising their warrants in Panacela or converting the Panacela Loan into additional shares of Panacela preferred stock, which may be at a discounted price based upon the terms of the Panacela Loan.

Cleveland Clinic Foundation

In July 2004, CBLI entered into an exclusive license agreement with CCF, or the CCF License, pursuant to which CBLI was granted an exclusive license to CCF s research base underlying our therapeutic platform including Entolimod, CBLB612, Curaxin CBL0102, Mobilan and several earlier stage compounds that are not currently material to our business. In consideration for the CCF License, we agreed to issue CCF common stock and make certain milestone, royalty and sublicense royalty payments as described below.

The CCF License requires milestone payments, which may be credited against future royalties owed to CCF, as described in the table below. CBLI has also agreed to make milestone payments of up to approximately $6.5 million for each Panacela Product that achieves certain developmental and regulatory milestones, provided that if CBLI or an affiliate of CBLI and CCF jointly own the Panacela Product, the milestone amounts will be reduced by 50%.

Milestone Description	For Products Limited to Biodefense Uses	For All Other Products (Maximum amount)*
For any IND filing for a product	$ 50,000	$ 50,000
For any product entering Phase II clinical trials or similar registration	100,000	250,000
For any product entering Phase III clinical trials		700,000
For any product license application, BLA or NDA Filing for a product	350,000	1,500,000
	1,000,000	4,000,000

Upon regulatory approval permitting any product to be sold to the commercial market	

* Maximum amounts listed for achievement of milestone in United States. If milestones are reached in another country first, milestone payments will be prorated for certain products under the license based on the market size for the product in such country as that market relates to the then current U.S. market.

Table of Contents

The CCF license requires royalty payments of (a) 2% of net sales of any product candidate under a licensed patent solely owned by CCF; and (b) 1% of net sales of any product candidate under a licensed patent that is jointly owned by CCF and CBLI or an affiliate of CBLI. Further, if CBLI receives upfront sublicense fees or sublicense royalty payments for sublicenses granted by CBLI to third parties for any licensed patents solely owned by CCF, CBLI will pay CCF (i) 35% of such fees if the sublicense is granted prior to filing an IND application, (ii) 20% of such fees if the sublicense is granted after an IND filing but prior to final approval of the Product License Application or NDA, or (iii) 10% of such fees if the sublicense is granted after final approval of the relevant Product License Application or NDA, provided that such sublicense fees shall not be less than 1% of net sales. The above sublicense fees and sublicense royalty payments are reduced by 50% if CCF and CBLI or an affiliate of CBLI jointly own the licensed patent.

Through December 31, 2013, CBLI had paid CCF $150,000 for milestone payments on products limited to biodefense uses, and $400,000 for all other products.

CCF may terminate the CCF License upon a material breach by us, as specified in the agreement. However, we may avoid such termination if we cure the breach within 90 days of receipt of a termination notice. CBLI may terminate the CCF License in its entirety or any specific patent licensed under the agreement by giving at least 90 days written notice of such termination to CCF. The agreement will, subject to certain exceptions, automatically terminate with respect to a licensed product if CCF does not receive a royalty payment for more than one-year after the payment of royalties has begun.

Roswell Park Cancer Institute

We have entered into a number of agreements with RPCI relating to the licensure and development of our product candidates including:

- Two exclusive license and option agreements effective December 2007 and September 2011;
- Various sponsored research agreements; and
- Clinical trial agreements for the conduct of the Phase 1 Entolimod oncology study and the Phase 1 CBL0137 intravenous administration study.

In December 2007, CBLI entered into an agreement with RPCI pursuant to which CBLI has an option to exclusively license any technological improvements to our foundational technology developed by RPCI for the term of the agreement. We believe our option to license additional technology under the agreement potentially provides us with access to technology that may supplement our product pipeline in the future. In consideration for this option and exclusive license, we agreed to make certain milestone, royalty and sublicense royalty payments. Additionally, RPCI may terminate the license upon a material breach by us. However, we may avoid such termination if we cure the breach within 90 days of receipt of a termination notice. The license does not have a specified term; however, as each patent covered by this license agreement expires, the royalties to be paid on each product relating to the licensed patent shall cease.

In September 2011, Panacela entered into an agreement with RPCI, or the Panacela-RPCI License, to exclusively license certain rights Panacela Products, including Mobilan and several earlier stage compounds that are not currently

material to our business, and to non-exclusively license certain know-how relating to the aforementioned product candidates for the limited purposes of research and development and regulatory, export and other government filings. Additionally, under the Panacela-RPCI License, Panacela has a right to exclusively license (i) any technological improvements to the Panacela Products developed by RPCI before September 2016, and (ii) any technology jointly developed by Panacela and RPCI. In consideration for the Panacela-RPCI License, Panacela agreed to issue RPCI common stock and to make certain milestone, royalty and sublicense royalty payments as described below.

Table of Contents

The Panacela-RPCI License requires milestone payments for developmental and regulatory milestones reached in the United States of up to approximately $2.5 million for each Panacela Product that achieves certain developmental and regulatory milestones. Additionally, Panacela will owe additional payments of up to approximately $275,000 for each other country where a licensed Panacela Product achieves similar milestones. Through December 31, 2013, Panacela had not made any milestone payments to RPCI related to the above mentioned license agreement.

The Panacela-RPCI License requires royalty payments on net sales based on percentages in the low single digits. In addition, if Panacela sublicenses any of the licensed Panacela Products, Panacela will owe sublicensing fees ranging from 5% to 15% of fees received from sublicense by Panacela or an affiliate depending upon whether or not an IND has been filed or final approval of the relevant NDA has been obtained for such licensed product.

As each patent covered by the Panacela-RPCI License expires, the license agreement will terminate as to such patent. In addition, the license agreement will terminate with respect of the licensed know-how after 20 years. RPCI may terminate the license upon a material breach by us, as specified in the agreement. However, we may avoid such termination if we cure the breach within 90 days of receipt of a termination notice (or 30 days if notice relates to non-payment of amounts due to RPCI). Panacela may terminate the license agreement in whole or as to any specific patent licensed under the agreement by giving at least 60 days written notice of such termination to RPCI. The agreement will, subject to certain exceptions, automatically terminate with respect to a licensed Panacela Product if Panacela fails to market, promote and otherwise exploit the licensed technology so that RPCI does not receive a royalty payment during any 12-month period after the first commercial sale of such licensed product.

We have also entered into a number of sponsored research agreements with RPCI pursuant to which we have sponsored research to be conducted by RPCI. Under these agreements, we own any invention that is described in our research plan, co-own any inventions not described in our research plan that are made by Dr. Andrei Gudkov, our Chief Scientific Officer who is also the Senior Vice President of Basic Science at RPCI, and RPCI owns any other inventions not described in our research plan. We further have a right to exclusively license RPCI s ownership in any invention developed under such sponsored research agreements that are owned by RPCI. These agreements with RPCI expire in 2014, although we expect to enter into similar future arrangements.

We entered into an asset transfer and clinical trial agreement with RPCI for the conduct, by RPCI, of our Phase 1 clinical trial to evaluate the safety and pharmacokinetic profile of Entolimod in patients with advanced cancers and a clinical trial agreement for RPCI to conduct, as one site in a multi-site trial, our Phase 1 clinical trial to evaluate the safety, pharmacokinetics and pharmacodynamics of intravenous administration of CBL0137 in patients with metastatic or unresectable advanced solid cancers and lymphomas. Either party may terminate these agreements upon 30 days notice to the other party.

INTELLECTUAL PROPERTY

Our intellectual property consists of patents, trademarks, trade secrets and know-how. Our ability to compete effectively depends in large part on our ability to obtain patents for our technologies and products, maintain trade secrets, operate without infringing the rights of others and prevent others from infringing our proprietary rights. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents, or are effectively maintained as trade secrets. As a result, patents or other proprietary rights are an essential element of our business. Our patent portfolio includes patents and patent applications with claims directed to compositions of matter, pharmaceutical formulations and methods of use. Some of our issued patents, and the patents that may be issued based on our patent applications, may be eligible for patent life extension under the Drug Price Competition and Patent Term Restoration Act of 1984 in the United States, supplementary protection certificates in the European Union or similar mechanisms in other countries or territories.

The following are the patent positions relating to our product candidates as of December 31, 2013.

Table of Contents

In the United States, we have 10 issued or allowed patents relating to our clinical-stage programs expiring on various dates between 2024 and 2030 as well as numerous pending patent applications and foreign counterpart patent filings which relate to our proprietary technologies. These patents and patent applications include claims directed to compositions of matter and methods of use.

We have 7 issued U.S. patents covering Entolimod, which expire between 2024 and 2029. These patents include method of use claims relating to our biodefense indication, reducing effects of chemotherapy and treatment of reperfusion injuries. In addition, we have pending U.S. patent applications related to compositions of matter and oncology methods of use, which, if issued, will expire between 2025 and 2032.

We have 1 issued U.S. patent covering CBL0137, which expires in 2030. This patent includes method of use claims relating to apoptosis induction along with inhibition of adaptive heat shock response. In addition, we have a pending U.S. patent application that includes CBL0137 composition of matter and method of use claims, which, if issued, will expire in 2029.

We have 2 issued U.S. patents covering CBLB612 and related agents, which expire between 2026 and 2027. These patents include composition of matter and methods of use claims. In addition, we have a pending U.S. patent application that includes method of use claims relating to increasing mobility of hematopoietic stem cells, which, if issued, will expire in 2028.

We have 1 pending U.S. patent application covering CBL0102, which, if issued, will expire in 2025. This patent includes method of use claims related to treatment of liver cancer.

In addition, as of December 31, 2013, we had more than a hundred additional patents and patent applications filed worldwide. Any patents that may issue from our pending patent applications would expire between 2024 and 2035, excluding patent term extensions. These patents and patent applications disclose compositions of matter and methods of use.

Our policy is to seek patent protection for the inventions that we consider important to the development of our business. We intend to continue to file patent applications to protect technology and compounds that are commercially important to our business, and to do so in countries where we believe it is commercially reasonable and advantageous to do so. We also rely on trade secrets to protect our technology where patent protection is deemed inappropriate or unobtainable. We protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, collaborators and contractors.

RESEARCH AND DEVELOPMENT

In 2013, we transferred 26 laboratory and preclinical employee positions to Buffalo BioLabs, LLC, or BBL, an entity owned in part by our Chief Scientific Officer and director, Dr. Andrei Gudkov, to enable us to better focus our on clinical development activities. In connection with this transaction, we entered into a Master Services Agreement with BBL, pursuant to which BBL agreed to perform laboratory and preclinical research services for us. As of December 31, 2013, our research and development group, including Russian-based personnel, consisted of 18 individuals. Our research and development focuses on management of outsourced preclinical research, clinical trials and manufacturing technologies. We invested $19.5 million, $22.5 million and $22.8 million in research and development in the years ended December 31, 2013, 2012 and 2011, respectively.

SALES AND MARKETING

We currently do not have marketing, sales or distribution capabilities. We do, however, currently have worldwide development and commercialization rights for products arising out of substantially all of our programs. In order to commercialize any of these drugs, if and when they are approved for sale, we will need to enter into partnerships for the commercialization of the approved product(s) or develop the necessary marketing, sales and distribution capabilities.

Table of Contents

COMPETITION

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and intense competition. This competition comes from both biotechnology and major pharmaceutical companies. Many of these companies have substantially greater financial, marketing and human resources than we do, including, in some cases, considerably more experience in clinical testing, manufacturing and marketing of pharmaceutical products. There are also academic institutions, governmental agencies and other research organizations that are conducting research in areas in which we are working. They may also develop products that may be competitive with our product candidates, either on their own or through collaborative efforts. We expect to encounter significant competition for any products we develop. Our product candidates competitive position among other biotechnology and biopharmaceutical companies will be based on, among other things, time to market, patent position, product efficacy, safety, reliability, availability, patient convenience, delivery devices and price. Additionally, competitive products may have superior safety or efficacy, be manufactured less expensively, or have better concept of operations, or CONOPs, usability for biodefense products. In these cases, we may not be able to commercialize our product candidates or achieve a competitive position in the market. This would adversely affect our business.

Specifically, the competition for Entolimod, CBL0137 and our other product candidates includes the following:

Entolimod Biodefense Indication

Product candidates for treatment of ARS face significant competition for U.S. government funding for both development and procurement of medical countermeasures and must satisfy government procurement requirements for biodefense products. Currently there are no FDA-approved drugs for the efficacious treatment of ARS. However, we are aware of a number of companies also developing radiation countermeasures to treat the effects of ARS including Aeolus Pharmaceuticals, Araim Pharmaceuticals, Inc., Cellerant Therapeutics, Exponential Biotherapies Inc., Humanetics Corporation, ImmuneRegen BioSciences, Inc., Neumedicines, Inc., Onconova Therapeutics, Inc., Pluristem Therapeutics, RxBio, Inc., Soligenix, Inc., and the University of Arkansas Medical Sciences Centers. Although their approaches to treatment of ARS are different, we compete with these companies for U.S. government development funding and may ultimately compete with them for U.S. and foreign government purchase and stockpiling of radiation countermeasures. Additionally, our ability to sell to the government also can be influenced by indirect competition from other products, such as Neupogen® (Amgen, Inc.) and potassium iodide, both of which were recently purchased for use as a radiation countermeasure.

Curaxins CBL0137 and CBL0102

Chemotherapy is a large cancer drug category. These treatments are the foundation for treatment of all cancer types and used in most combination regimens. Drugs in this category include, among others, irinotecan, carboplatin, taxanes and doxorubicin. These drugs act on various cell division pathways and ultimately cause cell death. This cell division pathway may not always be specific to the cancer cell but often effects normal cells such as red blood cells, white blood cells and other healthy tissues. Although these drugs as a treatment category in general carry higher toxicities than targeted therapies, they are nonetheless an important drug category for improving patient survival.

Entolimod Oncology Program

The number of cancer therapies is extremely large, numbering in the thousands. Immunotherapies and targeted therapies are primary drivers of growth in this segment. Examples of marketed drugs in these categories include: Avastin® (Roche) for a range of solid tumors including colorectal, lung, breast, renal and gastric cancers, Rituximab® (Roche) for CD20 positive, B-cell non-Hodgkin s lymphoma and Arzerra® (GSK) and Campath® (Bayer Healthcare

Pharmaceuticals) for CD20 positive chronic lymphocytic leukemia; Yervoy® (Bristol-Myers Squibb) for melanoma, Herceptin® (Roche) for human epidermal growth factor receptor-2, or HER-2, positive

Table of Contents

tumors, Gleevec® (Novartis) for Philadelphia chromosome tumor mutations, Erbitux® (Eli Lilly) and Iressa® (AstraZeneca) for epidermal growth factor receptor, or EGRF, expressing tumors and Zelboraf® (Genentech) for BRAF mutated tumors.

CBLB612

Stem cell mobilization is a significant therapeutic category within oncology. G-CSF, marketed as Neupogen® (Amgen, Inc.), is the current standard against which all other mobilization agents for stem cells are measured. Its primary use was established in cancer patients with neutropenia (low white blood cells) due to chemotherapy. In recent years a long-acting release formulation of G-CSF, Neulasta® (Amgen, Inc.), was approved and is prescribed to approximately 50% of U.S. cancer patients with neutropenia. However, Neupogen® is still widely prescribed due to stronger reimbursement and is more often used in Europe. Mozobil® (Genzyme Corporation) is a more recent FDA approved drug designed to help increase the number of stem cells collected from a patient s blood before being transplanted back into the body after chemotherapy.

MANUFACTURING

Our product candidates are biologics and small molecules that can be readily synthesized by processes that we have developed. We do not own or operate manufacturing facilities for the production of our product candidates for pre-clinical, clinical or commercial quantities. We rely on third-party manufacturers, and in most cases only one third-party, to manufacture critical raw materials, drug substance and final drug product for our research, pre-clinical development and clinical trial activities. Commercial quantities of any drugs we seek to develop will have to be manufactured in facilities and by processes that comply with the FDA and other regulations, and we plan to rely on third parties to manufacture commercial quantities of products we successfully develop.

GOVERNMENT REGULATION

Government authorities in the U.S. and in other countries, regulate the research, development, testing, manufacture, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, quality control, labeling and export and import of pharmaceutical products such as those that we are developing. We cannot provide assurance that any of our product candidates will prove to be safe or effective, will receive regulatory approvals or will be successfully commercialized.

U.S. Drug Development Process

In the U.S., the FDA regulates drugs and drug testing under the Federal Food, Drug, and Cosmetic Act and in the case of biologics, also under the Public Health Service Act. Our product candidates must follow an established process before they may be marketed in the U.S.:

Preclinical laboratory and animal tests performed in compliance with Good Laboratory Practices, or GLP;

Development of manufacturing processes which conform to current Good Manufacturing Practices, or cGMP;

Submission and acceptance of an IND application which must become effective before human clinical trials may begin;

Performance of adequate and well-controlled human clinical trials in compliance with current Good Clinical Practices, or cGCP, to establish the safety and efficacy of the proposed drug for its intended use; provided, however, that for Entolimod development under the Animal Rule, we are required to perform pivotal animal studies in compliance with GLP to establish efficacy;

Submission to and review and approval by the FDA of a NDA or BLA prior to any commercial sale or shipment of a product;

Table of Contents

Nonclinical testing. Nonclinical testing includes laboratory evaluation of a product candidate, its chemistry, formulation, safety and stability, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the nonclinical tests must comply with federal regulations and requirements including cGMP and GLP. Prior to the initiation of GLP animal studies, including our pivotal studies for development of Entolimod under the Animal Rule, an Institutional Animal Care and Use Committee, or IACUC, at each testing site must review and approve each study protocol and any amendments thereto.

We must submit to the FDA the results of nonclinical studies, which may include laboratory evaluations and animal studies, together with manufacturing information and analytical data, and the proposed clinical protocol for the first clinical trial of the drug as part of an IND. An IND is a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to the interstate shipment and administration of any new drug that is not the subject of an approved NDA or BLA. Nonclinical tests and studies can take several years to complete, and despite completion of those tests and studies, the FDA may not permit clinical testing to begin.

The IND process. The FDA requires a 30-day waiting period after the submission of each IND application before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period or at any time thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold that may affect one or more specific studies or all studies conducted under the IND. In the case of a clinical hold, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials placed on hold can begin or continue. The IND application process may be extremely costly and could substantially delay development of our products. Moreover, positive results of preclinical animal tests do not necessarily indicate positive results in clinical trials.

Prior to the initiation of clinical studies, each clinical protocol must be submitted to the IND and to an independent Institutional Review Board, or IRB, at each medical site proposing to conduct the clinical trial. The IRB must review and approve each study protocol, and any amendments thereto, and study subjects must sign an informed consent. Protocols include, among other things, the objectives of the study, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor patient safety. Progress reports of work performed in support of IND studies must be submitted at least annually to the FDA. Reports of serious and unexpected adverse events must be submitted to the FDA and the investigators in a timely manner.

Clinical trials. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase 1: The drug is introduced into healthy human subjects or patients (in the case of certain inherently toxic products for severe or life-threatening diseases such as cancer) and tested for safety, dosage tolerance, absorption, distribution, metabolism and excretion.

Phase 2: Involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide, if appropriate, an adequate basis for product labeling.

We cannot be certain that we will successfully complete any phase of clinical testing of our product candidates within any specific time period, if at all. Clinical testing must meet requirements of IRB oversight, informed consent and cGCP. The FDA, the sponsor, or the IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk.

Table of Contents

During the development of a new drug, sponsors are given an opportunity to meet with the FDA at certain points. These meetings typically occur prior to submission of an IND, at the end of Phase 2 and before NDA or BLA submission. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the end-of-Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug.

The NDA or BLA process. If clinical trials are successful, the next step in the drug regulatory approval process is the preparation and submission to the FDA of an NDA or BLA, as applicable. The NDA or BLA, as applicable, is a vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for marketing and sale in the U.S. The NDA or BLA, as applicable, must contain a description of the manufacturing process and quality control methods, as well as results of preclinical tests, toxicology studies, clinical trials and proposed labeling, among other things. A substantial user fee must also be paid with the application, unless an exemption applies. Every newly marketed pharmaceutical must be the subject of an approved NDA or BLA.

Upon submission of an NDA or BLA, the FDA will make a threshold determination of whether the application is sufficiently complete to permit review, and, if not, will issue a refuse-to-file letter. If the application is accepted for filing, the FDA will attempt to review and take action on the application in accordance with performance goal commitments the FDA has made in connection with the prescription drug user fee law in effect at that time. Current timing commitments under the user fee law vary depending on whether an NDA or BLA is for a priority drug or not, and in any event are not a guarantee that an application will be approved or even acted upon by any specific deadline. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria or if the FDA determines that the data do not adequately establish the safety and efficacy of the drug. In addition, the FDA may approve a product candidate subject to the completion of post-marketing studies, commonly referred to as Phase 4 trials, to monitor the effect of the approved product. The FDA may also grant approval with restrictive product labeling, or may impose other restrictions on marketing or distribution such as the adoption of a special risk management plan. The FDA has broad post-market regulatory and enforcement powers, including the ability to issue warning letters, levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals.

Manufacturing and post-marketing requirements. If approved, a pharmaceutical may only be marketed in the dosage forms and for the indications approved in the NDA or BLA, as applicable. Special requirements also apply to any samples that are distributed in accordance with the Prescription Drug Marketing Act. The manufacturers of approved products and their manufacturing facilities are subject to continual review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing requirements, including the FDA s cGMP requirements. Once the FDA approves a product, a manufacturer must provide certain updated safety and efficacy information, submit copies of promotional materials to the FDA, and make certain other required reports. Product and labeling changes, as well as certain changes in a manufacturing process or facility or other post-approval changes, may necessitate additional FDA review and approval. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as untitled letters, warning letters, suspension of manufacturing, seizure of product, voluntary recall of a product, injunctive action or possible criminal or civil penalties. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval. Because we intend to contract with third parties for manufacturing of our products, our ability to control third party compliance with FDA requirements will be limited to contractual remedies and rights of inspection. Failure of third party manufacturers to

comply with cGMP or other FDA requirements applicable to our products may result in, among other things, total or partial suspension of production, failure of the government to grant approval for marketing, and withdrawal, suspension,

Table of Contents

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

The FDA s policies may change, and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Animal Rule

In 2002, the FDA amended its requirements applicable to BLAs/NDAs to permit the approval of certain drugs and biologics that are intended to reduce or prevent serious or life-threatening conditions based on evidence of safety from clinical trial(s) in healthy subjects and effectiveness from appropriate animal studies when human efficacy studies are not ethical or feasible. These regulations, which are known as the Animal Rule , authorize the FDA to rely on animal studies to provide evidence of a product s effectiveness under circumstances where there is a reasonably well-understood mechanism for the activity of the agent. Under these requirements, and with the FDA s prior agreement, drugs used to reduce or prevent the toxicity of chemical, biological, radiological or nuclear substances may be approved for use in humans based on evidence of effectiveness derived from appropriate animal studies and any additional supporting data. Products evaluated for under this rule must demonstrate effectiveness through pivotal animal studies, which are generally equivalent in design and robustness to Phase 3 clinical studies. The animal study endpoint must be clearly related to the desired benefit in humans and the information obtained from animal studies must allow for selection of an effective dose in humans. Safety under this rule is established under preexisting requirements, including safety studies in both animals (toxicology) and humans. Products approved under the Animal Rule are subject to additional requirements including post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

We intend to utilize the Animal Rule in seeking marketing approval for Entolimod as a radiation countermeasure because we cannot ethically expose humans to lethal doses of radiation. Other countries may not at this time have established criteria for review and approval of these types of products outside their normal review process, i.e. there is no Animal Rule equivalent in countries other than the U.S., but some may have similar policy objectives in place for these product candidates. Given the nature of nuclear and radiological threats, we do not believe that the lack of established criteria for review and approval of these types of products in other countries will significantly inhibit us from pursuing sales of Entolimod to foreign countries.

All data obtained from the pre-clinical studies and clinical trials of Entolimod, in addition to detailed information on the manufacture and composition of the product, would be submitted in a BLA to the FDA for review and approval for the manufacture, marketing and commercial shipments of Entolimod.

Table of Contents

Emergency Use Authorization

The Commissioner of the FDA, under delegated authority from the Secretary of the Department of Health and Human Services, or HHS, may, under certain circumstances, issue an Emergency Use Authorization, or EUA, that would permit the use of an unapproved drug product or unapproved use of an approved drug product. Before an EUA may be issued, the Secretary must declare an emergency based on one of the following grounds:

- a determination by the Secretary of Department of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological or nuclear agent or agents;

- a determination by the Secretary of the Department of Defense, or DoD, that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent of agents; or

- a determination by the Secretary of HHS of a public health emergency that effects or has the significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agent.

In order to be the subject of an EUA, the FDA Commissioner must conclude that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating or preventing a disease attributable to the agents described above; that the product s potential benefits outweigh its potential risks; and that there is no adequate, approved alternative to the product.

Although an EUA cannot be issued until after an emergency has been declared by the Secretary of HHS, the FDA strongly encourages an entity with a possible candidate product, particularly one at an advanced stage of development, to contact the FDA center responsible for the candidate product before a determination of actual or potential emergency. Such an entity may submit a request for consideration that includes data to demonstrate that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition. This is called a pre-EUA submission and its purpose is to allow FDA review considering that during an emergency, the time available for the submission and review of an EUA request may be severely limited. In 2014, we plan to meet with the FDA regarding human dose-conversion of Entolimod and, if appropriate after such meeting, submit a pre-EUA in order to inform and expedite the FDA s issuance of an EUA, should one become necessary in the event of an emergency. The FDA does not have review deadlines with respect to pre-EUA submissions. Additionally, if we submit a pre-EUA, there is no guarantee that the FDA will agree that Entolimod meets the criteria for EUA, or, if they do agree, that such agreement by the FDA will lead to procurement by the U.S. or other governments or further development funding.

Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act, or PREP Act, provides immunity for manufacturers from all claims under state or federal law for loss arising out of the administration or use of a covered countermeasure. However, injured persons may still bring a suit for willful misconduct against the manufacturer under some circumstances. Covered countermeasures include security countermeasures and qualified pandemic or epidemic products , including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines,

as well as treatments intended to address conditions caused by such products. For these immunities to apply, the Secretary of HHS must issue a declaration in cases of public health emergency or credible risk of a future public health emergency. Since 2007, the Secretary of HHS has issued 8 declarations and six amendments under the PREP Act to protect countermeasures that are necessary to prepare the nation for potential pandemics or epidemics from liability.

Table of Contents

Fast Track Designation

Entolimod has been granted Fast Track designation by the FDA for reducing the risk of death following total body irradiation. The FDA s Fast Track designation program is designed to facilitate the development and review of new drugs, including biological products that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for the conditions. Fast Track designation applies to a combination of the product and the specific indication for which it is being studied. Thus, it is the development program for a specific drug for a specific indication that receives Fast Track designation. The sponsor of a product designated as being in a Fast Track drug development program may engage in early communication with the FDA, including timely meetings and early feedback on clinical trials and may submit portions of an NDA or BLA on a rolling basis rather than waiting to submit a complete application. Products in Fast Track drug development programs also may receive priority review or accelerated approval, under which an application may be reviewed within six months after a complete NDA or BLA is accepted for filing or sponsors may rely on a surrogate endpoint for approval, respectively. The FDA may notify a sponsor that its program is no longer classified as a Fast Track development program if the Fast Track designation is no longer supported by emerging data or the designated drug development program is no longer being pursued. Receipt of Fast Track Status does not guarantee that we will experience a faster development process, review or approval as compared to conventional FDA procedures or that we will qualify or be able to take advantage of the FDA s expedited review procedures.

Orphan Drug Designation

Entolimod and CBL0102 have been granted Orphan Drug designation by the FDA for prevention of death following a potentially lethal dose of total body irradiation and treatment of hepatocellular carcinoma, respectively. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition which is defined as one affecting fewer than 200,000 individuals in the United States or more than 200,000 individuals where there is no reasonable expectation that the product development cost will be recovered from product sales in the United States. Orphan drug designation must be requested before submitting an NDA or BLA and does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If an orphan drug-designated product subsequently receives the first FDA approval for the disease for which it has such designation, the product will be entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances for seven years as compared to five years for a standard new drug approval. As referenced above, we have received Orphan Drug status for two of our products. We intend to seek Orphan Drug status for our other products as appropriate, but an Orphan Drug designation may not provide us with a material commercial advantage.

Foreign Regulation

In addition to regulations in the United States, we are and will be subject to a variety of foreign regulations governing clinical trials and will be subject to a variety of foreign regulation governing commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Other countries, at this time, do not have an equivalent to the Animal Rule and, as a result, do not have established criteria for review and approval of these types of products outside their normal review process, but some countries may have similar policy objectives in place for these product candidates.

17

Table of Contents

As in the United States, the European Union may grant orphan drug status for specific indications if the request is made before an application for marketing authorization is made. The European Union considers an orphan medicinal product to be one that affects less than five of every 10,000 people in the European Union. A company whose application for orphan drug designation in the European Union is approved is eligible to receive, among other benefits, regulatory assistance in preparing the marketing application, protocol assistance and reduced application fees. Orphan drugs in the European Union also enjoy economic and marketing benefits, including up to ten years of market exclusivity for the approved indication, unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan designated product.

Our activities in Russia, through our subsidiaries, are regulated by the Ministry of Health and Social Development of the Russian Federation, or Minsotsrazvitiye. This federal executive authority is responsible for developing state policies as well as normative and legal regulations in the healthcare and pharmaceutical industries, including policies and regulations regarding the quality, efficacy and safety of pharmaceutical products. In addition, the Federal Service on Surveillance in Healthcare and Social Development, or Roszdravnadzor, is the subordinate executive authority to Minsotzrazvitiye, which, among other things (i) performs control and surveillance of certain activities, including pre-clinical and clinical trials and checks for compliance with state standards for medical products and pharmaceutical activities; (ii) issues licenses for the manufacture of drug products and pharmaceutical activities; (iii) grants allowance for clinical trials, use of new medical technologies and import and export of medical products, including import of products for use in clinical trials; and (iv) reviews and grants or denies registrations of medical products for commercial sale in Russia. The principal statute that governs our activities in Russia is the Federal Law of the Russian Federation from 12 April 2010 No. 61-FZ On the [Use and Circulation] of Medicines . This law regulates the research, development, testing, pre-clinical and clinical studies, governmental registration, quality control, manufacture, storage, transporting, export and import, licensing, advertisement, sale, transfer, utilization and destruction of medical products within the Russian Federation. All medical products must be registered in Russia and comply with stringent safety and quality controls and testing. In addition to Law No. 61-FZ, we are subject to a number of other laws and orders that regulate our activities in Russia relating to our drug development activities, taxation, corporate existence, labor laws and other areas. In particular, the existence, legal relations and transactions effected by our Russian subsidiaries are governed by the federal law No. 14-FZ On Companies with Limited Liability , which was enacted on February 8, 1998 and amended on November 30, 2011. Pursuant to this law, each subsidiary must hold an annual general meeting of its participants no later than four months after the end of each fiscal year, at which time, among other things, the annual financial results are reviewed and adopted. There are also equity holder and other approval requirements applicable to large transactions and affiliated transactions. Additionally, under the applicable Russian labor code, our Russian subsidiaries must enter into employment contracts with each employee, afford them at least 28 paid vacation days, limit the working week to 40 hours per week and follow the code s specific procedures and safeguards that serve to protect an employee s rights in the event the employee in Russia is terminated.

EMPLOYEES

As of March 14, 2014, we had 44 employees, 23 of whom are located in the U.S. and 21 of whom are located outside of the U.S.

ENVIRONMENT

We have made, and will continue to make, expenditures for environmental compliance and protection. Expenditures for compliance with environmental laws and regulations have not had, and are not expected to have, a material effect on our capital expenditures, results of operations, or competitive position.

18

Table of Contents

AVAILABLE INFORMATION

Our internet website address is http://www.cbiolabs.com/. Through our website, we make available, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, any amendments to those reports, proxy and registration statements, and all of our insider Section 16 reports, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the U.S. Securities and Exchange Commission, or the SEC. These SEC reports can be accessed through the Investors section of our website. The information found on our website is not part of this or any other report we file with, or furnish to, the SEC. Paper copies of our SEC reports are available free of charge upon request in writing to Corporate Secretary, Cleveland BioLabs, Inc. 73 High Street, Buffalo NY 14203. The content on any website referred to in this Form 10-K is not incorporated by reference into this Form 10-K unless expressly noted.

Item 1A. Risk Factors

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL FINANCING

We will require substantial additional financing in order to meet our business objectives.

Since our inception, most of our resources have been dedicated to the pre-clinical and clinical development of our product candidates. In particular, we are currently conducting multiple clinical trials of our product candidates, each of which will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future developing our pre-clinical and clinical product candidates. These expenditures will include costs associated with research and development, conducting pre-clinical and clinical trials, obtaining regulatory approvals and products from third-party manufacturers, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts of capital necessary to successfully complete the development and commercialization of our product candidates.

As of December 31, 2013, and after giving effect to our equity raise in January 2014, our cash, cash equivalents and short-term investments amounted to $16.8 million. We believe that our existing cash, cash equivalents, and marketable securities will allow us to fund our operating plan into the first quarter of 2015.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amounts of our total capital requirements. Our future capital requirements depend on many factors, including:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting pre-clinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;

the cost of commercialization activities for any of our product candidates that are approved for sale, including marketing, sales and distribution costs;

the cost of manufacturing our product candidates and any products we successfully commercialize;

our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;

whether we realize the full amount of any projected cost savings associated with our strategic restructuring;

the occurrence of a breach or event of default under our loan agreement with Hercules or under any other agreements with third parties;

Table of Contents

the success of any pre-EUA submission we make with the FDA; and

the timing, receipt and amount of sales of, or royalties on, our future products, if any.

In addition, it is possible that Hercules Technology II, L.P., or Hercules, could take the position that the decision of Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services, or BARDA, to terminate negotiations of our proposal constitutes a material adverse effect under our loan and security agreement with Hercules, under which we had $6.6 million in liability as of December 31, 2013, including a $550,000 end of term charge on the loan. Such determination by Hercules could trigger a repayment of all principal and interest due under the loan, as well as the prepayment charge under the loan, unless Hercules waives such event of default.

If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, or if we identify additional opportunities to do so, we may seek to sell additional equity or debt securities or obtain additional credit facilities. The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock or through additional credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of our common stock and could contain covenants that would restrict our operations. Furthermore, any funds raised through collaboration and licensing arrangements with third parties may require us to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. In any such event, our business prospects, financial condition and results of operations could be materially adversely affected.

We may require additional capital beyond our currently forecasted amounts and additional funds may not be available when we need them, on terms that are acceptable to us, or at all. In particular, the decline in the market price of our common stock could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. In addition, the variable rate clauses associated in many of our stock purchase agreements that prohibit certain types of capital raising activities for certain periods of time and pledge of assets in our loan and security agreement with Hercules may inhibit our ability to attract future investors and/or lenders. Additionally, our corporate structure, including the ownership of several of our product candidates in our non-wholly owned subsidiaries, may deter third parties from entering into collaboration and licensing arrangements with us. If we fail to raise sufficient additional financing, on terms and dates acceptable to us, we may not be able to continue our operations and the development of our product candidates, and may be required to reduce staff, reduce or eliminate research and development, slow the development of our product candidates, outsource or eliminate several business functions or shut down operations.

We have a history of operating losses. We expect to continue to incur losses and may not continue as a going concern.

We incurred net losses of approximately $20.1 million, $22.4 million and $5.2 million for the years ended December 31, 2013, 2012 and 2011, respectfully. We expect significant losses to continue for the next few years as we spend substantial sums on the continued research and development of our proprietary product candidates, and there is no certainty that we will ever become profitable as a result of these expenditures. As a result of losses that will continue throughout our development stage, we may exhaust our financial resources and be unable to complete the development of our product candidates.

Our ability to become profitable depends primarily on the following factors:

our ability to obtain adequate sources of continued financing;

our ability to obtain approval for, and if approved, to successfully commercialize our product candidates;

our ability to successfully enter into license, development or other partnership agreements with third-parties for the development and/or commercialization of one or more of our product candidates;

Table of Contents

our R&D efforts, including the timing and cost of clinical trials; and

our ability to enter into favorable alliances with third-parties who can provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales, marketing and distribution.

Even if we successfully develop and market our product candidates, we may not generate sufficient or sustainable revenue to achieve or sustain profitability.

We may be unable to service our existing debt due to lack of cash flow, which could lead to default.

In September 2013, we entered into a loan and security agreement with Hercules Technology II, L.P., or Hercules, under which we borrowed $6.0 million. The current interest rate is 10.45%, with the initial 12 months of the facility requiring interest only payments and the following 30 months requiring interest and principal payments. The loan matures on January 1, 2017. Since entering into the agreement with Hercules, we have been making monthly interest-only payments to Hercules of approximately $54,000 per month and plan to continue making such payments until November 2014 when our payments will increase to approximately $228,000 per month, with a principal and interest payment of approximately $907,000 due in January 2017. As of December 31, 2013, the outstanding principal owed to Hercules was $6.0 million. Additionally, upon termination of the loan, we will also owe Hercules an end-of-term fee of $550,000. We granted Hercules a first priority security interest in substantially all of our assets, with the exception of our intellectual property, where the security interest is limited to proceeds of intellectual property.

If we do not make the required payments when due, either at maturity, or at applicable installment payment dates, or if we breach the agreement, default under the agreement by having a material adverse event happen to the business of the Company or become insolvent, Hercules could elect to declare all amounts outstanding together with all accrued and unpaid interest and penalties, to be immediately due and payable. In order to continue our planned operations and satisfy our debt obligations with Hercules, we will need to raise additional capital in the future. Additional capital may not be available on terms acceptable to us, or at all. Even if we were able to repay the full amount in cash, any such repayment could leave us with little or no working capital for our business. If we are unable to repay these amounts, Hercules will have a first claim on our assets pledged under the loan agreement. If Hercules should attempt to foreclose on the collateral, there may not be any assets remaining for distribution to shareholders after repayment in full of such secured indebtedness. Any default under the loan agreement and resulting foreclosure would have a material adverse effect on our financial condition and our ability to continue our operations.

Additionally, in September 2013, our majority owned subsidiary Panacela entered into a $1.5 million Convertible Loan Agreement with Rusnano, or the Rusnano Loan, and is required to pay all unpaid principal and interest under the loan in September 2015. The loan may be converted into shares of Panacela stock at any time at Rusnano s option or will automatically convert upon certain financing events. In the event Panacela defaults on the loan and such default is not cured, Rusnano shall have the right to exercise a Warrant to purchase shares of Cleveland BioLabs common stock equal to 69.2% of the outstanding amount remaining unpaid under the Rusnano Loan at the time of exercise, divided by the exercise price of $1.694 per share.

Our ability to use our net operating loss carryforwards may be limited.

As of December 31, 2013, we had federal net operating loss carryforwards, or NOLs, of $109.9 million to offset future taxable income, which begin to expire if not utilized by 2023. Under the provisions of the Internal Revenue Code, substantial changes in our ownership, in certain circumstances, will limit the amount of NOLs that can be utilized annually in the future to offset taxable income. In particular, section 382 of the Internal Revenue Code imposed

limitations on a company s ability to use NOLs if a company experiences a more than 50% ownership change over a three-year period. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to utilize our NOLs fully. A full valuation allowance has been recorded against our deferred tax assets, including the net operating loss carryforwards, as we believe it is more likely than not we will be unable to realize the benefit of these assets.

Table of Contents

RISKS RELATED TO PRODUCT DEVELOPMENT

We may not be able to successfully and timely develop our products.

Our product candidates range from ones currently in the research stage to ones currently in the clinical stage of development and all require further testing to determine their technical and commercial viability. Our success will depend on our ability to achieve scientific, clinical and technological advances and to translate such advances into reliable, commercially competitive products on a timely basis. In addition, the success of our subsidiaries will depend on their ability to meet developmental milestones in a timely manner or to fulfill certain other development requirements under contractual agreements, which are pre-requisites to their receipt of additional funding from their non-controlling interest holders or the government agency funding their government contracts. Products that we may develop are not likely to be commercially available for several years. The proposed development schedules for our products may be affected by a variety of factors, including, among others, technological difficulties, proprietary technology of others, the government approval process, the availability of funds and changes in government regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects and the unproven technology involved, we may not be able to complete successfully the development or marketing of any products.

We may fail to develop and commercialize some or all of our products successfully or in a timely manner because:

- pre-clinical study or clinical trial results may show the product to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;

- we fail to receive the necessary regulatory approvals or there is a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or a pre-EUA, NDA or BLA preparation, discussions with the FDA, an FDA request for additional pre-clinical or clinical data or unexpected safety or manufacturing issues;

- they fail to conform to a changing standard of care for the diseases they seek to treat;

- they are less effective or more expensive than current or alternative treatment methods;

- of manufacturing costs, pricing or reimbursement issues, or other factors that make the product not economically feasible; or

- proprietary rights of others and their competing products and technologies may prevent our product from being commercialized.

Our collaborative relationships with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return.

We anticipate substantial reliance upon strategic collaborations for marketing and commercialization of our product candidates and we may rely even more on strategic collaborations for R&D of our product candidates. Our business depends on our ability to sell drugs to both government agencies and to the general pharmaceutical market. Offering Entolimod for its biodefense indication use to government agencies may require us to develop new sales, marketing or distribution capabilities beyond those already existing in the Company and we may not be successful in selling Entolimod for its biodefense indication use in the United States or in foreign countries despite our efforts. Selling oncology drugs will require a more significant infrastructure. We plan to sell oncology drugs through strategic partnerships with pharmaceutical companies. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our revenue and drug development may be limited. To date, we have not entered into any strategic collaboration with a third party capable of

Table of Contents

providing these services and we can make no guarantee that we will be able to enter into a strategic collaboration in the future. In addition, we have not yet marketed or sold any of our product candidates or entered into successful collaborations for these services in order to ultimately commercialize our product candidates. We also rely on third-party collaborations with our manufacturers. Manufacturers producing our product candidates must follow current Good Manufacturing Practice, or cGMP, regulations enforced by the FDA and foreign equivalents.

Establishing strategic collaborations is difficult and time-consuming. Our discussion with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our product candidates or the generation of sales revenue. In addition to the extent that we enter into collaborative arrangements, our drug revenues are likely to be lower than if we directly marketed and sold any drugs that we may develop.

We will not be able to commercialize our product candidates if our pre-clinical development efforts are not successful, our clinical trials do not demonstrate safety or our clinical trials or animal studies do not demonstrate efficacy.

Before obtaining required regulatory approvals for the commercial sale of any of our product candidates, we must conduct extensive pre-clinical testing and clinical trials to demonstrate that our product candidates are safe and clinical or animal trials to demonstrate the efficacy of our product candidates. Pre-clinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful and interim results of a clinical trial or animal efficacy study does not necessarily predict final results. In addition, we must outsource our clinical trials and a majority of our animal studies required to obtain regulatory approval of our products. We are not certain that we will successfully or promptly finalize agreements for the conduct of these studies. Delay in finalizing such agreements would delay the commencement of our pre-clinical and clinical studies, such as animal efficacy studies for Entolimod s biodefense indication and clinical trials of Entolimod, CBL0102 and CBL0137 for oncology indications. In addition, we are seeking FDA agreement on the scope and design of our pivotal animal efficacy and human safety program for Entolimod s biodefense indication. Delay in agreement with the FDA on this program will delay conduct of the pivotal animal efficacy and human safety studies.

Agreements with contract research organizations, or CROs, and study investigators, for clinical or animal testing and with other third parties for data management services place substantial responsibilities on these parties, which could result in delays in, or termination of, our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with Good Clinical Practices or our pivotal animal studies fail to comply with Good Laboratory Practices we may be unable to use the data generated at those sites. In these studies, if contracted CROs or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or for other reasons, our clinical or animal studies may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for or successfully commercialize our product candidates.

Our clinical trial operations will be subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we or they may receive warning letters or other correspondence detailing deficiencies and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions that we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be the subject of an enforcement action, the

government may refuse to approve our marketing applications or allow us to manufacture or market our products or we may be criminally prosecuted.

Table of Contents

In addition, a failure of one or more of our clinical trials or animal studies can occur at any stage of testing and such failure could have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations. We may experience numerous unforeseen events during, or as a result of, pre-clinical testing and the clinical trial or animal study process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- Regulators or institutional review boards, or IRB, may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site or an institutional animal care and use committee, or IACUC, may not authorize us to commence an animal study at a prospective study site;

- We may decide, or regulators may require us, to conduct additional pre-clinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our pre-clinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;

- We might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable safety risks;

- Regulators or IRBs may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or if it is believed that the clinical trials present an unacceptable safety risk to the patients enrolled in our clinical trials;

- The cost of our clinical trials or animal studies could escalate and become cost prohibitive;

- Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;

- We may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials or certain animals used in our animal studies or facilities conducting our studies may not be available at the time that we plan to initiate a study; and

- The effects of our product candidates may not be the desired effects, may include undesirable side effects, or the product candidates may have other unexpected characteristics;

- Our collaborators that conduct our clinical or pivotal animal studies could go out of business and not be available for FDA inspection when we submit our product for approval.

Even if we or our collaborators complete our animal studies and clinical trials and receive regulatory approval, it is possible that a product may be found to be ineffective or unsafe due to conditions or facts that arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such

product from the market. To the extent that our success will depend on any regulatory approvals from government authorities outside of the United States that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist.

Our majority-owned subsidiaries have significant non-controlling interest holders and, as such, are not operated solely for our benefit.

As of December 31, 2013, we owned 59.2% of the equity interests in Incuron and 54.6% of the equity interests in Panacela. Additionally, we anticipate that Incuron will receive their last funding tranche from BioProcess Capital Partners in early 2014 and that following such investment our ownership interest in Incuron will fall below 50% if we do not invest $3 million of additional funds. Although these subsidiaries are currently majority-owned by us and are consolidated in our results, they have significant non-controlling interest holders, each of which are funds regulated by the Russian Federation government. As such, we share ownership and management of our subsidiaries with one or more parties who may not have the same goals, strategies, priorities, or resources as we do.

In each of our majority-owned subsidiaries, both we and our co-owners have certain rights in respect of such subsidiaries. Our majority-owned subsidiaries provide the right to each party to designate certain of the board

Table of Contents

members and certain decisions in respect of these subsidiaries may not be made without a supermajority vote of the equity holders or the consent of all of the equity holders. The right to transfer ownership interests in our majority-owned subsidiaries is restricted by provisions such as rights of first refusal and tag along and drag along rights. In addition, the use of funds and other matters are subject to monitoring and oversight by both groups of equity holders. Furthermore, we are required to pay more attention to our relationship with our co-owners as well as with the subsidiaries, and if a co-owner changes, our relationship may be materially adversely affected. These various restrictions may lead to additional organizational formalities as well as time-consuming procedures for sharing information and making decisions. In addition, the benefits from a successful joint venture are shared among the co-owners, so that we would not receive all the benefits from our successful joint ventures.

The co-owners of our majority-owned subsidiaries are required to make additional payments to the subsidiaries to finance their operations. Such additional contributions are dependent on the satisfaction of various developmental milestones by our majority-owned subsidiaries, which may not be achieved within set time periods, and if such contributions or investments are not achieved, may result in a material adverse effect in our business, financial condition and results of operations.

If parties on whom we rely to manufacture our product candidates do not manufacture them in satisfactory quality, in a timely manner, in sufficient quantities or at an acceptable cost, clinical development and commercialization of our product candidates could be delayed.

We do not own or operate manufacturing facilities. Consequently, we rely on third parties as sole suppliers of our product candidates. We do not expect to establish our own manufacturing facilities and we will continue to rely on third-party manufacturers to produce supplies for pre-clinical, clinical and pivotal animal studies and for commercial quantities of any products or product candidates that we market or may supply to our collaborators. Our dependence on third parties for the manufacture of our product candidates may adversely affect our ability to develop and commercialize any product candidates on a timely and competitive basis.

To date, our product candidates have only been manufactured in quantities sufficient for pre-clinical studies and initial clinical trials. We rely on a single collaborator for production of each of our product candidates. For a variety of reasons, dependence on any single manufacturer may adversely affect our ability to develop and commercialize our product candidates on a timely and competitive basis. In addition, our current contractual arrangements alone may not be sufficient to guarantee that we will be able to procure the needed supplies as we complete clinical development and/or enter commercialization.

Additionally, in connection with our application for commercial approvals and if any product candidate is approved by the FDA or other regulatory agencies for commercial sale, we will need to procure commercial quantities from qualified third-party manufacturers. We may not be able to contract for increased manufacturing capacity for any of our product candidates in a timely or economic manner or at all. A significant scale-up in manufacturing may require additional validation studies and commensurate financial investments by the contract manufacturers. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage of supply, which could limit our sales and could initiate regulatory intervention to minimize the public health risk.

Other risks associated with our reliance on contract manufacturers include the following:

Contract manufacturers may encounter difficulties in achieving volume production, quality control and quality assurance and also may experience shortages in qualified personnel and obtaining active ingredients for our product candidates.

If, for any circumstance, we are required to change manufacturers, we could be faced with significant monetary and lost opportunity costs with switching manufacturers. Furthermore, such change may take a significant amount of time. The FDA and foreign regulatory agencies must approve these manufacturers in advance. This requires prior approval of regulatory submissions as well as successful completion of pre-approval inspections to ensure compliance with FDA and foreign regulations and standards.

Table of Contents

Contract manufacturers are subject to ongoing periodic, unannounced inspection by the FDA and state and foreign agencies or their designees to ensure strict compliance with cGMP and other governmental regulations and corresponding foreign standards. We do not have control over compliance by our contract manufacturers with these regulations and standards. Our contract manufacturers may not be able to comply with cGMP and other FDA requirements or other regulatory requirements outside the United States. Failure of contract manufacturers to comply with applicable regulations could result in delays, suspensions or withdrawal of approvals, seizures or recalls of product candidates and operating restrictions, any of which could significantly and adversely affect our business.

Contract manufacturers may breach the manufacturing agreements that we have with them because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient to us.

Changes to the manufacturing process during the conduct of clinical trials or after marketing approval also require regulatory submissions and the demonstration to the FDA or other regulatory authorities that the product manufactured under the new conditions complies with cGMP requirements. These requirements especially apply to moving manufacturing functions to another facility. In each phase of investigation, sufficient information about changes in the manufacturing process must be submitted to the regulatory authorities and may require prior approval before implementation with the potential of substantial delay or the inability to implement the requested changes.

RISKS RELATING TO REGULATORY APPROVAL

We may not be able to obtain regulatory approval in a timely manner or at all and the results of clinical trials may not be favorable.

The testing, marketing and manufacturing of any product for use in the United States will require approval from the FDA. We cannot predict with any certainty the amount of time necessary to obtain FDA approval and whether any such approval will ultimately be granted. Pre-clinical studies and clinical trials may reveal that one or more products are ineffective or unsafe, in which event, further development of such products could be seriously delayed, terminated or rendered more expensive. Moreover, obtaining approval for certain products may require testing on human subjects of substances whose effects on humans are not fully understood or documented.

In addition, we expect to rely on an FDA regulation known as the Animal Rule to obtain approval for Entolimod s biodefense indication. The Animal Rule permits the use of animal efficacy studies together with human clinical safety trials to support an application for marketing approval of products when human efficacy studies are neither ethical nor feasible. These regulations are relatively new and we have limited experience in the application of these rules to the product candidates that we are developing. As such, we cannot predict the time required for them to confirm the relevant rules, or the scope thereof. Additionally, we may submit an application with the FDA for pre- EUA, so that Entolimod may be used in an emergency situation. If and when we provide the FDA with the data to support a pre-EUA for Entolimod in the event of a radiation emergency we cannot guarantee that the FDA will review the data in a timely manner, or that, when the data is reviewed, that the FDA will accept the data. The FDA may decide that our data are insufficient for pre-EUA or BLA approval and require additional pre-clinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. If we are not successful in completing the development, licensure and commercialization of Entolimod for its biodefense indication use, or if we are significantly delayed in doing so, our business will be materially harmed.

The receipt of FDA approval may be delayed for reasons other than the results of pre-clinical studies and clinical trials. For example, in 2011, the IND application for Entolimod s biodefense indication was transferred within the FDA

from the Division of Biologic Oncology Products, or DBOP, to the Division of Medical Imaging Products, or DMIP. As a result of this transfer, we requested and participated in nine meetings with DMIP during

Table of Contents

2011-2013 to review the product mechanisms of action, safety profile and preliminary estimation of an effective human dose. DMIP has agreed on the scope and design of the proposed pivotal animal efficacy program and has acknowledged that specific cytokines do play an important role in Entolimod s mechanism of action and, as such, can be used as biomarkers for animal-to-human dose-conversion. DMIP has also provided advice on the design of the remaining program needed for BLA submission. However, we are still in the process of reaching an agreement with FDA on the certain elements of the design of our remaining clinical studies for Entolimod. There can be no guarantee that we will reach a satisfactory agreement in a timely manner, or at all, or that DMIP may request any additional information related to our pre-clinical or clinical programs.

Delays in obtaining FDA or any other necessary regulatory approvals of any proposed product or the failure to receive such approvals would have an adverse effect on our ability to develop such product, the product s potential commercial success and/or on our business, prospects, financial condition and results of operations.

Failure to obtain regulatory approval in international jurisdictions could prevent us from marketing our products abroad.

We intend to market our product candidates, including specifically the product candidates being developed by our subsidiaries, in the United States, the Russian Federation and other countries and regulatory jurisdictions. In order to market our product candidates in the United States, Russia and other jurisdictions, we must obtain separate regulatory approvals in each of these countries and territories. The procedures and requirements for obtaining marketing approval vary among countries and regulatory jurisdictions and can involve additional clinical trials or other tests. In addition, we do not have in-house experience and expertise regarding the procedures and requirements for filing for and obtaining marketing approval for drugs in countries outside of the United States, Europe and Japan and may need to engage and rely upon expertise of third parties when we file for marketing approval in countries outside of the United States, Europe and Japan. Also, the time required to obtain approval in markets outside of the United States may differ from that required to obtain FDA approval, while still including all of the risks associated with obtaining FDA approval. We may not be able to obtain all of the desirable or necessary regulatory approvals on a timely basis, if at all. Approval by a regulatory authority in a particular country or regulatory jurisdiction, such as the FDA in the United States or the Roszdravnadzor in Russia, does not ensure approval by a regulatory authority in another country.

We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any or all of the countries or regulatory jurisdictions in which we desire to market our product candidates. At this time, other countries do not have an equivalent to the Animal Rule and, as a result, such countries do not have established criteria for review and approval for this type of product outside their normal review process. Specifically, because such other countries do not have an equivalent to the Animal Rule, we may not be able to file for or receive regulatory approvals for Entolimod s biodefense indication outside the United States based on our animal efficacy and human safety data.

The Fast Track designation for Entolimod may not actually lead to a faster development or regulatory review or approval process.

We have obtained a Fast Track designation from the FDA for Entolimod s biodefense indication. However, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw our Fast Track designation if the FDA believes that the designation is no longer supported by data from our clinical development program. Our Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the FDA s expedited review procedures or that any application that we may submit to the FDA for regulatory approval will be accepted for filing or ultimately approved.

27

Table of Contents

Any pre-EUA submission we make to the FDA may not be successful and even if such submission is successful it may not accelerate BLA approval of Entolimod or result in any purchase by the U.S. government for this product.

In 2014, we plan to meet with the FDA regarding human dose-conversion of Entolimod and, if appropriate after such meeting, submit a pre-EUA in order to inform and expedite the FDA s issuance of an EUA, should one become necessary in the event of an emergency. The FDA does not have review deadlines with respect to pre-EUA submissions and, therefore, the timing of any approval of a pre-EUA submission is uncertain. If we submit a pre-EUA, the FDA may decide not to accept the data or decide that our data are insufficient for pre-EUA and require additional pre-clinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. An acceptance of our pre-EUA submission does not guarantee, and may not accelerate, BLA approval of Entolimod as a radiation countermeasure. Further, even if our pre-EUA submission is authorized, there is no guarantee that such authorization will lead to procurement by the U.S. or other governments or any additional development funding. If we are not successful in partnering Entolimod or completing the development, licensure and commercialization of Entolimod for its biodefense indication use, or if we are significantly delayed in doing so, our business may be materially harmed.

Even if our drug candidates obtain regulatory approval, we will be subject to on-going government regulation.

Even if our drug candidates obtain regulatory approval, our products will be subject to continuing regulation by the FDA, including record keeping requirements, submitting periodic reports to the FDA, reporting of any adverse experiences with the product and complying with Risk Evaluation and Mitigation Strategies and drug sampling and distribution requirements. In addition, updated safety and efficacy information must be maintained and provided to the FDA. We or our collaborative partners, if any, must comply with requirements concerning advertising and promotional labeling, including the prohibition against promoting and non-FDA approved or off-label indications or products. Failure to comply with these requirements could result in significant enforcement action by the FDA, including warning letters, orders to pull the promotional materials and substantial fines.

After FDA approval of a product, the discovery of problems with a product or its class, or the failure to comply with requirements may result in restrictions on a product, manufacturer, or holder of an approved marketing application. These include withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay or prevent further marketing. Newly discovered or developed safety or effectiveness data, including from other products in a therapeutic class, may require changes to a product s approved labeling, including the addition of new warnings and contraindications. Also, the FDA requires post-market clinical testing of products approved under the Animal Rule at the time of a declared emergency and may require post-market clinical testing of other products. They may also require surveillance to monitor the product s safety or efficacy to evaluate long-term effects. It is also possible that rare but serious adverse events not seen in our drug candidates may be identified after marketing approval. This could result in withdrawal of our product from the market.

Compliance with post-marketing regulations may be time-consuming and costly and could delay or prevent us from generating revenue from the commercialization of our drug candidates.

If physicians and patients do not accept and use our drugs, we will not achieve sufficient product revenues and our business will suffer.

Even if we gain marketing approval of our drug candidates, government purchasers, physicians and/or patients may not accept and use them. Acceptance and use of these products may depend on a number of factors including:

Perceptions by members of the government healthcare community, including physicians, about the safety and effectiveness of our drugs;

Published studies demonstrating the safety and effectiveness of our drugs;

Table of Contents

Adequate reimbursement for our products from payors; and

Effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of our drugs, if approved for marketing, to gain acceptance in the market would harm our business and could require us to seek additional financing.

RISKS RELATED TO OUR DEPENDENCE ON U.S. GOVERNMENT CONTRACTS AND GRANTS

If we are unable to procure additional government funding, we may not be able to fund future R&D and implement technological improvements, which would materially harm our financial conditions and operating results.

In 2013, we received 26.8% of our revenues from government contract and grant development work in connection with grants from the DoD. In 2012 and 2011, we received 34.8% and 87.6% of our revenues from U.S. government contract and grant development work.

These revenues have funded some of our personnel and other R&D and General and Administrative costs and expenses. Our current grants and contracts with the U.S. government expire in March 2014. It is possible that we may not choose to apply for or, if we do apply, be able to procure new grants and contracts that provide sufficient funding, or any funding at all. In addition, the finalization of new contracts and grants may require a significant time from the initial request and negotiations for such contracts and grants are subject to a significant amount of uncertainty.

For example, in May 2011, we announced that we had concluded advanced stages of contract negotiation with BARDA for the funding of certain development activities relating to Entolimod s biodefense indication in our 2010 proposal to BARDA. BARDA indicated that further contract-related negotiations would require clarification of the development path for Entolimod s biodefense indication with the FDA, which is in the process of actively reviewing our IND application for Entolimod. BARDA indicated that we might resubmit an updated proposal upon confirmation from the FDA that they do not have any objections to us proceeding with our development plan as a result of this review. We received a confirmatory letter from the FDA in late 2011 and submitted a white paper to BARDA under its currently open Broad Agency Announcement, or the BAA. In April 2012, we announced that BARDA had declined to invite the Company to submit a full proposal pursuant to the white paper submitted. After further discussions with both the FDA and BARDA, we announced in October 2012, that the Company had submitted a proposal to BARDA under the BAA for the remaining development steps needed for FDA licensure of Entolimod as a medical radiation countermeasure. In January 2014, we announced that BARDA had terminated negotiations of our proposal due to lack of availability of funds. If and when we do submit additional funding proposals to BARDA or other U.S. or foreign government agencies there is no assurance that such agencies will make a positive decision with regard to funding our proposal(s) or award a contract (if one is awarded) in a timely manner.

If we are unable to obtain sufficient grants and contracts on a timely basis or if our existing grants and contracts are not funded, our ability to fund future R&D would be diminished, which would negatively impact our ability to compete in our industry and could materially and adversely affect our business, financial condition and results of operations.

Our future business may be harmed as a result of the government contracting process as it involves risks not present in the commercial marketplace.

We expect that a significant portion of the business that we will seek in the near future will be under government contracts or subcontracts, both U.S. and foreign, which may be awarded through competitive bidding. Competitive bidding for government contracts presents a number of risks that are not typically present in the commercial contracting process, which may include:

- The need to devote substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;

Table of Contents

The need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;

The risk that the government will issue a request for proposal to which we would not be eligible to respond;

The risk that third parties may submit protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal;

The expenses that we might incur and the delays that we might suffer if our competitors protest or challenge contract awards made to us pursuant to competitive bidding and the risk that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in termination, reduction or modification of the awarded contract; and

The risk that review of our proposal or award of a contract or an option to an existing contract could be significantly delayed for reasons including, but not limited to, the need for us to resubmit our proposal or limitations on available funds due to government budget cuts.

The U.S. government may choose to award future contracts for the supply of medical radiation countermeasures to our competitors instead of to us. If we are unable to win particular contracts, or if the government chooses not to fully exercise all options under contracts awarded to us, we may not be able to operate in the market for products that are provided under those contracts for a number of years. If we are unable to consistently win new contract awards and have the options under our existing contracts exercised over an extended period, or if we fail to anticipate all of the costs and resources that will be required to secure such contract awards, our growth strategy and our business, financial condition and operating results could be materially adversely affected.

The market for U.S. and other government funding is highly competitive.

Our biodefense product candidate, Entolimod, faces significant competition for U.S. government funding for both development and procurement of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. In addition, we may not be able to compete effectively if our products and product candidates do not satisfy procurement requirements of the U.S. government with respect to biodefense products. Our opportunities to succeed in this industry could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than any products that we may develop.

U.S. government agencies have special contracting requirements, which create additional risks.

We have historically entered into contracts with various U.S. government agencies. Due to these contracts with government agencies, we are subject to various federal contract requirements. Future sales to U.S. government agencies will depend, in part, on our ability to meet these requirements, certain of which we may not be able to satisfy.

U.S. government contracts typically contain unfavorable termination provisions and are subject to audit by the government at its sole discretion even after the end of the period of performance under the contract, which subjects us to additional risks. These risks include the ability of the U.S. government to unilaterally:

Suspend or prevent us for a set period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations;

Terminate our existing contracts;

Reduce the scope and value of our existing contracts;

Audit and object to our contract-related costs and fees, including allocated indirect costs;

Control and potentially prohibit the export of our products; and

Change certain terms and conditions in our contracts.

Table of Contents

Pursuant to our government contracts, we are generally permitted to retain title to any patentable invention or discovery made while performing the contract. However, the U.S. government is generally entitled to receive a non-exclusive, non-transferable, irrevocable, paid-up license to the subject inventions throughout the world. In addition, our government contracts generally provide that the U.S. government retains unlimited rights in the technical data produced under such government contract.

Our business could be adversely affected by a negative audit by the U.S. government.

As a U.S. government contractor, we may become subject to periodic audits and reviews by U.S. government agencies such as the Defense Contract Audit Agency, or the DCAA. These agencies review a contractor s performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. The DCAA also reviews the adequacy of, and a contractor s compliance with, its internal control systems and policies, including the contractor s purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, which such costs already reimbursed must be refunded.

Based on the results of these audits, the U.S. government may adjust our contract-related costs and fees, which have already been paid to us, including allocated indirect costs. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. In addition, under U.S. government purchasing regulations, some of our costs, including most financing costs, amortization of intangible assets, portions of our R&D costs and some marketing expenses, may not be reimbursable or allowed under our contracts. Further, as a U.S. government contractor, we may become subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities to which purely private sector companies are not.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

We rely upon licensed patents to protect our technology. We may be unable to obtain or protect such intellectual property rights and we may be liable for infringing upon the intellectual property rights of others.

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies and the proprietary technology of others with which we have entered into licensing agreements. We have entered into five separate exclusive license agreements to license our product candidates that are not owned by us and some product candidates are covered by up to three separate license agreements. Pursuant to these license agreements we maintain patents and patent applications covering our product candidates. We do not know whether any of these patent applications that are still in the approval process will ultimately result in the issuance of a patent with respect to the technology owned by us or licensed to us. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the United States Patent and Trademark Office use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others.

Our technology may be found in the future to infringe upon the rights of others or be infringed upon by others. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including

treble damages, if we are found to have willfully infringed on such parties patent rights. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief which could effectively block our ability to further develop, commercialize and sell products. In addition to any

Table of Contents

damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our products so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology and the technology exclusively licensed by us or developed with our collaborative partners. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

Moreover, the cost to us of any litigation or other proceeding relating to our patents and other intellectual property rights, even if resolved in our favor, could be substantial and the litigation would divert our management s efforts and our resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If we fail to comply with our obligations under our license agreement with third parties, we could lose our ability to develop our product candidates.

The manufacture and sale of any products developed by us may involve the use of processes, products or information, the rights to certain of which are owned by others. Although we have obtained exclusive licenses for our product candidates from CCF, RPCI and CCIA with regard to the use of patent applications as described above and certain processes, products and information of others, these licenses could be terminated or expire during critical periods and we may not be able to obtain licenses for other rights that may be important to us, or, if obtained, such licenses may not be obtained on commercially reasonable terms. Furthermore, some of our product candidates require the use of technology licensed from multiple third parties, each of which is necessary for the development of such product candidates. If we are unable to maintain and/or obtain licenses, we may have to develop alternatives to avoid infringing upon the patents of others, potentially causing increased costs and delays in product development and introduction or precluding the development, manufacture, or sale of planned products. Additionally, the patents underlying any licenses may not be valid and enforceable. To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical.

Our current exclusive licenses impose various development, royalty, diligence, record keeping, insurance and other obligations on us. If we breach any of these obligations and do not cure such breaches within the relevant cure period, the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology.

In addition, while we cannot currently determine the dollar amount of the royalty and other payments we will be required to make in the future under the license agreements, if any, the amounts may be significant. The dollar amount of our future payment obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any.

If we are not able to protect and control our unpatented trade secrets, know-how and other technology, we may suffer competitive harm.

We also rely on a combination of trade secrets, know-how, technology and nondisclosure and other contractual agreements and technical measures to protect our rights in the technology. However, trade secrets are difficult to protect and we rely on third parties to develop our products and thus must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our

collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements will typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these

Table of Contents

agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. If any trade secret, know-how or other technology not protected by a patent or intellectual property right were disclosed to, or independently developed by, a competitor, our business, financial condition and results of operations could be materially adversely affected.

RISKS RELATING TO OUR INDUSTRY AND OTHER EXTERNAL FACTORS

The biopharmaceutical market in which we compete is highly competitive.

The biopharmaceutical industry is characterized by rapid and significant technological change. Our success will depend on our ability to develop and apply our technologies in the design and development of our product candidates and to establish and maintain a market for our product candidates. In addition, there are many companies, both public and private, including major pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions engaged in developing pharmaceutical and biotechnology products. Many of these companies have substantially greater financial, technical, research and development resources and human resources than us. Competitors may develop products or other technologies that are more effective than those that are being developed by us or may obtain FDA or other governmental approvals for products more rapidly than us. If we commence commercial sales of products, we still must compete in the manufacturing and marketing of such products, areas in which we have no experience.

Our growth could be limited if we are unable to attract and retain key personnel and consultants.

We have limited experience in filing and prosecuting regulatory applications to obtain marketing approval from the FDA or other regulatory authorities. The loss of services of one or more of our key employees or consultants could have a negative impact on our business or our ability to expand our research, development and clinical programs. We depend on our scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial and marketing personnel, particularly as we expand our activities in clinical trials, the regulatory approval process, external partner solicitations and sales and manufacturing. We routinely enter into consulting agreements with our scientific and clinical collaborators and advisors, opinion leaders and heads of academic departments in the ordinary course of our business. We also enter into contractual agreements with physicians and institutions who recruit patients into our clinical trials on our behalf in the ordinary course of our business. In addition, as a result of our 2013 corporate restructuring and workforce reductions, we may face additional challenges in retaining our existing senior management and key employees and recruiting new employees to join our company as our business needs change. We face significant competition for this type of personnel and for employees from other companies, research and academic institutions, government entities and other organizations. We cannot predict our success in hiring or retaining the personnel we require for continued growth.

We may be subject to damages resulting from claims that we, our employees, or our consultants have wrongfully used or disclosed alleged trade secrets of their former employers.

We engage as employees and consultants individuals who were previously employed at other biotechnology or pharmaceutical companies, including at competitors or potential competitors. Although no claims against us are currently pending, we may become subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their 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 costs and distract management.

We may incur substantial liabilities from any product liability and other claims if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if the product candidates are sold commercially. An individual

Table of Contents

may bring a product liability claim against us if one of the product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

Decreased demand for our product candidates;

Injury to our reputation;

Withdrawal of clinical trial participants;

Costs of related litigation;

Diversion of our management s time and attention;

Substantial monetary awards to patients or other claimants;

Loss of revenues;

The inability to commercialize product candidates; and

Increased difficulty in raising required additional funds in the private and public capital markets.

We currently have product liability insurance and intend to expand such coverage from coverage for clinical trials to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage that will be adequate to satisfy any liability that may arise.

From time to time, we may also become subject to litigation, such as stockholder derivative claims or securities fraud claims, which could involve our directors and officers as defendants. We currently have director and officer, or D&O, insurance to cover such risk exposure for our directors and officers. Our bylaws require us to indemnify our current and past directors and officers from reasonable expenses related to the defense of any action arising from their service to us. Our certificate of incorporation and by-laws include provisions to indemnify the directors and officers to the fullest extent permitted by the Delaware General Corporation Law, including circumstances under which indemnification is otherwise discretionary. If our D&O insurance is insufficient to cover all such expenses for all directors and officers, we would be obligated to cover any shortfall, which may be substantial. Such expenditure could have a material adverse effect on our results of operation, financial condition and liquidity. Further, if D&O insurance becomes prohibitively expensive to maintain in the future, we may be unable to renew such insurance on economic terms or unable renew such insurance at all. The lack of D&O insurance may make it difficult for us to retain and attract talented and skilled directors and officers to serve our company, which could adversely affect our business.

We have been named as a defendant in a lawsuit that could result in substantial costs and divert management s attention.

We have been named as a defendant in a lawsuit initiated earlier this year that generally alleges we misrepresented the state of our funding negotiations with BARDA during the period leading up to the sale of our common stock and warrants in January 2014, and as a result, the plaintiffs were harmed when our stock price declined following the announcement that BARDA had terminated negotiations with us. The complaint asserts claims under Section 10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, as well as claims for fraudulent inducement, breach of contract, and indemnification. Any conclusion of these matters in a manner adverse to us would have a material adverse effect on our financial condition and business. For example, we could incur substantial costs not covered by our directors and officers liability insurance, suffer a significant adverse impact on our reputation and divert management s attention and resources from other priorities, including the execution of business plans and strategies that are important to our ability to grow our business, any of which could have a material adverse effect on our business. In addition, any of these matters could require payments that are not covered by our available directors and officers liability insurance, which could have a material adverse effect on our operating results or financial condition. Additional similar lawsuits might be filed.

Table of Contents

Our former laboratories used certain chemical and biological agents and compounds that may be deemed hazardous and we were subject to various safety and environmental laws and regulations. Our prior compliance with these laws and regulations may result in significant costs, which could materially reduce our ability to become profitable.

Until late 2013, we had laboratories that used hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. As appropriate, we stored these materials and wastes resulting from their use at our laboratory facility pending their ultimate use or disposal. We contracted with a third party to properly dispose of these materials and wastes. We were subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. We may incur significant costs if we unknowingly failed to comply with environmental laws and regulations.

Political or social factors may delay or impair our ability to market our products.

Entolimod is being developed to treat radiation sickness, which is a disease that may be caused by terrorist acts. The political and social responses to terrorism have been highly charged and unpredictable. Political or social pressures may delay or cause resistance to bringing our products to market or limit pricing of our products, which would harm our business. Changes to favorable laws, such as the Project BioShield Act, could have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations.

We hope to receive funding from U.S. or foreign government agencies for the development of Entolimod and our products. Changes in government budgets and agendas, however, have previously resulted in termination of our contract negotiations and may, in the future, result in future funding being decreased and de-prioritized, government contracts contain provisions that permit cancellation in the event that funds are unavailable to the government agency. Furthermore, we cannot be certain of the timing of any future funding and substantial delays or cancellations of funding could result from protests or challenges from third parties. If the U.S. government fails to continue to adequately fund R&D programs, we may be unable to generate sufficient revenues to continue development of Entolimod or continuation of our other operations. Similarly, if our pre-EUA submission for Entolimod is authorized by the FDA or we develop another product candidate that is approved by the FDA, but the U.S. government does not place sufficient orders for this product, our future business may be harmed.

Failure to comply with the United States Foreign Corrupt Practices Act and similar foreign laws could subject us to penalties and other adverse consequences.

We are required to comply with the United States Foreign Corrupt Practices Act, or FCPA, which prohibits U.S. companies from engaging in bribery or other prohib