CLEVELAND BIOLABS INC
Form 10-K
February 23, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K
(Mark One)
x Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2015
or
¨ Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the 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. x
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 ¨
Non-accelerated filer ¨	Smaller reporting company x

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 $13,983,177. There were 10,987,166 shares of common stock outstanding as of February 12, 2016.

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant's 2016 Annual Meeting of Stockholders is incorporated by reference in Part III to the extent described therein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2015.

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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,” “int “may,” “plan,” “project,” “will,” and similar expressions, as they relate to us, are intended to identify forward-looking statements.

Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the commercialization of our product candidates, if approved;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our plans and expectations with respect to future clinical trials and commercial scale-up activities;
- future agreements with third parties in connection with the commercialization of any approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates.

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.

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PART I

Item 1. Business

When used in this Annual Report on Form 10-K, unless otherwise stated or the context otherwise requires, the terms "Cleveland BioLabs," the "Company," "CBLI" "we," "us" and "our" refer to Cleveland BioLabs, Inc. and its consolidated subsidiaries, BioLab 612, LLC and Panacela Labs, Inc.

GENERAL OVERVIEW

Cleveland BioLabs is an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. Our proprietary platform of Toll-like immune receptor activators has applications in mitigation of radiation injury and immuno-oncology. 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 most advanced product candidate is entolimod, an immuno-stimulatory agent, which we are developing as a radiation countermeasure and an immunotherapy for oncology and other indications.

Entolimod is a Toll-like receptor 5 ("TLR5"), agonist, which we are developing as a radiation countermeasure for prevention of death from Acute Radiation Syndrome ("ARS"), and as an oncology drug. We believe that entolimod is the most efficacious medical 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 United States Food & Drug Administration's ("FDA's"), Animal Efficacy Rule (the "Animal Rule"), for the indication of reducing the risk of death following exposure to potentially lethal irradiation occurring as a result of a radiation disaster (see "– Government Regulation – Animal Rule"). We have completed two clinical studies designed to evaluate the safety, pharmacokinetics and pharmacodynamics of entolimod in a total of 150 healthy volunteers. We have completed a Good Laboratory Practices ("GLPs"), 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 met with the FDA in July 2014 to present our human dose-conversion and to discuss our intent to submit an application for pre-Emergency Use Authorization ("pre-EUA"). The FDA confirmed that our existing efficacy and safety data and animal-to-human dose conversion were sufficient to proceed with a pre-EUA application and agreed to accept a pre-EUA application for review, which was filed in the second quarter of 2015. If the FDA authorizes the application, then Federal agencies are free to procure drug product for stockpiling so that the drug is available to distribute in the event of an emergency, i.e. prior to the drug being formally approved by FDA under a Biologics License Application ("BLA").

In September 2015, we announced two awards totaling approximately $15.8 million in funding from the United States Department of Defense ("DoD"), office of Congressionally Directed Medical Research Programs to support further development of entolimod as a medical radiation countermeasure. These awards will fund additional pre-clinical and clinical studies of entolimod, which are needed for a BLA.

Additionally, we completed a Phase 1 open-label, dose-escalation trial of entolimod in 26 patients with advanced cancer in the U.S. Data for this study were presented at the 2015 annual meeting of the American Society of Clinical Oncology ("ASCO"), on May 30, 2015. A small expansion study in the Russian Federation ("Russia") was temporarily halted due to changes in a development contract with the Russian Federation Ministry of Industry and Trade ("MPT").

In February 2016, we announced the start of dosing in a new Phase 2 clinical study conducted in Russia of the safety and tolerability of entolimod as a neo-adjuvant therapy in treatment-naïve patients with primary colorectal cancer who are recommended for surgery. Our goal is to accumulate additional clinical data regarding immune cell response to administrations of entolimod in order to guide future oncology development. This study is supported by the development contract with MPT.

CORPORATE INFORMATION

We were incorporated in Delaware in June 2003 as a spin-off company from The Cleveland Clinic. We exclusively license our founding intellectual property from The Cleveland Clinic. In 2007, we relocated our operations to Buffalo,

New York and became affiliated with Roswell Park Cancer Institute ("RPCI"), through technology licensing and research collaboration relationships. Our common stock is listed on the NASDAQ Capital Market under the symbol “CBLI.”

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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.

Since inception we have formed several subsidiaries to best capitalize on our unique ability to leverage financial and clinical development resources in Russia. In December 2009, we created Incuron LLC (“Incuron”) with BioProcess Capital Ventures ("BCV") to develop Curaxin compounds (defined below). In September 2011, we created Panacela Labs, Inc. (“Panacela”), a U.S. entity, with Open Joint Stock Company “Rusnano” ("Rusnano") to develop Mobilan and other product candidates (described below.) Simultaneous with the formation of Panacela, was the creation of a wholly-owned Russian subsidiary of Panacela named, Panacela Labs, LLC. Finally, we have a wholly-owned Russian subsidiary, BioLab 612, LLC. As more fully described in Note 5, “Noncontrolling Interests” in our audited financial statements included in Item 8: "Financial Statements and Supplementary Data," Incuron was included in our consolidated financial results through November 25, 2014, and then accounted for as an equity investment through April 29, 2015, after which our remaining equity interest in Incuron was sold by June 30, 2015. Currently we no longer own equity in Incuron, but do maintain a right to royalty payments, as later described. As such, we conduct drug development activities in the U.S. and Russia.

CBLI and Panacela, each have worldwide development and commercialization rights to product candidates in development, subject to certain financial obligations to our current licensors.

The CBLI logo and CBLI product names are proprietary trade names of CBLI, its subsidiaries. We may indicate U.S. trademark registrations and U.S. trademarks with the symbols “®” and “™”, respectively. 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 both internally developed and in-licensed intellectual property from our innovation partners, The Cleveland Clinic and RPCI. In building the Company’s product development pipeline, we intentionally pursued 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:

CBLI

PRODUCT Indication	DISCOVERY	PRECLINICAL	PIVOTAL ANIMAL STUDIES	HUMAN SAFETY / DOSE CONVERSION
ENTOLIMOD-Biodefense Acute Radiation Syndrome				

PRODUCT Indication	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PHASE III
ENTOLIMOD-Oncology Advanced Solid Tumors					
ENTOLIMOD-Oncology Neo-adjuvant Therapy of Colorectal Cancer					
CBLB612 Chemotherapy-induced Myelosuppression					

Panacela

PRODUCT Indication	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PHASE III
MOBILAN Targeted Therapy of Prostate Cancer					

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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 system and gastrointestinal 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 Nuclear Factor kappa-B ("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 includes CBL0137, currently being developed by our former subsidiary, Incuron, LLC ("Incuron").

In recent years, our understanding of the mechanisms of actions underlying the activity of these compounds has grown substantially beyond the initial founding concepts around modulation of apoptosis.

Entolimod Biodefense Indication

Our most advanced 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 medical radiation countermeasure for prevention of death from ARS, which we refer to as a Biodefense Indication; and (ii) as an oncology immunotherapy (discussed in the following section).

The market for medical radiation countermeasures grew dramatically following the September 11, 2001 terrorist attacks and the subsequent use of anthrax in a biological attack in the U.S. 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, which maintains a national stockpile of products for emergency use (the "National Stockpile"), we believe the potential markets for the sale of radiation countermeasures include U.S. federal, state and local governments, including defense and public health agencies; foreign governments; non-governmental organizations; multinational corporations; transportation and security companies; healthcare providers; and, nuclear power facilities.

Acute high-dose whole body or significant partial body radiation exposure induces massive apoptosis of cells of the hematopoietic system and gastrointestinal tract, which leads to ARS, a potentially fatal condition. 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. We believe the significant limitations of the two currently approved treatments to deal with such an event make 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.

We met with the FDA in July 2014 to present our human dose-conversion and to discuss our intent to submit a pre-EUA application. As a result of this meeting, the FDA agreed to accept a pre-EUA application for review, which was filed in the second quarter of

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2015. If authorized by the FDA, 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 BLA, but precedes full licensure, and, importantly, would position entolimod for potential sales in advance of full licensure in the U.S. 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-irradiated non-human primates established the dose-dependent effect of entolimod on biomarkers for animal-to-human dose conversion.
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 a Phase 1 oncology study in 26 patients with advanced cancer that was reported at ASCO in 2015, 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"). In January 2016, the European Medicines Agency ("EMA"), granted entolimod Orphan Drug Designation for treatment of ARS (see "– Government Regulation - Orphan Drug Designation").
Entolimod Oncology Indication
In addition to developing entolimod as a radiation countermeasure for prevention of death from ARS, we are also developing entolimod as an oncology immunotherapy. 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 animal models.

We have completed a Phase 1 open-label, dose-escalation trial of entolimod in 26 patients with advanced cancer in the U.S. and data were presented at the 2015 annual meeting of ASCO on May 30, 2015. Twenty-six patients with previously treated metastatic cancers, including colorectal, non-small cell lung, anal and urothelial bladder tumors were enrolled in the study. Stable disease for more than 6 weeks was observed in 8 patients with various cancer types; among these, 3 patients (with anal, colorectal and urothelial cancers) had maintenance of stable disease for more than 12 weeks. Patients exhibited $CD8^+$ T-cell activation with stable or decreased levels of myeloid-derived suppressive cells, accompanied by increased immunostimulatory cytokines (G-CSF, IL-6, and IL-8). The tolerability profile in patients with advanced cancer was similar to that observed in two previously conducted studies in 150 healthy volunteers receiving entolimod. As expected with activation of innate immune pathways, common adverse events were flu-like symptoms and fever, with some patients having transient, spontaneously resolving tachycardia, hypotension and hyperglycemia. Overall, treatment with entolimod was well tolerated. A small expansion study in Russia at the highest doses achieved in the US study was temporarily halted due to changes in the MPT development contract.
In February 2016, we announced the start of dosing in a new Phase 2 clinical study of the safety and tolerability of entolimod as a neo-adjuvant therapy in treatment-naïve patients with primary colorectal cancer who are recommended for surgery. This study is being conducted in Russia. Our goal is to accumulate additional clinical data regarding immune cell response to administrations of entolimod in order to guide future oncology development. This study is

supported by the MPT development contract.

In October 2013, we received a 149 million ruble, matching funds development contract from MPT (see Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations”).

In February 2016, we announced the publication of studies elucidating immunotherapeutic mechanisms through which entolimod suppresses metastasis in Proceedings of the National Academy of Sciences of the United States of America ("PNAS"). The studies presented in the PNAS publication decipher the cascade of cell-signaling events that are triggered by entolimod activation of the TLR5 pathway in the liver. The data also define the functional roles of natural killer ("NK"), dendritic, and CD8+ T-cells in the drug’s activity as a suppressor of metastasis. The studies demonstrate that entolimod administration induces chemokines that attract

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NK cells to the liver via a CXCR3-dependent mechanism. CXCR3 is a chemokine receptor that is highly expressed on both NK and effector T cells and plays an important role in cell trafficking to tissues. Once in the liver, NK cells, which are components of the innate immune system, engage an adaptive antitumor immune response through dendritic cell activation. This NK-to-dendritic cell interaction generates CD8+ T-cell-dependent antitumor memory that results in tumor rejection upon animal re-challenge with tumor. Importantly, localized antitumor effects in the liver combine with systemic responses that enable suppression of metastasis to the lung.

We have worldwide development and commercialization rights to entolimod.

CBLB612

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 pathways via specific binding to TLR2 on a subset of body tissues and cell types that express this receptor. Preclinical studies have shown that CBLB612 stimulates white blood cell regeneration. More recent research indicates that stimulation of these toll-like receptors may also enhance anti-tumor efficacy. We believe an opportunity may exist for CBLB612 to offer a single-dose alternative to existing hematopoietic growth factors, such as filgrastim (Neupogen™), which comprises a multi-billion-dollar market in support of chemotherapy administration. Filgrastim modestly shortens the duration of chemotherapy-related neutropenia, but does not improve thrombocytopenia or anemia, and does not provide antitumor efficacy.

In July 2015, we reported the results of a Phase 1, single-center, blind, placebo-controlled, single ascending dose study in Russia evaluating the safety and tolerability of CBLB612 in healthy volunteers and measuring response of various hematopoietic stem and progenitor cell types in order to gain a preliminary estimate of the drug's hematopoietic stem cell ("HSC") stimulatory efficacy. Analysis of data from the 56 healthy volunteers enrolled in the study indicates that single subcutaneous injections of CBLB612 in doses ranging from 0.5 to 4 micrograms were generally well-tolerated, with the 4 microgram dose identified as the max tolerated dose ("MTD"). Observed adverse events were typically mild or moderate in severity, transient, and related to the drug's mechanism of action. Single injections of CBLB612 induced dose-dependent increases in absolute neutrophil counts lasting approximately 20 hours. Administrations of CBLB612 also resulted in rapid, dose-dependent increases of plasma levels of the specified cytokines. Cytokine levels returned to baseline levels several hours after administration of the drug.

In January 2016, we announced the start of dosing in a Phase 2, randomized, placebo-controlled clinical study of CBLB612 as myelosuppressive prophylaxis in patients with breast cancer receiving doxorubicin-cyclophosphamide chemotherapy. Objectives of the study include evaluation of the depth and duration of chemotherapy-induced neutropenia and thrombocytopenia, progenitor cell and reticulocyte mobilization, changes in plasma cytokines, and safety.

These Russian studies are supported by 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 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

Mobilan is the lead product candidate of Panacela. Mobilan is a recombinant non-replicating adenovirus that directs expression of TLR5 and its agonistic ligand, a secretory non-glycosylated version of entolimod. 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. In March 2015, enrollment was opened in a Phase 1 multicenter, randomized, placebo-controlled, single-blinded study in Russian evaluating single injections of ascending doses of Mobilan administered directly into the prostate of patients with prostate cancer. This study is being performed under a 149 million ruble matching funds development contract that Panacela received in October 2013 from MPT (see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations"). Panacela holds worldwide development and commercialization rights to Mobilan. As of December 31, 2015, we owned 66.77% of Panacela.

CBL0137

CBL0137 is a small molecule with a multi-targeted mechanism of action that may be broadly useful for the treatment of many different types of cancer and is being developed by Incuron. During 2015 we sold our remaining equity interest in Incuron but retain a 2% royalty on (a) product sales of CBL0137, (b) consideration received by Incuron from a licensee or sublicensee, and

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(c) consideration received in connection with the first change of control of Incuron. Incuron's royalty obligations continue until April 29, 2025; however, Incuron has the right, exercisable any time before December 31, 2017, to buy-out its royalty obligations for a pre-agreed amount ranging from $1,500,000 to $6,000,000 depending on the time of exercise.

CBL0137 may offer greater efficacy and substantially lower risk for the development of drug resistance than conventional chemotherapeutic agents. CBL0137 inhibits NF-kB, Heat Shock Factor Protein-1 ("HSF-1"), and Hypoxia-inducible factor 1-alpha ("HIF1 alpha"); these are transcription factors that are important for the viability of many types of tumors. The drug also activates tumor suppressor protein p53 by modulating intracellular localization and activity of chromatin remodeling complex Facilitates Chromatin Transcription ("FACT"). CBL0137 has been shown to be efficacious in animal models of colon, lung, breast, renal, pancreatic, head and neck and prostate cancers; melanoma; glioblastoma; and neuroblastoma. It has also been shown to be efficacious in animal models of hematological cancers, including lymphoma, leukemia and multiple myeloma.

Incuron is currently enrolling patients with advanced, solid tumors into two Phase 1 studies, one in Russia evaluating the oral administration of CBL0137 and one in the U.S. evaluating the intravenous administration of CBL0137. These studies are designed to investigate the safety, pharmacokinetics, pharmacodynamics, and antitumor activity of CBL0137. Incuron is conducting these parallel evaluations of oral and intravenous routes of administration and continuous low-dose versus interrupted high-dose schedules to reduce the company's developmental risk by fully characterizing the clinical pharmacology of CBL0137. In addition, the FDA has allowed Incuron's investigational new drug application ("IND") for a Phase 1 dose escalating and cohort-expansion study of intravenous formulation of CBL0137 in previously treated patients with hematological cancers.

Incuron holds worldwide development and commercialization rights to CBL0137.

STRATEGIC PARTNERSHIPS

Since our inception, strategic alliances and collaborations have been integral to our business. We have exclusively licensed rights in each of our technologies from The Cleveland Clinic and RPCI and maintain innovative partnerships with each. We have also leveraged the experience, contacts and knowledge of our founders to engage financial partners in Russia. Through these partnerships we have collaborated with world-class scientists to develop our novel technologies and accessed non-traditional funding sources, including U.S. federal and foreign government contracts and project-oriented funding. We have received project-oriented funding from Rusnano through the formation of Panacela.

Both Panacela, as well as our wholly-owned subsidiary BioLab 612, maintain operations in Russia and benefit from programs supporting domestic pharmaceutical industry development in Russia.

The Cleveland Clinic

In July 2004, CBLI entered into an exclusive license agreement with The Cleveland Clinic ("The Cleveland Clinic License"), pursuant to which CBLI was granted an exclusive license to The Cleveland Clinic's research base underlying our therapeutic platform. We amended The Cleveland Clinic License effective as of September 22, 2011, pursuant to which we were granted an exclusive license to The Cleveland Clinic's research base underlying certain product candidates in development by Panacela ("Panacela Products"), including Mobilan and several earlier stage compounds that are not currently material to our business. In consideration for The Cleveland Clinic License, we agreed to issue The Cleveland Clinic common stock and make certain milestone, royalty and sublicense royalty payments as described below.

The Cleveland Clinic License requires milestone payments, which may be credited against future royalties owed to The Cleveland Clinic, as described in the table below. We have 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 The Cleveland Clinic 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
Upon regulatory approval permitting any product to be sold to the commercial market	1,000,000	4,000,000

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* Maximum amounts listed for achievement of milestone in U.S. 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.

** New Drug Application ("NDA")

The Cleveland Clinic License requires royalty payments of (a) 2% of net sales of any product candidate under a licensed patent solely owned by The Cleveland Clinic; and (b) 1% of net sales of any product candidate under a licensed patent that is jointly owned by The Cleveland Clinic 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 The Cleveland Clinic, CBLI will pay The Cleveland Clinic (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 The Cleveland Clinic and CBLI or an affiliate of CBLI jointly own the licensed patent.

Through December 31, 2015, CBLI had paid The Cleveland Clinic $150,000 for milestone payments on products limited to biodefense uses, and $400,000 for all other products.

As each patent covered by The Cleveland Clinic License expires, the license agreement will terminate as to such patent. The Cleveland Clinic may terminate The Cleveland Clinic 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 Cleveland Clinic License in its entirety or any specific patent licensed under the agreement by giving at least 90 days written notice of such termination to The Cleveland Clinic. The agreement will, subject to certain exceptions, automatically terminate with respect to a licensed product if The Cleveland Clinic does not receive a royalty payment for more than 1-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 entered into between January 2007 to present; and
- Clinical trial agreements for the conduct of our Phase 1 entolimod oncology study and Incuron’s 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 (the "Panacela-RPCI License") to exclusively license from RPCI certain rights to the Panacela Products, including Mobilan and several earlier stage compounds that are not currently material to our business, and to non-exclusively license from RPCI 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 from RPCI (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.

The Panacela-RPCI License requires milestone payments for developmental and regulatory milestones reached in the U.S. 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.

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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 any fees received from the sublicensee 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 to 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 both parties have sponsored research to be conducted by the other party. Under our sponsored research agreement with RPCI, title to any inventions under the agreement is determined in a manner substantially similar to U.S. patent law, and we have the option to license from RPCI, on an exclusive basis, the right to develop any inventions of RPCI (whether solely or jointly developed) under the agreement for commercial purposes. In addition, the sponsored research agreement may be terminated by one party if the other party becomes subject to bankruptcy or insolvency, the other party is debarred by the U.S. government or the other party breaches a material provision of the agreement and fails to cure such breach within 20 days of receiving written notice.

Under the sponsored research agreements with RPCI, 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, and RPCI owns any other inventions not described in our research plan. We further have a right to exclusively license from RPCI any invention developed under such sponsored research agreements that are owned by RPCI. Such sponsored research agreements with RPCI expire in 2016, 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, which has now been largely completed.

Rusnano

In 2011, we formed Panacela with Rusnano to carry out a complete cycle of development and commercialization in Russia 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 exclusively licensed, as applicable, to Panacela 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 (the "Panacela Loan"). In December of 2015, together with Rusnano, we recapitalized Panacela to fully retire the Panacela Loan and certain other trade payables. Rusnano maintained its ownership percentage in Panacela, while CBLI's ownership stake grew to 66.77%.

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 U.S., supplementary protection certificates in the European Union ("E.U.") or similar mechanisms in other countries or territories. The

following are the patent positions relating to our product candidates as of December 31, 2015.

In the U.S., we have 17 issued patents or allowed patent applications relating to our clinical-stage programs expiring on various dates between 2024 and 2032 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.

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We have 14 issued or allowed U.S. patents covering entolimod, which expire between 2024 and 2032. These patents include composition of matter claims, as well as method of use claims relating to our biodefense and oncology indications, reducing effects of chemotherapy, and treatment of reperfusion injuries. In addition, we have pending U.S. patent applications related to compositions of matter, oncology methods of use, and others biodefense methods, which, if issued, will expire between 2025 and 2036.

We have 3 issued or allowed 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 and another method of use application which, if issued, will expire in 2035.

We have issued or allowed patents covering Mobilan and related agents, which expire in 2030 that cover a broad list of international territories including the U.S., E.U., Australia, Japan and Russia. These patents include composition of matter and methods of use claims.

In addition, as of December 31, 2015, 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 2036, 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

As of December 31, 2015, our research and development group, including Russian-based personnel, consisted of 16 individuals. Our research and development focuses on management of outsourced preclinical research, clinical trials and manufacturing technologies. We invested $7.1 million, and $9.7 million in research and development in the years ended December 31, 2015, and 2014, 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, as discussed above. 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.

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, efficacy, safety, reliability, availability, patient convenience, ease of delivery, manufacturing cost and price. 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 and our other clinical-stage 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 the only FDA-approved drugs for the treatment of ARS are filgrastim (Neupogen™) and peg-filgrastim (Neulasta™).

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Filgrastim (granulocyte colony-stimulating factor (“GCS-F”) and peg-filgrastim (PEGylated form of GCS-F) stimulate neutrophils and may reduce infection related to ARS. Unlike entolimod, these drugs do not improve platelet count or lessen bleeding, or gastrointestinal dysfunction due to ARS. In label-supporting survival studies, filgrastim and peg-filgrastim were administered repeatedly and treatment was accompanied by laboratory monitoring and required intensive supportive care (including platelet transfusions). By contrast, entolimod survival studies included only a single injection, without any intensive medical support, which we believe makes it significantly more suitable for use in a mass-casualty situation. 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, Inc., Humanetics Corporation, Neumedicines, Inc., Onconova Therapeutics, Inc., Pluristem Therapeutics, Inc, 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 competition from other products, such as filgrastim, which was purchased by the U.S. government for use as a radiation countermeasure in 2013.

Entolimod Oncology Program

Immunotherapies are major drivers of commercial growth in cancer therapy and constitute the primary competition for a potential immunotherapeutic agent like entolimod. Examples of marketed drugs in these categories include: pembrolizumab (Keytruda™) (Merck) for advanced melanoma, nivolumab (Opdivo™) (Bristol-Myers Squibb Company) for advanced melanoma and metastatic squamous non-small cell lung cancer, ipilimumab (Yervoy™) (Bristol-Myers Squibb) for advanced melanoma, and Bacillus Calmette-Guerin ("BCG") (TheraCys®, TICE® BCG) (Sanofi Pasteur, Merck) for non-muscle-invasive bladder cancer. These drugs may be appropriate combination partners for entolimod in the appropriate treatment settings. However, these drugs may also be competitors for entolimod market share in the treatment of various tumor types.

CBLB612

Mitigation of chemotherapy-induced myelosuppression is a multi-billion-dollar commercial category within oncology. Filgrastim, (Neupogen®) (Amgen), and peg-filgrastim (Neulasta®) (Amgen), or various biosimilar versions of these drugs, are the current standards for treatment of this condition. These drugs modestly ameliorate chemotherapy-related neutropenia, but do not improve thrombocytopenia, or have antitumor efficacy. CBLB612 may offer improvements in neutrophil, and platelet counts and may also offer the potential for antitumor effects. Thus, CBLB612 may have advantages relative to these other drugs. However, filgrastim and peg filgrastim are well established as neutrophil support factors in patients with cancer undergoing myelosuppressive 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 processes consistent with

these legislations before they may be marketed in the U.S.:

- preclinical laboratory and animal tests performed in compliance with current GLPs;

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- development of manufacturing processes which conform to current Good Manufacturing Practices, or ("GMPs");
- 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 ("GCPs"), to establish the safety and efficacy of the proposed drug for its intended use; or in the case of entolimod for reducing the risk of death following exposure to potentially lethal radiation, we are required to perform pivotal animal studies in compliance with GLP and some aspects of GCP to establish efficacy; and
- submission to and review and approval by the FDA of a NDA or BLA prior to any commercial sale or shipment of a product; or in the case of entolimod a pre-EUA prior to sales to the National Stockpile.

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 ("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 pre-EUA, 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 an 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 each clinical study, the corresponding clinical protocol must be submitted to the IND and to an independent Institutional Review Board ("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, unexpected and related 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 with advanced disease (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; and
- 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.

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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 the requirements of IRB oversight, informed consent and GCP. 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 participants are being exposed to an unacceptable health risk.

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 Phases 1 and 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 Risk Evaluation and Mitigation Strategies ("REMS"). 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 GMP 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 GMP 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, 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.

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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 U.S. 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 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 and requirements to provide information to patients.

We intend to utilize the Animal Rule in seeking marketing approval for entolimod as a medical 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 shipment of entolimod.

Emergency Use Authorization

The Commissioner of the FDA, under delegated authority from the Secretary of the U.S. Department of Health and Human Services ("DHHS"), may, under certain circumstances, issue an Emergency Use Authorization ("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 DoD that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a specified biological, chemical, radiological or nuclear agent or agents; or
- a determination by the Secretary of DHHS of a public health emergency that effects, or has the significant potential to effect, 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 DHHS, 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

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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.

We met with the FDA in July 2014 to present our human dose-conversion and our intent to submit a pre-EUA for entolimod. As a result of this meeting, the FDA confirmed that our existing efficacy and safety data and animal-to-human dose conversion were sufficient to proceed with a pre-EUA submission and agreed to accept a pre-EUA for review. We submitted a pre-EUA in the second quarter of 2015 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, 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 ("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 DHHS must issue a declaration in cases of public health emergency or "credible risk" of a future public health emergency. Since 2007, the Secretary of DHHS has issued nine declarations and seven amendments under the PREP Act to protect countermeasures that are necessary to prepare the nation for potential pandemics or epidemics from liability.

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 designation 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 has been granted Orphan Drug designation by the FDA for prevention of death following a potentially lethal dose of total body irradiation. 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 U.S. 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 U.S. 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 designation for entolimod. We intend to seek Orphan Drug designation for our other products as appropriate, but an Orphan Drug designation may not provide us with a material commercial advantage.

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Entolimod has been granted Orphan Drug Designation in the E.U. As in the U.S., the E.U. may grant orphan drug status for specific indications if the request is made before an application for marketing authorization is made. The E.U. considers an orphan medicinal product to be one that affects less than five of every 10,000 people in the E.U. A company whose application for orphan drug designation in the E.U. 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 E.U. 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.

Foreign Regulation

In addition to regulations in the U.S., 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.

Our Russian activities are regulated by the Ministry of Health of the Russian Federation ("Minzdrav"). 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 of the Russian Federation ("Roszdravnadzor") is the executive authority subordinated to Minzdrav, which, among other things, (i) performs control and surveillance of certain activities, including preclinical and clinical trials, and monitors compliance with the 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 sale in Russia.

The principal statute that governs our activities in Russia is the Federal Law No. 61-FZ “On Medicine Circulation” of April 12, 2010 (as amended). This law regulates the research, development, testing, preclinical and clinical studies, state registration, quality control, manufacture, storage, transporting, export and import, licensing, advertisement, sale, transfer, utilization and destruction of medical products within Russia, among other things. All medical products must be registered in Russia and comply with stringent safety and quality controls and testing.

In addition, our activities are subject to a number of other Russian laws, regulations and orders relating to the drug development activities, taxation, corporate governance, employment and other areas. In particular, the incorporation, corporate governance, shareholders rights and contractual matters related to our Russian subsidiaries and joint ventures are governed by the Civil Code of the Russian Federation and the Federal Law No. 14-FZ “On Limited Liability Companies” of February 8, 1998 (as amended). In accordance with this legislation we must comply with certain shareholders’ and board of directors’ approval requirements, including those applicable to major and interested party transactions.

Also, pursuant to the Russian Labor Code, our Russian subsidiaries and joint ventures must enter into employment contracts with each employee, afford them at least 28 days paid vacation period, limit the working week to 40 hours per week and follow the code’s specific procedures in case of employment termination.

EMPLOYEES

As of February 12, 2016, CBLI and its consolidated subsidiaries had 27 employees, 17 of whom are located in the U.S. and 10 of whom are located outside of the U.S. Of these employees, 16 were employed on a full-time basis and 11 were employed on a part-time basis.

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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.

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 pre-clinical and clinical research and development ("R&D") of our product candidates. In particular, we are currently developing several 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 in the development of these product candidates. These expenditures will include costs associated with pre-clinical and clinical R&D, obtaining regulatory approvals, product manufacturing, corporate administration, and marketing and selling for approved products. In addition, other unanticipated costs may arise. As of December 31, 2015, our cash, cash equivalents and short-term investments amounted to $19.6 million. We believe that our existing cash, cash equivalents, and marketable securities will allow us to fund our operating plan for at least the next 12 months.

Because the outcome and timing 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. 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 success of the pre-EUA submission we made with the FDA and any future submissions that we may make; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

When our available cash and cash equivalents become insufficient to satisfy our liquidity requirements, or if and when we identify additional opportunities to do so, we will likely 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 stockholders 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, a 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. If we fail to raise sufficient additional financing, on terms and dates acceptable to us, we may not be able to continue our operations

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and the development of our product candidates, our patent licenses may be terminated, and we 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 have incurred significant losses to date. We reported net losses of approximately $(13.0) million, and $0.0 million million for the years ended December 31, 2015, and 2014, respectively. However, were it not for a one-time, non-cash gain of $14.2 million associated with the deconsolidation of Incuron, we would have incurred a net loss of approximately $(14.2) million for the year ended December 31, 2014. We expect significant losses to continue for the next few years as we spend substantial sums on the continued R&D 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;
- 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.

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

As of December 31, 2015, we had federal net operating loss carryforwards ("NOLs"), of $128.7 million to offset future taxable income, which begin to expire if not utilized by 2023, and approximately $3.8 million of federal tax credit carryforwards which begin to expire if not utilized by 2024. The Company also has U.S. state net operating loss carryforwards of approximately $118.1 million, which begin to expire if not utilized by 2027 and state tax credit carryforwards of approximately $0.3 million, which begin to expire if not utilized by 2022.

The purchase of 6,459,948 shares of common stock by Mr. Davidovich yielded a post-transaction ownership percentage of 60.2% for him. We believe it highly likely that this transaction will be viewed by the U.S. Internal Revenue Service as a change of ownership as defined by Section 382 of the Internal Revenue Code ("Section 382"). Consequently, the utilization of these NOL and tax credit carryforwards, as well as any additional NOL and tax credit carryforwards generated in 2015 through the issuance date of July 9, 2015, will be limited according to the provisions of Section 382, which could significantly limit the Company’s ability to use these carryforwards to offset taxable income on an annual basis in future periods. As such, a significant portion of these carryforwards could expire before they can be utilized, even if the Company is able to generate taxable income that, except for this transaction, would have been sufficient to fully utilize these carry forwards.

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 in a timely manner. 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 R&D efforts. 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, disagreements with the financial partners in our subsidiaries, and changes in government regulation, many of which will not be within our control. Any delay in the development, introduction

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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 successfully complete 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 or clinical study results may show the product to be less effective than desired (e.g., a study may fail to meet its primary objectives) or to have harmful or problematic side effects;
- we fail to receive the necessary regulatory approvals or there may be 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 pre-EUA, NDA or BLA preparation, discussions with the FDA and other regulatory agencies, and their request for additional pre-clinical or clinical data or unexpected safety or manufacturing issues;
- we fail to receive funding necessary for the development of one or more of our products;
- 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;
- the economic feasibility of the product is not attainable due to high manufacturing costs, pricing or reimbursement issues, or other factors;
- one or more of our financial partners in our subsidiaries and us do not agree on the development strategy of our products;
- 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 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 in the U.S. 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 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 GMP 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 pivotal 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 and clinical studies to demonstrate that our product candidates are safe and clinical or pivotal animal trials to demonstrate that our product candidates are efficacious. And for entolimod's biodefense indication we must demonstrate a logical dosing correlation between animals and humans. These R&D activities are expensive, difficult to design and implement, can take many

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years to complete and are 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 do not necessarily predict final results. In addition, we will likely outsource all or part of individual R&D activities and may not successfully or promptly finalize agreements for the conduct of these activities. Consequently, delays in completion of contracted activities may result. In addition, we are seeking final FDA agreement on the scope and design of our pivotal animal efficacy and human safety program for an entolimod biodefense BLA. Delay in agreement with the FDA on this program will delay conduct of the pivotal animal efficacy and human safety studies.

Engagement of contract research organizations ("CROs"), study investigators, and other third parties for clinical or animal testing or data management services, for example, transfers substantial responsibilities to these parties. As such we are dependent on these parties to timely execute their contracted work in a quality manner that complies with relevant standards and regulations such as GLPs. Failure of these parties to deliver timely and quality services could result in delays in, or termination of, contracted R&D activities. For example, if any of our clinical trial sites fail to comply with GCPs or our pivotal animal studies fail to comply with GLP regulations we may be unable to use the data generated. Consequently, if contracted CROs or other third parties do not properly execute their duties or fail to meet expected deadlines, our research activities may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for or successfully commercialize our product candidates.

Our pivotal nonclinical and clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our trial sites are not in compliance with applicable regulatory requirements for conducting such 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.

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 IRBs may not authorize us to commence a clinical trial, conduct a clinical trial at a prospective trial site or continue a clinical trial following amendment of a clinical trial protocol or an 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 or clinical studies, 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 may 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;
-

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; and

- 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

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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 U.S. that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist.

Panacela has a significant non-controlling interest holder and, as such, may not be operated solely for our benefit.

As of December 31, 2015, we owned 66.77% of the equity interests in Panacela. Rusnano, a fund regulated by the Russian government, is a significant shareholder along with other minority shareholders. As such, we share ownership and management of Panacela with other parties who may not have the same goals, strategies, priorities or resources as we do.

Both we and Rusnano have certain rights, including the right to designate board members and the need for either supermajority votes or consent of all members of Panacela's board of directors in order to take certain actions. Additionally, the right to transfer ownership is restricted by rights of first refusal, tag along and drag along rights. Consequently, if a co-owner sells their equity interest to a new party, the new party may adversely affect the operation of Panacela. These restrictions lead to organizational formalities that may be time-consuming. In addition, the benefits from a successful product development effort are shared among the co-owners.

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. We also rely on third parties as sole providers of certain testing of our products. Our dependence on third parties for the manufacture and testing 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 in a timely and competitive manner. 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 of the product candidate 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 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;
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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 GMPs 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

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able to comply with GMPs and other FDA requirements or other regulatory requirements outside the U.S. 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; and

- 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 GMPs 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 future clinical trials and pivotal efficacy studies may not be favorable.

The testing, marketing and manufacturing of any product for use in the U.S. 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. Obtaining approval for products requires manufacturing the product and testing in animals and human subjects of substances whose effects on humans are not fully understood or documented. The manufacturing processes for our product candidates are not yet fully developed and identifying a reproducible process may prove difficult. Additionally, pre-clinical studies, animal efficacy studies or 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.

In addition, we expect to rely on the FDA Animal Rule to obtain approval for entolimod’s biodefense indication in the U.S. 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 have limited prior use and we have limited experience in the application of these rules to the product candidates that we are developing. Additionally, we submitted an application with the FDA for pre-EUA in the second quarter of 2015, so that entolimod may be used in an emergency situation. We cannot guarantee that the FDA will review the data submitted in a timely manner, or that the FDA will accept the data when reviewed. 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, 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 ("DBOP"), to the Division of Medical Imaging Products ("DMIP"). As a result of this transfer, we requested and participated in nine meetings with DMIP during 2011-2014 to review the product mechanisms of action, safety profile and preliminary estimation of an effective human dose. In 2013, DMIP 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. There can be no guarantee that we will reach a satisfactory agreement in a timely manner, or at all, or that DMIP will not request any additional information related to our pre-clinical, clinical or manufacturing 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 Russian subsidiaries, in the U.S., Russia and other countries and regulatory jurisdictions. In order to market our product candidates in the U.S., 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 may involve additional clinical trials or other tests. In addition, we do not have in-house experience and expertise regarding the procedures and

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requirements to file for and obtain marketing approval for drugs in countries outside of the U.S., 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 U.S., Europe and Japan. Also, the time required to obtain approval in markets outside of the U.S. 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 U.S. or the EMA in the E.U., 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 U.S. 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 or pivotal 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.

The pre-EUA submission we made to the FDA in the second quarter of 2015 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 July 2014, we met with the FDA regarding human dose-conversion of entolimod and based on the results of that meeting, we submitted a pre-EUA dossier in the second quarter of 2015 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 may decide that our data are insufficient for pre-EUA. The FDA may require additional CMC, pre-clinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. Additionally, an authorization of our pre-EUA submission will 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 as it is possible that the U.S. or other government may not be interested in our product or our proposed terms of sale for any number of reasons including, but not limited to, lack of available funding, potential lack of government co-sponsorship of our pre-EUA, perceptions about the safety and effectiveness of entolimod, the storage requirements for entolimod or one of our competitors receiving pre-EUA authorization for their product. 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 international health authorities, including record keeping requirements, submitting periodic reports, 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 authorities. We or our collaborative partners, if any, must comply with requirements concerning advertising and promotional labeling, including the prohibition against promoting non-approved or "off-label" indications or products. Failure to comply with these requirements could result in significant enforcement action by

the international health authorities, including warning letters, orders to pull the promotional materials and substantial fines.

After the 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 regulatory agency-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

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require changes to a product's approved labeling, including the addition of new warnings and contraindications. Also, the FDA and other international health authorities is likely to require post-market clinical testing of products approved under the Animal Rule or similar regulations 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;
- 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. AND FOREIGN 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 September 2015, we announced the grant of two awards from DoD, totaling approximately $15.8 million for advanced development of entolimod as a medical radiation countermeasure. These awards will be earned as the contracted development work is performed over a three to five year period. For the years ended December 31, 2015, and 2014, we received 7.9%, and 0.6% or our revenues from the U.S. government; and, 59.6%, and 95.2% of our revenues from the Russian government, respectively.

These revenues have funded some of our operating costs and expenses and the two recently announced DoD awards are expected to similarly fund some of our operating costs and expenses in the future. However, we will continue to incur substantial additional costs to fund our operations for which we may apply for other sources of government funding. If we do submit proposals for new grants or contracts, the review of such proposals and ultimate funding of an award may take significant time. Contract and grant awards are subject to a significant amount of uncertainty, including, but not limited to, successful negotiation and availability of funds. In addition, in our experience, contracts from Russian government entities require matching funds and posting of performance guarantees. Therefore, we expect that our acceptance of new contracts or grants from Russian government entities will also be subject to our ability to provide matching funds and to post performance guarantees.

If we are unable to obtain sufficient grants and contracts on a timely basis or if our current grants or contracts are terminated, our ability to fund future operations 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 operating results.

Our future business may be harmed as a result of the foreign and U.S. 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. For example, as described above, we recently received funding from DoD to support further development of entolimod. Additionally, in Russia we may seek additional funding from the Skolkovo Foundation ("Skolkovo") or MPT. Competitive bidding for government contracts presents a number of risks that are not typically present in the commercial contracting

process, which may include:

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- 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;
- 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, 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.

Additionally, government authorities have a high degree of discretion in Russia and have at times exercised their discretion selectively or arbitrarily, without hearing or prior notice, and sometimes in a manner that is perceived to be influenced, or may be influenced, by political or commercial considerations. The government also has the power, in certain circumstances, to interfere with the performance of, nullify or terminate contracts.

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

We plan to submit applications for funding of various research studies of our product candidates to the U.S. and other governments. There is no guarantee that any proposals that we plan to submit will be funded even if we receive positive reviews of such proposals as funding by the government is highly competitive and limited to the availability of funds. Failure to receive funding from U.S. and other government sources for the development of our product candidates could impair our ability to fund the development programs for our product candidates and thus could result in delays in development, or even stopping of development, of certain indications for our product candidates.

Notably, 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 entolimod does not satisfy procurement requirements of the U.S. government with respect to biodefense products. Our opportunities to succeed in the biodefense 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;

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- 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.

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 ("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 accounting, purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed and, 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 from third parties 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 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.

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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 The Cleveland Clinic and RPCI 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, solvency 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 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

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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. To mitigate this risk, in July 2015 we entered into employment agreements with a number of our key employees. In these agreements, certain of our employees have agreed to be employed by the Company through June 2020 in consideration for certain guaranteed base pay and severance, in the event they are terminated without cause prior to the term of the agreement. Additionally, we depend on our scientific, manufacturing, regulatory clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. In addition, to the extent that we are unable to engage certain collaborators or advisors for certain periods of time due to lack of relevant work or lack of available funds, there is a risk that such collaborators or advisors will not be available to provide services in the future at such time when there is available work and/or funds. 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, manufacturing, business development, regulatory, clinical collaborators, advisors, and opinion leaders 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. 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 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

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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 ("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 were 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.

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

Until late 2013, we operated laboratories that used hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment and we currently sublease these laboratories for operation by other companies, which currently use hazardous materials. As appropriate, we stored these materials and wastes resulting from their use at our laboratory facility pending their ultimate use or disposal and we currently require that our laboratory sub-lessors do the same. We contracted with a third party to properly dispose of these materials and wastes and our laboratory sub-lessors now manage such contracts. We were and continue to be 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.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

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

Entolimod is being developed to treat ARS, 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 announced in September 2015 that we received two awards from the DoD for the further development of entolimod. We hope to receive additional funding in the future 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. In addition, 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 continue our other operations. Similarly, if our pre-EUA

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submission for entolimod is authorized 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 U.S. Foreign Corrupt Practices Act and similar foreign laws could subject us to penalties and other adverse consequences.

We are required to comply with the U.S. Foreign Corrupt Practices Act ("FCPA"), which prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business. Foreign companies, including some that may compete with us, are not subject to these prohibitions. Furthermore, foreign jurisdictions in which we operate may have laws that are similar to the FCPA to which we are or may become subject. This may place us at a significant competitive disadvantage. Corruption, extortion, bribery, pay-offs, theft and other fraudulent practices may occur from time to time in the foreign markets where we conduct business. Although we inform our personnel that such practices are illegal, we can make no assurance that our employees or other agents will not engage in illegal conduct for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA and similar foreign anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, such anti-bribery laws present particular challenges in the biotech or pharmaceutical industry, because, in many countries, hospitals are operated by the government and doctors and other hospital employees may be considered foreign officials.

RISKS RELATED TO CONDUCTING BUSINESS IN RUSSIA

Political, economic and governmental instability in Russia could materially adversely affect our operations and financial results.

BioLab 612 and Panacela Labs, LLC, which is the wholly-owned subsidiary of Panacela, conduct business, including clinical trials, in Russia through Russian legal entities. Also, Rusnano is a Russian joint-stock company created as a private equity and venture capital vehicle by the government of Russia. BioLab 612 owns the Russian intellectual property rights for entolimod’s medical applications and CBLB612. Panacela Labs, LLC owns the worldwide rights to Mobilan. Rusnano has certain shareholder rights which could block our ability to execute strategic transactions such as an asset sale or licensing arrangement. All clinical development activity conducted by these Russian entities is funded by grants from MPT and which include a phase 2 trial for CBLB612 and a phase 1 and a phase 2 trial for entolimod in oncology indications, all of which are being performed by BioLab 612; and a phase 1 trial for Mobilan being performed by Panacela Labs, LLC. As such, any political, economic or governmental instability in Russia could impact the conduct of these trials, continued funding by MPT, our access to trial data and our access to intellectual property for out-licensing purposes.

Political, ethnic, religious, historical and other differences have, on occasion, given rise to tensions within certain regions of Russia. Further, political and economic relations between Russia and the U.S., two of the jurisdictions in which we operate, are complex. Recent situations in Ukraine, Crimea, Iran and Syria along with the response of the governments of Russia, the U.S., member states of the European Union, the European Union itself and other nations, have the potential to materially adversely affect our operations in Russia through a variety of situations including the imposition of sanctions against Russian officials, Russian businesses and certain businessmen, including sectorial sanctions applicable to businesses operating in certain sectors of the economy, including energy and finance. Russia has responded with certain countermeasures, including limiting the import of certain goods from the U.S. and other countries. While we do not anticipate that current sanctions will materially affect our business, if further sanctions are ordered, such sanctions may materially adversely affect our operations in Russia.

In addition to geopolitical events, other factors, including the steady fall in oil prices, the global strengthening of the U.S. dollar and the Russian Central Bank’s reduction of currency rate support, have negatively affected the value of the Russian ruble relative to the U.S. dollar. Fluctuations in the rates at which the U.S. dollar are exchanged into Russian

rubles may result in both foreign currency transaction and translation losses. We are subject to exchange rate fluctuations if we or one of our subsidiaries exchanges one currency into another, in order to conduct cross-border operations, and as we translate ruble denominated assets and liabilities that fluctuate from period-to-period. The former results in a transaction gain/loss that is reflected in our operating results. The later results in a translation gain/loss reflected in other comprehensive income/loss in equity. Additionally, translation of historical operating results at average exchange rates for respective periods of time will also generate foreign currency translation adjustments

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that are reflected in our operating results. Presently, BioLab 612 and Panacela conduct most of their activities in Russia. As such we expect most of the foreign currency fluctuations to be related to accounting translations, versus transaction gains and losses.

Even before the current events mentioned above, and since the early 1990s, Russia has sought to transform from a one-party state with a centrally planned economy to a democracy with a market economy. As a result of the sweeping nature of various reforms and the failure of some of them, the political system of Russia remains vulnerable to popular dissatisfaction, including demands for autonomy from particular regional and ethnic groups. Current and future changes in the Russian government, major policy shifts or lack of consensus between various branches of the government and powerful economic groups could disrupt or reverse economic and regulatory reforms. Furthermore, the Russian economy is vulnerable to market downturns and economic slowdowns elsewhere in the world, and has experienced periods of considerable instability. Although the Russian economy showed positive trends until 2008, including annual increases in the gross domestic product, a relatively stable currency, strong domestic demand, rising real wages and a reduced rate of inflation, these trends were interrupted by the global financial crisis in late 2008, in which Russia experienced adverse economic and financial effects including a substantial decrease in the growth rate of gross domestic product, depreciation of local currency and a decline in domestic and international demand for its products and services. Economic instability in Russia could materially adversely affect our business, financial condition and results of operations.

Emerging markets, such as Russia, are subject to greater risks than more developed markets and financial turmoil in Russia could disrupt our business.

Investors in emerging markets, such as Russia, should be aware that these markets are subject to greater risks than more developed markets, including significant economic risks. For example, the Russian economy has periodically experienced high rates of inflation and is experiencing increased rates of inflation at present. According to The World Bank, the annual inflation rate in Russia, as measured by the consumer price index, was 6.8% in 2013, 7.8% in 2014 and 10.0% in 2015. Periods of higher inflation may slow economic growth. Inflation also is likely to increase some of our costs and expenses including the costs for our Russian subsidiaries to conduct business operations, including any outsourced product testing costs.

As an example of how financial turmoil may affect our business, as noted in Footnote 2 to our audited Financial Statements included in Part II of this Annual Report on Form 10-K, we wrote off approximately $1 million in the fourth quarter of 2015 due to deposits held at a Russian bank that went into bankruptcy.

Prospective investors in our common stock should note that emerging markets are subject to rapid change and that the information set forth in our filings with the SEC about our operations in Russia may become outdated relatively quickly.

The legal system in Russia can create an uncertain environment for business activity, which could materially adversely affect our business and operations in Russia.

The legal framework to support a market economy remains new and in flux in Russia and, as a result, its legal system can be characterized by: inconsistencies between and among laws and governmental, ministerial and local regulations, orders, decisions, resolutions and other acts; gaps in the regulatory structure resulting from the delay in adoption or absence of implementing regulations; selective enforcement of laws or regulations, sometimes in ways that have been perceived as being motivated by political or financial considerations; limited judicial and administrative guidance on interpreting legislation; relatively limited experience of judges and courts in interpreting recent commercial legislation; a perceived lack of judicial and prosecutorial independence from political, social and commercial forces; inadequate court system resources; a high degree of discretion on the part of the judiciary and governmental authorities; and underdeveloped bankruptcy procedures that are subject to abuse.

In addition, as is true of civil law systems generally, judicial precedents generally have no binding effect on subsequent decisions. Not all legislation and court decisions in Russia are readily available to the public or organized in a manner that facilitates understanding. Enforcement of court orders can in practice be very difficult. All of these factors make judicial decisions difficult to predict and effective redress uncertain. Additionally, court claims and governmental prosecutions may be used in furtherance of what some perceive to be political or commercial aims.

The untested nature of much of recent legislation in Russia and the rapid evolution of its legal system may result in ambiguities, inconsistencies and anomalies in the application and interpretation of laws and regulations. Any of these factors may affect our ability to enforce our rights under our contracts or to defend ourselves against claims by others, or result in our being subject to unpredictable requirements. These uncertainties also extend to property rights and the expropriation or nationalization of any of our entities, their assets or portions thereof, potentially without adequate compensation, could materially adversely affect our business, financial condition and results of operations.

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Changes in the tax system in Russia or the arbitrary or unforeseen application of existing rules could materially adversely affect our financial condition and results of operations.

There have been significant changes to the taxation system in Russia in recent years as the authorities have gradually replaced legislation regulating the application of major taxes such as corporate income tax, value added tax, corporate property tax and other taxes with new legislation. Effective January 1, 2015, the Russian tax law was amended as part of the government's "deoffshorization" policy to, among other things, introduce a concept analogous to that of controlled foreign corporations found in other jurisdictions.

Tax authorities in Russia have also been aggressive in their interpretation of tax laws and their many ambiguities, as well as in their enforcement and collection activities. Technical violations of contradictory laws and regulations, many of which are relatively new and have not been subject to extensive application or interpretation, can lead to penalties. High-profile companies, particularly those operating in strategically sensitive sectors, can be perceived to be particularly vulnerable to aggressive application of unclear requirements. Many companies must negotiate their tax bills with tax inspectors who may demand higher taxes than applicable law appears to provide. BioLab 612 and Panacela Labs, LLC's tax liabilities may become greater than the estimated amount that they have expensed to date and paid or accrued on the balance sheets, particularly if the tax benefits currently received in Russia are changed or removed. Any additional tax liability, as well as any unforeseen changes in tax laws, could materially adversely affect our future results of operations, financial condition or cash flows in a particular period.

In October 2006, the Supreme State Commercial (Arbitrazh) Court of Russia issued a ruling that introduced the concept of an "unjustified tax benefit," which is a benefit that may be disallowed for tax purposes. Specific examples cited by the court include benefits obtained under transactions lacking a business purpose (i.e., when the only purpose of a deal or structure is to derive tax benefits). The tax authorities have actively sought to apply this concept when challenging tax positions taken by taxpayers. Although the intention of the ruling was to combat tax abuse, in practice there is no assurance that the tax authorities will not seek to apply this concept in a broader sense than may have been intended by the court. In addition, the tax authorities and the courts have indicated a willingness to interpret broadly the application of criminal responsibility for tax violations.

The tax system in Russia imposes additional burdens and costs on our operations there and complicate our tax planning and related business decisions. For example, the tax environment in Russia has historically been complicated by contradictions in Russian tax law and ambiguity in areas such as the deductibility of certain expenses. This uncertainty could result in a greater than expected tax burden and potentially exposes us to significant fines and penalties and enforcement measures, despite our best efforts at compliance. These factors raise the risk of a sudden imposition of arbitrary or onerous taxes on our operations in Russia. This could materially adversely affect our financial condition and results of operations.

Selective or arbitrary government action may have an adverse effect on our business.

Government authorities have a high degree of discretion in Russia and have at times exercised their discretion selectively or arbitrarily, without hearing or prior notice, and sometimes in a manner that is perceived to be influenced, or may be influenced, by political or commercial considerations. The government also has the power, in certain circumstances, to interfere with the performance of, nullify or terminate contracts. Selective or arbitrary actions have included withdrawal of licenses, sudden and unexpected tax audits, criminal prosecutions and civil actions. Federal and local government entities have also used common defects in documentation as pretexts for court claims and other demands to invalidate and/or to void transactions, apparently for political purposes. We cannot assure you that regulators, judicial authorities or third parties will not challenge our compliance with applicable laws, decrees and regulations in Russia. Selective or arbitrary government action could have a material adverse effect on our business and on the value of our common stock.

Shareholder liability under Russian legislation could cause us to become liable for the obligations of our subsidiaries.

The Russian Civil Code and the Law on Limited Liability Companies generally provide that shareholders in a Russian limited liability company are not liable for the obligations of the company and bear only the risk of loss of their investment. This may not be the case, however, when one person, an effective parent, is capable of determining decisions made by another, an effective subsidiary. The effective parent bears joint and several responsibilities for transactions concluded by the effective subsidiary in carrying out these decisions in certain circumstances (i.e.

transactions were made in fulfillment of mandatory instructions of parent company).

In addition, a parent maybe secondarily liable for an effective subsidiary's debts if an effective subsidiary becomes insolvent or bankrupt as a result of the action or inaction of the parent. It is assumed that the subsidiary has become insolvent (bankrupt) as a result of the action or inaction of the parent, if one of the following circumstances is established by the court:

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- One or several transactions of the subsidiary executed with the parent or in favor of the parent and/or approved by the parent violate the creditors' rights; or
- Undue bookkeeping makes it substantially difficult to perform bankruptcy procedures (formation and sale of bankruptcy assets).

The latter is relevant only if the parent is in charge of bookkeeping for the subsidiary.

Accordingly, in Cleveland BioLab's position as a parent, there is a risk that it could be held liable in certain limited circumstances for the debts of its effective subsidiaries consequently, it is possible that Cleveland BioLabs could face material liability in this regard in the future, which could materially adversely affect our business and our results of operations.

Russia may depart from its international obligations in exceptional circumstances

In July 2015 the Constitutional Court of the Russian Federation issued a resolution which introduced a mechanism for Russian state bodies to avoid enforcement of decisions of the European Court of Human Rights ("ECHR") in cases where such enforcement would contradict the Constitution of the Russian Federation.

Namely, if a Russian court or other governmental body comes to a conclusion that a resolution of ECHR, which is to be enforced by a Russian court / governmental body, is grounded on an interpretation of the European Convention on Human Rights which leads to contradiction with the Constitution of the Russian Federation - such court/body must apply to the Constitutional Court which will finally determine whether enforcement is permissible or not.

The resolution creates a risk for businesses and persons who might seek legal recourse from the ECHR after failing to receive remedy in all Russian instances, despite the fact that Russia signed and ratified the European Convention of Human Rights.

In addition, there is a risk that such interpretation could be extended to other obligations of Russia in the area of international law. Thus, we might face difficulties enforcing Russian awards obtained from other intergovernmental institutions or tribunals if Russian state authorities consider that award to be grounded on an interpretation of international treaties that is contrary to the norms of the Constitution of the Russian Federation.

Our Russian operating entities can be forced into liquidation on the basis of formal noncompliance with certain legal requirements.

BioLab 612 and Panacela Labs, LLC were organized under the laws of Russia. Certain provisions of Russian law may allow a court to order the liquidation of a locally organized legal entity on the basis of its formal noncompliance with certain requirements during formation, reorganization or during its operations. Additionally, Russian corporate law allows the government to liquidate a company if its net assets fall below a certain threshold. Similarly, there have also been cases in Russia in which formal deficiencies in the establishment process of a legal entity or noncompliance with provisions of law have been used by courts as a basis for liquidation of a legal entity. Weaknesses in the legal systems of Russia create an uncertain legal environment, which makes the decisions of a court or a governmental authority difficult, if not impossible, to predict. If involuntary liquidation of either of the aforementioned entities were to occur, such liquidation could materially adversely affect our financial condition and results of operations.

Crime and corruption could disrupt our ability to conduct our business.

Political and economic changes in Russia in recent years have resulted in significant dislocations of authority. The local and international press has reported the existence of significant organized criminal activity, particularly in large metropolitan centers. In addition, the local and international press has reported high levels of corruption, including the bribing of officials for the purpose of initiating investigations by government agencies. Press reports have also described instances in which state officials have engaged in selective investigations and prosecutions to further the interests of the state and individual officials, as well as private businesses, including competitors and corporate raiders. Corruption in Russia is perceived to be pervasive and, in some cases, is worsening. The government in Russia has recently pursued a campaign against corruption. However, there is no assurance that such laws or other laws enacted elsewhere will be applied with any effectiveness by the local authorities and the continuing effects of corruption, money laundering and other criminal activity could have a negative effect on the Russian economy and could materially adversely affect our business in Russia.

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RISKS RELATING TO OUR SECURITIES

Our principal stockholder has the ability to control our business, which may be disadvantageous to other stockholders.

As of the date of this filing, David Davidovich, a venture capital investor, beneficially owns or controls approximately 58.8% of the voting power of our outstanding common stock. As a result of his ability to control a majority of the voting power of our outstanding common stock, Mr. Davidovich has the ability to control all matters requiring approval by our stockholders, including the election and removal of directors, amendments to our certificate of incorporation and bylaws, any proposed merger, consolidation or sale of all or substantially all of our assets and other corporate transactions. Additionally, we granted Mr. Davidovich contractual rights to choose a majority of the directors nominated for election by our Board. Mr. Davidovich may have interests that are different from those of other stockholders and may vote in a way with which other stockholders disagree and that may be adverse to other stockholders' interests. Moreover, this concentration of share ownership makes it impossible for other stockholders to replace directors and management without the consent of Mr. Davidovich. In addition, this significant concentration of share ownership may adversely affect the price at which prospective buyers are willing to pay for our common stock because investors may perceive disadvantages in owning stock in companies with controlling stockholders and may have the effect of delaying, preventing or deterring a change of control of the Company and could deprive our stockholders of an opportunity to receive a premium for their company stock as part of a sale of the Company. Additionally, our corporate structure, including the ownership of Mobilan in Panacela, may deter third parties from entering into collaboration and licensing arrangements with us.

We are a "controlled company" within the meaning of the NASDAQ rules and, as a result, qualify for and intend on relying upon exemptions from certain corporate governance requirements. Accordingly, you will not have the same protections afforded to stockholders of companies that are subject to such requirements.

Because Mr. Davidovich holds common stock that represents a majority of the voting power of our outstanding common stock, we may be considered a "controlled company" within the meaning of the NASDAQ corporate governance standards. Under these rules, a company of which more than 50% of the voting power is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including the requirements that:

- a majority of the board of directors consists of independent directors;
- we have a nominating and corporate governance committee that is composed entirely of independent directors; and
- we have a compensation committee that is composed entirely of independent directors.

We are currently utilizing these exemptions and therefore, we do not offer the same protections afforded to stockholders of companies that are subject to all of the NASDAQ corporate governance requirements.

There is uncertainty regarding the application of the federal and state securities laws to our February 2015 offering of common stock and warrants, and there is a corresponding risk that we could be required to refund the purchase price of securities offered to purchasers who so elect.

We conducted an offering under a registration statement filed with the Securities and Exchange Commission ("SEC") and a concurrent private placement intended to comply with the requirements of Section 4(a)(2) under the Securities Act of 1933, as amended, and Rule 506(b) promulgated thereunder. Shares of common stock and warrants were offered and sold in combination. The shares of common stock and Series B pre-funded warrants were intended to be offered and sold in a transaction registered under the Securities Act, while the other warrants and shares of common stock issuable thereunder were intended to be offered and sold in a private placement exempt from the registration requirements of the Securities Act.

While we are aware of other transactions using a concurrent public/private offering approach, the SEC has not addressed whether concurrent public and private offerings and sales to the same prospective investors would adversely impact the public offering or preclude the private offering from satisfying the requirements of Rule 506(b). If the securities offered in our concurrent private placement do not satisfy the conditions of Rule 506(b), the offering would be a violation of Section 5 of the Securities Act and each purchaser would have the right to rescind its purchase of the securities, meaning that we would be required to refund the purchase price of the securities to each purchaser electing rescission. If that were to occur, we would face severe financial demands and reputational harm that could adversely affect our business and operations. Additionally, if we did not in fact qualify for the exemptions upon which it has

relied, we may become subject to significant fines and penalties imposed by SEC. It is also possible that additional remedies may be available to purchasers under applicable state law.

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Significant stockholders or potential stockholders may attempt to effect changes to our company, which could adversely affect our corporate governance, results of operations and financial condition.

Stockholders may from time to time attempt to effect changes, engage in proxy solicitations or advance stockholder proposals. Responding to proxy contests and other actions by activist stockholders can generally be costly and time-consuming, disrupting our operations and diverting the attention of our board of directors and senior management from the pursuit of business strategies. Additionally, stockholder campaigns could result in corporate governance changes that could adversely affect our results of operations and financial condition.

The price of our common stock has been and could remain volatile, which may in turn expose us to securities litigation.

The market price of our common stock has historically experienced and may continue to experience significant volatility. From January 1, 2014 through December 31, 2015, the market price of our common stock, which is listed on the NASDAQ Capital Market, fluctuated from a high of $25.40 per share in the first quarter of 2014 to a low of $1.84 in the second quarter of 2015. The listing of our common stock on the NASDAQ Capital Market does not assure that a meaningful, consistent and liquid trading market will exist, and in recent years, the market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility in addition to volatility caused by the occurrence of industry and company specific events. Factors that could cause fluctuations include, but are not limited to, the following:

- our progress in developing and commercializing our products;
- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in our earnings or fluctuations in our operating results or in the expectations of securities analysts;
- general economic conditions and trends;
- major catastrophic events;
- sales of large blocks of our stock;
- departures of key personnel;
- changes in the regulatory status of our product candidates, including results of our pre-clinical studies and clinical trials;
- status of contract and funding negotiations relating to our product candidates;
- events affecting our collaborators;
- events affecting our competitors;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;
- regulatory developments in the U.S. and other countries;
- failure of our common stock to be listed or quoted on the NASDAQ Capital Market, other national market system or any national stock exchange;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

As a result of the volatility of our stock price, we could be subject to securities litigation, which could result in substantial costs and divert management’s attention and company resources from our business.

Issuance of additional equity may adversely affect the market price of our stock.

We are currently authorized to issue 160,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of this filing, 10,987,166 shares of our common stock were issued and outstanding, we had outstanding warrants to purchase 2,222,155 shares of our common stock at an average exercise price of $13.98 per share, and options to purchase 343,643 shares of our common stock at an average exercise price of $46.60 per share. To the extent we issue shares of common stock or our outstanding options and warrants are exercised, holders of our common stock will experience dilution.

In the event of any other future issuances of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution. Furthermore, certain of our outstanding

warrants contain provisions that,

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in certain circumstances, could result in the number of shares of common stock issuable upon the exercise of such securities to increase and/or the exercise price of such warrants to decrease.

Moreover, our board of directors is authorized to issue preferred stock without any action on the part of our stockholders. Our board of directors also has the power, without stockholder approval, to set the terms of any such preferred stock that may be issued, including voting rights, conversion rights, dividend rights, preferences over our common stock with respect to dividends or if we liquidate, dissolve or wind up our business and other terms. For example, on February 6, 2015, we issued 717.4 shares of Series A Convertible Preferred Stock convertible into 239,134 shares of our common stock at a conversion price of $3.00 per share. As of the date of this filing, the Series A Preferred Stock issued in the transaction are no longer outstanding. If we issue additional shares of preferred stock in the future that have preference over our common stock with respect to the payment of dividends or upon our liquidation, dissolution or winding up, or if we issue preferred stock with voting rights that dilute the voting power of our common stock, the market price of our common stock could decrease. Additionally, the conversion of any preferred stock issued in the future into our common stock could result in significant dilution to the holders of our common stock.

The eventual public resale by certain of our significant stockholders could have a negative effect on the trading price of our common stock.

During the year ended December 31, 2015, we issued an aggregate of 6,716,163 shares of our Company’s common stock to Mr. Davidovich and Rusnano. The issuances of these shares were not registered under the Securities Act of 1933, and the shares will only be able to be resold pursuant to a separate registration statement or an applicable exemption from registration (under both federal and state securities laws). The shares owned by Mr. Davidovich are subject to contractual restrictions prohibiting from selling his shares until July 9, 2017. However, pursuant to the terms of registration rights agreements entered into between the Company and each of Mr. Davidovich and Rusnano, we have filed a registration statement on Form S-3 with the SEC to register the public offer and resale of the shares held by these stockholders. If all or a substantial portion of these shares are resold into the public markets under such registration statement, once declared effective by the SEC, such transactions may cause a decline in the trading price of our common stock.

We do not intend to pay dividends for the foreseeable future.

We do not intend to declare or pay any cash dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the development of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

We also consider from time to time various strategic alternatives that could involve issuances of additional shares of common stock or shares of preferred stock, including but not limited to acquisitions and business combinations.

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these reports and we currently do not have any industry analysts covering us. In the event we do regain analyst coverage, there can be no assurance that analysts will provide favorable coverage. Our stock price may be adversely impacted by our current lack of analyst coverage as we may have less visibility in the financial markets than other companies in our industry, which may cause declined trading volume and stock price.

Item 1B. Unresolved Staff Comments

None.

Item 2. Description of Properties

Our corporate headquarters is located at 73 High Street, Buffalo, New York 14203. We have approximately 32,000 square feet of laboratory and office space under a twelve-year lease through June of 2019 with successive two-year renewals, of which 10,058 square feet was subleased to various companies. The subleases covering the majority of the

subleased space may be terminated by either party upon 30 days written notice to the other party. This space serves as our corporate headquarters and U.S. corporate

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headquarters for Panacela. In addition, we have less than 1,098 square feet under lease outside of the U.S. expiring at varying times through 2016. We do not own any real property.

Item 3. Legal Proceedings

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially affect our results of operations, cash flows or financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management resources and other factors.

While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of December 31, 2015, that, in the opinion of management, might have a material adverse effect on our financial position, results of operations or cash flows.

Item 4. Mine Safety Disclosure

None.

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PART II

Item 5: Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

STOCK EXCHANGE LISTING

Our common stock trades on The NASDAQ Capital Market under the symbol "CBLI." We have not paid dividends on our common stock. We currently intend to retain all future income for use in the operation of our business and for future stock repurchases and, therefore, we have no plans to pay cash dividends on our common stock at this time.

STOCK PRICES

The following table sets forth the range of high and low sale prices on The NASDAQ Capital Market, for each quarter during 2015 and 2014. On February 12, 2016, the last reported sale price of our common stock was $3.45 per share.

2015	High	Low
First Quarter	$6.90	$3.07
Second Quarter	7.24	1.84
Third Quarter	5.29	3.38
Fourth Quarter	4.85	3.38
2014[(1)]		
First Quarter	$25.40	$12.60
Second Quarter	16.20	9.10
Third Quarter	13.80	6.67
Fourth Quarter	10.20	5.20

(1) - As adjusted to account for the Company's 1:20 reverse stock split effected on January 28, 2015.

STOCKHOLDERS

As of February 12, 2016, there were approximately 21 stockholders of record of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial stockholders represented by these record holders.

DIVIDENDS

We have never declared or paid any cash dividends on our capital stock. We currently intend to use the net proceeds from any offerings of our securities and our future earnings, if any, to finance the further development and expansion of our business and do not intend or expect to pay cash dividends in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, outstanding indebtedness and plans for expansion and restrictions imposed by lenders, if any.

UNREGISTERED SALE OF SECURITIES

We did not sell any equity securities during the fiscal year ended December 31, 2015 in transactions that were not registered under the Securities Act, other than as previously disclosed in our Current Reports on Form 8-K filed with the SEC on February 9, 2015, June 24, 2015, July 10, 2015 and December 24, 2015.

ISSUER PURCHASES OF EQUITY SECURITIES

We made no repurchases of our securities during the year ended December 31, 2015.

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Item 6: Selected Financial Data

Not required for smaller reporting company filers.

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

OVERVIEW

We are an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. Our proprietary platform of Toll-like immune receptor activators has applications in mitigation of radiation injury and immuno-oncology. 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 most advanced product candidate is entolimod, an immune-stimulatory agent, which we are developing as a radiation countermeasure and an immunotherapy for oncology and other indications. During the two years ended December 31, 2015, we conducted business in the U.S. and Russia through several subsidiaries, one of which is wholly-owned, BioLab 612; one of which is owned in collaboration with a financial partner, Panacela; and, a former subsidiary, Incuron. We held a majority ownership interest in Incuron until November 25, 2014, at which time Incuron was deconsolidated. As such, results of operations were consolidated through November 25, 2014, after which we recognized only our equitable interest in Incuron's results of operation as a single line item classified as "Equity in Loss of Incuron, LLC" in our Statements of Operations through April 29, 2015, as Incuron's operations were an extension of our core business. Subsequent to April 29, 2015, Incuron was accounted for on the cost basis until we sold our remaining interest in Incuron on June 30, 2015. See Item 1, "Business" for more information on our product candidates and our strategic partnerships.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect our reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, income taxes, stock-based compensation, investments and in-process R&D. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable, collectability is reasonably assured, contractual obligations have been satisfied and title and risk of loss have been transferred to the customer. We generate our revenue from two different types of contractual arrangements: cost-reimbursable grants and contracts and fixed-price grants and contracts. Costs consist primarily of actual internal labor charges, subcontractor and material costs incurred, plus an allocation of fringe benefits, overhead and general and administrative expenses ("G&A"), based on the terms of the contract.

Revenues on cost-reimbursable grants and contracts are recognized in an amount equal to the costs incurred during the period, plus an estimate of the applicable fee earned. The estimate of the applicable fee earned is determined by reference to the contract: if the contract defines the fee in terms of risk-based milestones and specifies the fees to be earned upon the completion of each milestone, then the fee is recognized when the related milestones are earned. Otherwise, we compute fee income earned in a given period by using a proportional performance method based on costs incurred during the period as compared to total estimated project costs and application of the resulting fraction to the total project fee specified in the grant or contract.

Revenues on fixed-price grants and contracts are recognized using a percentage-of-completion method, which uses assumptions and estimates, as appropriate. These assumptions and estimates are developed in coordination with the principal investigator performing the work under the fixed-price grant or contract to determine levels of accomplishments throughout the life of the grant or contract.

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Stock-Based Compensation

We expense all share-based awards to employees and consultants, including grants of stock options and shares, based on their estimated fair value at the date of grant. Costs of all share-based payments are recognized over the requisite service period that an employee or consultant must provide to earn the award (i.e., the vesting period) and allocated to the functional operating expense associated with that employee or consultant.

Fair Value of Financial Instruments

The carrying value of cash and cash equivalents, accounts receivable, short-term investments, accounts payable and accrued expenses approximates fair value due to the relatively short maturity of these instruments. Common stock warrants, which are classified as liabilities, are recorded at their fair market value as of each reporting period.

The measurement of fair value requires the use of techniques based on observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. The inputs create the following fair value hierarchy:

- Level 1 – Quoted prices for identical instruments in active markets.
- Level 2 – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations where inputs are observable or where significant value drivers are observable.
- Level 3 – Instruments where significant value drivers are unobservable to third parties.

We use the Black-Scholes model to determine the fair value of certain common stock warrants on a recurring basis and classify such warrants in Level 3. The Black-Scholes model utilizes inputs consisting of: (i) the closing price of our common stock; (ii) the expected remaining life of the warrants; (iii) the expected volatility using a weighted-average of historical volatilities of CBLI and a group of comparable companies; and (iv) the risk-free market rate.

As of December 31, 2015, we held approximately $4.0 million in accrued expenses classified as Level 3 securities for warrants to purchase common stock.

Income Taxes

Determining the consolidated provision for income tax expense, deferred tax assets and liabilities and related valuation allowance, if any, involves judgment. On an on-going basis, we evaluate whether a valuation allowance is needed to reduce our deferred income tax assets to an amount that is more likely than not to be realized. The evaluation process includes assessing historical and current results in addition to future expected results. Upon determining that we would be able to realize our deferred tax assets, an adjustment to the deferred tax valuation allowance would increase income in the period we make such determination.

Revenue

Our revenue originates from grants and contracts from both U.S. federal government sources and Russian government sources and service contracts with Incuron. U.S. federal grants and contracts are provided to advance research and development for product candidates that are of interest for potential sale to the DoD or BARDA. State grants are usually designed to stimulate economic activity. Russian government contracts are provided to develop the biotechnology and pharmaceutical industries in Russia. We provide various research, management, business development and clinical advisory and management services to Incuron.

Research and Development Expenses

R&D costs are expensed as incurred. Advance payments are deferred and expensed as performance occurs. R&D costs include the cost of our personnel consisting of salaries, incentive and stock-based compensation, out-of-pocket pre-clinical and clinical trial costs usually associated with CROs, drug product manufacturing and formulation and a pro-rata share of facilities expense and other overhead items.

General and Administrative Expenses

G&A functions include executive management, finance and administration, government affairs and regulations, corporate development, human resources, legal and compliance. The specific costs include the cost of our personnel consisting of salaries,

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incentive and stock-based compensation, out-of-pocket costs usually associated with attorneys (both corporate and intellectual property), bankers, accountants and other advisors and a pro-rata share of facilities expense and other overhead items.

Other Income and Expenses

Other recurring income and expenses primarily consists of interest income on our investments, interest on our debt instruments, changes in the market value of our derivative financial instruments and foreign currency transaction gains or losses.

YEAR ENDED DECEMBER 31, 2015 COMPARED TO YEAR ENDED DECEMBER 31, 2014

Revenue

Revenue decreased from $3.7 million for the year ended December 31, 2014 to $2.7 million for the year ended December 31, 2015, representing a decrease of $(1.0) million, or (27)%, principally because two prior sources of revenue, the Curaxin research contract held by Incuron and the Xenomycin MPT contract held by Panacela, ended in 2014. Partially offsetting the termination of these two sources of revenue, two new cost reimbursable DoD contracts were awarded to us in September 2015 for the continued development of entolimod's biodefense indication: JWMRP for continued preclinical development and PRMRP for clinical development. Both of these contracts were starting up during the fourth quarter of 2015. Revenue from these DoD contracts should significantly increase in 2016 as the underlying contracted research activities continue to ramp up. Regarding our Russian trials funded by MPT, reported contract revenue for 2015 decreased as compared to 2014 in general due to changes in the ruble to U.S. dollar exchange rate. Additionally, CBLB612 was enrolling a trial in 2014 which ended in 2015 and is being followed by another trial that commenced in 2016. As a result there was less development activity in 2015. And, our entolimod oncology Phase 1 study experienced patient recruitment delays during 2015, which in turn delayed contract revenue recognition. The non DoD revenue sources will continue to generate revenue into 2016 in aggregate amounts similar to 2015. Since these revenue sources are cost reimbursable in nature, variances in these activities, period to period, are directly aligned with variances in the underlying costs of service. Differences in our revenue sources, by program, between the years are set forth in the following table:

		Year Ended December 31,						
Funding Source	Program	2015		2014			Variance	
DoD	JWMRP Contract	$193,216	7.1 %	$—	—	%	$193,216	
DoD	PRMRP Grant	20,174	0.7 %	—	—	%	20,174	
DoD	MCS Contract	—	— %	23,390	0.6	%	(23,390	)
MPT[(1)]	CBLB612	484,783	17.9 %	519,302	14.0	%	(34,519	)
MPT[(1)]	Entolimod oncology	474,167	17.5 %	969,252	26.2	%	(495,085	)
Incuron	Service Contracts	881,732	32.6 %	154,687	4.2	%	727,045	
		2,054,072	75.8 %	1,666,631	45.0	%	387,441	
Skolkovo[(1)]	Curaxin research	—	— %	1,000,770	27.0	%	(1,000,770	)
MPT[(1)]	Xenomycins pre-clinical	—	— %	28,605	0.8	%	(28,605	)
MPT[(1)]	Mobilan	654,153	24.2 %	1,005,893	27.2	%	(351,740	)
		$2,708,225	100.0 %	$3,701,899	100.0	%	$(993,674	)

(1) The contracts received from Russian government entities are denominated in Russian rubles. The revenue above was calculated using average exchange rates for the periods presented.

We anticipate our revenue over the next year will continue to be derived primarily from government grants and contracts and service contracts from Incuron. The following table sets forth information regarding our currently active contracts as of December 31, 2015:

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Funding source	Program	Total award value	Funded award value	Cumulative revenue recognized	Funded backlog	Unfunded backlog
DoD	JWMRP Contract	$9,226,455	$9,226,455	$193,216	$9,033,239	$—
DoD	PRMRP Grant	6,573,992	6,573,992	20,174	6,553,818	—
MPT[(1)]	CBLB612	3,344,510	3,344,510	3,049,653	294,857	—
MPT[(1)]	Entolimod oncology	2,977,900	2,431,817	2,044,852	386,965	546,083
		22,122,857	21,576,774	5,307,895	16,268,879	546,083
MPT[(1)]	Mobilan	3,143,629	2,597,546	2,597,546	—	546,083
		$25,266,486	$24,174,320	$7,905,441	$16,268,879	$1,092,166

(1) The contract values above are calculated based on the cumulative revenue recognized to date plus our backlog valued at the December 31, 2015 exchange rate for Russian ruble denominated values. Since December 31, 2015, the Russian ruble-to-Dollar exchange rate has increased from 72.8827 to 79.1144 as of February 12, 2016. Based on the February 12, 2016 exchange rate, the funded backlog value decreased from $0.7 million to $0.6 million and the unfunded backlog value decreased from $1.1 million to $1.0 million.

Research and Development Expenses

R&D expenses decreased from $9.7 million for the year ended December 31, 2014 to $7.1 million for the year ended December 31, 2015, representing a decrease of $(2.5) million, or (26)%. Variances in individual development programs are noted in the table below. Significant reductions include reduction of funds spent on: Curaxins, which is largely attributed to the deconsolidation of Incuron and the completion of the Curaxin research contract noted above, entolimod's biodefense indication is lower as significant activities in 2014 were underway to file the pre-EUA dossier which occurred in the second quarter of 2015, followed by relatively minimal activities in the remainder of 2015 to ramp up the newly awarded DoD contracts discussed above, and the Panacela product candidates are lower mainly due to periodic drug manufacturing costs incurred in 2014 that were not required in 2015.The increase in expenses related to entolimod's oncology indication is attributable to an ongoing Phase 2 study in the Russian Federation that was not active in 2014, along with preparatory research for follow-on development efforts. We expect that costs associated with entolimod's biodefense indication to significantly increase in 2016, entolimod's oncology indication should decrease and the other research efforts should remain relatively constant.

	Year Ended December 31,		
	2015	2014	Variance
Entolimod's biodefense indication	$2,800,583	$3,926,110	$(1,125,527)
CBLB612	397,440	508,247	(110,807)
Entolimod's oncology indications	2,649,054	1,289,692	1,359,362
	5,847,077	5,724,049	123,028
Curaxins	811,463	2,708,516	(1,897,053)
Panacela product candidates	484,753	1,221,579	(736,826)
Total research & development expenses	$7,143,293	$9,654,144	$(2,510,851)

General and Administrative Expenses

G&A expenses decreased from $8.5 million for the year ended December 31, 2014 to $6.4 million for the year ended December 31, 2015, representing a decrease of $(2.1) million, or (25.0)%. $0.9 million of this decrease was due to the deconsolidation of Incuron, which occurred in the fourth quarter of 2014. In addition, compensation expense decreased by $0.6 million and recurring professional fees and other costs decreased by $1.2 million. These reductions were partially offset by a one-time increase of $0.6 million related to costs associated with our equity offering in February 2015, as more fully described in Note 7, "Stockholders' Equity," to our consolidated financial statements. The majority of the costs of the February equity offering were expensed, and not otherwise charged to equity, as the majority of the net proceeds were considered derivative liabilities. We expect G&A expenses to decrease in 2016 due to the one-time expenses described above and continued cost control efforts.

Other Income and Expenses

Other net income decreased from $14.5 million for the year ended December 31, 2014 to other net expense of $(2.3) million for the year ended December 31, 2015, representing a net expense increase of $(16.8) million or (116)%. Expense increases include: a one-time gain reported in 2014 of $14.2 million on the deconsolidation of Incuron, $2.9 million attributable to the change in

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periodic warrant valuation, $1.1 million in deposit losses associated with the NOTA-Bank failure more fully discussed in Note 2, "Summary of Significant Accounting Principles," and $0.1 million of equity investment losses associated with Incuron. These expense increases which total $18.2 million were offset by expense reductions of $1.0 million in debt service costs associated with our debt to Hercules Technology Growth Capital and Rusnano, both of which were retired in 2015 and more fully described in Note 6, "Debt," and $0.5 million due to lower foreign exchange losses.

Liquidity and Capital Resources

We incurred net losses of $(148.0) million from our inception through December 31, 2015. Historically, we have not generated, and do not expect to generate, revenue from sales of product candidates in the immediate future. Since our founding in 2003, we have funded our operations through a variety of means:

- From inception through December 31, 2015, we have raised $144.7 million of net equity capital, including amounts received from the exercise of options and warrants. We have also received $7.3 million in net proceeds from the issuance of long-term debt instruments;
- DoD and BARDA have funded grants and contracts totaling $60.4 million for the development of entolimod for its biodefense indication;
- The Russian Federation has funded a series of contracts totaling $17.3 million, based on the exchange rates in effect on the date of funding. These contracts include requirements for us to contribute matching funds, which we have satisfied or expect to satisfy with both the value of developed intellectual property at the time of award, incurred development expenses and future expenses;
- We have been awarded $4.0 million in grants and contracts not described above, all of which has been recognized at December 31, 2015;
- Incuron was formed to develop and commercialize the Curaxins product line, including its lead oncology drug candidate CBL0137. As more fully described in Note 5, "Noncontrolling Interests" we sold our remaining ownership interest in Incuron during 2015 for which we received approximately $3 million in April and $1 million in July. We also assigned the remainder of our Curaxin intellectual property to Incuron for a 2% royalty; and
- Panacela was formed to develop and commercialize preclinical compounds, which were transferred to Panacela through assignment and lease agreements. Rusnano contributed $9.0 million and we contributed $3.0 million plus intellectual property at formation. As more fully described in Note 5, "Noncontrolling Interests" we recapitalized Panacela in December 2015 with Rusnano converting $0.7 million of debt to equity and CBLI obtaining $2.2 million of Panacela equity through a combination of cash payments, debt forgiveness and common stock issuance. As of the date of this filing, CBLI owns 66.77% of Panacela.

We have incurred cumulative net losses and expect to incur additional losses related to our R&D activities. We do not have commercial products and have limited capital resources. As of December 31, 2015 we had $19.6 million in cash, cash equivalents and short-term investments which, along with the active government contracts described above, are expected to fund our projected operating requirements beyond one year. However, until we are able to commercialize our product candidates at a level that covers our cash expenses, we will need to raise substantial additional capital, which we may be unable to raise in sufficient amounts, when needed and at acceptable terms. Our plans with regard to these matters may include seeking additional capital through debt or equity financing, the sale or license of drug candidates, or obtaining additional research funding from the U.S. or Russian governments. There can be no assurance that we will be able to obtain future financing on acceptable terms, or that we can obtain additional government financing for our operations. If we are unable to raise adequate capital and/or achieve profitable operations, future operations might need to be scaled back or discontinued. The financial statements do not include any adjustments relating to the recoverability of the carrying amount of recorded assets and liabilities that might result from the outcome of these uncertainties.

Operating Activities

The following table provides information regarding our cash flows for the nine months ended December 31, 2015 and 2014:

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	For the year ended December 31,		
	2015	2014	Variance
Net cash used in operating activities	$(12,080,120)	$(14,455,188)	$2,375,068
Net cash used in investing activities	(10,276,623)	(1,786,744)	(8,489,879)
Net cash provided by financing activities	24,935,624	10,590,030	14,345,594
Effect of exchange rate change on cash and equivalents	235,574	(1,292,595)	1,528,169
Increase (Decrease) in cash and cash equivalents	2,814,455	(6,944,497)	9,758,952
Cash and cash equivalents at beginning of period	3,103,969	10,048,466	(6,944,497)
Cash and cash equivalents at end of period	$5,918,424	$3,103,969	$2,814,455

Operating Activities

Net cash used in operations decreased by $2.4 million to $(12.1) million for the year ended December 31, 2015 from $(14.5) million for the year ended December 31, 2014. Net cash used in operating activities for the period ending December 31, 2015 consisted of a reported net loss of $(13.0) million, which was adjusted down for $2.4 million of net noncash operating activities, and a $(1.4) million net increase due to changes in operating assets and liabilities. Of the net noncash operating activities of $2.4 million, $1.1 million was due to an investment loss in connection with our NOTA-Bank deposit, as more fully described in Note 2, "Summary of Significant Accounting Policies- Restricted Cash," $0.6 million was due to warrant issuance costs associated with the sale of equity in February 2015, $0.4 million was due to our equity in Incuron losses, and $0.5 million was due to depreciation, amortization, noncash compensation expense and other noncash expenses. These expenses were partially offset by a $0.2 million gain on the settlement of debt associated with the Panacela restructuring transaction more fully described in Note 5, "Noncontrolling Interests." Of the net $(1.4) million of changes in operating assets and liabilities, $0.6 million was due to reduction in accounts payables and accrued expenses primarily associated with the payment of vendor debt as part of the Panacela recapitalization in December of 2015 as more fully described in Note 5, "Noncontrolling Interests," $0.4 million was due to increases in accounts receivable associated with our services provided to Incuron and our new DoD contracts, $0.3 million was due to prepaid expenses associated with the prepayment of insurance and $0.1 was due to recognition of previously deferred revenue. Net cash used in operating activities for the period ending December 31, 2014 consisted of reported net income of $35 thousand, which was adjusted down for $(15.1) million of net noncash operating activities, and a $0.6 million net increase due to changes in operating assets and liabilities. Of the net noncash operating activities of $(15.1) million, $(14.2) million was due to the recorded gain on deconsolidation of Incuron, $(2.7) million was due to the change in value of our warrant liability, $0.6 million was due to a charge associated with the early extinguishment of a portion of the Hercules loan, $0.5 million was due to noncash compensation expense, $0.3 million was due to our equity in Incuron losses, $0.4 was due to depreciation, and other noncash expenses. Of the net $0.6 million of changes in operating assets and liabilities, $0.7 million was due to reductions in accounts payable and accrued expenses primarily due to the deconsolidation of Incuron, $0.6 million was due to reductions in accounts receivable and $(0.7) million was due to reductions in deferred revenue associated with the completion of a grant funding Curaxin research.

Investing Activities

Net cash used in investing activities changed by $(8.5) million to $(10.3) million used for the year ended December 31, 2015 from $(1.8) million used above for the year ended December 31, 2014. The net cash used in investing activities for the year ended December 31, 2015 consisted primarily of net purchases of short-term investments of $13.3 million, offset by $3.0 million in cash received in connection with the sale of Incuron. The net cash used in investing activities for the year ended December 31, 2014 consisted primarily of cash divested upon the deconsolidation of Incuron.

Financing Activities

Cash provided by financing activities increased by $14.3 million to $24.9 million for the year ended December 31, 2015, from $10.6 million for the year ended December 31, 2014. Net cash provided by financing activities for the year ended December 31, 2015 primarily consisted of the sale of $27.6 million in equity securities and treasury stock, offset by $(2.7) million in principal and interest payments associated with debt repayments more fully described in Note 6, "Debt." Net cash provided by financing activities for the year ended December 31, 2014 primarily consisted of

the sale of $9.7 million in equity securities, a noncontrolling equity contribution of $5.2 million into Incuron, offset by $(4.2) million in principal and interest payments associated with debt repayments more fully described in Note 6, "Debt."

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Off-Balance Sheet Arrangements

The Company does not have any off-balance sheet arrangements at December 31, 2015.

Item 7A: Quantitative and Qualitative Disclosures About Market Risk

Not required for smaller reporting company filers.

Item 8: Financial Statements and Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Cleveland BioLabs, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Cleveland BioLabs, Inc. and Subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2015. These financial statements are the responsibility of the entity's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Cleveland BioLabs, Inc. and Subsidiaries as of December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

/s/ Meaden & Moore, Ltd.
MEADEN & MOORE, LTD.
Certified Public Accountants
Cleveland, Ohio
February 23, 2016

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	$5,918,424	$3,103,969
Short-term investments	13,701,273	—
Accounts receivable	631,084	267,199
Other current assets	442,642	174,179
Total current assets	20,693,423	3,545,347
Equipment, net	122,958	244,537
Restricted cash	37,663	1,699,759
Other long-term assets	26,560	56,131
Investment in Incuron, LLC	—	4,268,458
Total assets	$20,880,604	$9,814,232
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$197,134	$1,057,743
Accrued expenses	1,584,826	1,804,456
Deferred revenue	11,892	156,317
Accrued warrant liability	4,048,900	862,074
Current portion of notes payable	—	2,640,968
Current portion of capital lease obligation	—	7,522
Total current liabilities	5,842,752	6,529,080
Noncurrent portion of capital lease obligation	—	—
Long-term debt	—	1,499,050
Commitments and contingencies	—	—
Total liabilities	5,842,752	8,028,130
Stockholders' equity:		
Preferred stock, $.005 par value; 10,000,000 shares authorized, 0 shares issued and outstanding as of December 31, 2015 and 2014, respectively	—	—
Common stock, $.005 par value; 160,000,000 shares authorized,10,987,166 and 2,858,126 shares issued and outstanding as of December 31, 2015 and 2014, respectively	54,932	14,287
Additional paid-in capital	158,764,985	132,693,988
Other comprehensive income/(loss)	(408,051)	(380,110)
Accumulated deficit	(147,978,831)	(133,935,562)
Treasury Stock, at cost; 158,900 and 0, respectively	(544,853)	—
Total Cleveland BioLabs, Inc. stockholders' equity/(deficit)	9,888,182	(1,607,397)
Noncontrolling interest in stockholders' equity	5,149,670	3,393,499
Total stockholders' equity	15,037,852	1,786,102
Total liabilities and stockholders' equity	$20,880,604	$9,814,232

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31,	
	2015	2014
Revenues:		
Grants and contracts	$2,708,225	$3,701,899
Operating expenses:		
Research and development	7,143,293	9,654,144
General and administrative	6,355,962	8,469,690
Total operating expenses	13,499,255	18,123,834
Loss from operations	(10,791,030)	(14,421,935)
Other income (expense):		
Interest and other expense	(99,488)	(1,089,582)
Foreign exchange loss	(509,513)	(1,036,459)
Investment loss provision	(1,060,834)	—
Gain on deconsolidation of Incuron, LLC	—	14,206,555
Change in value of warrant liability	(221,915)	2,662,329
Equity in loss of Incuron, LLC	(362,137)	(285,542)
Total other income	(2,253,887)	14,457,301
Net income (loss)	(13,044,917)	35,366
Net loss attributable to noncontrolling interests	407,280	1,593,738
Net income (loss) attributable to Cleveland BioLabs, Inc.	$(12,637,637)	$1,629,104
Net income (loss) available to common stockholders per share of common stock, basic and diluted	$(1.79)	$0.60
Weighted average number of shares used in calculating net income (loss) per share, basic and diluted	7,060,396	2,702,884

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	For the Year Ended December 31,	
	2015	2014
Net income (loss) including noncontrolling interests	$(13,044,917)	$35,366
Other comprehensive loss		
Unrealized loss on short-term investments	(6,190)	—
Foreign currency translation adjustment	30,025	(1,816,840)
Comprehensive loss including noncontrolling interests	(13,021,082)	(1,781,474)
Comprehensive loss attributable to noncontrolling interests	449,752	2,477,469
Comprehensive income (loss) attributable to Cleveland BioLabs, Inc.	$(12,571,330)	$695,995

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,	
	2015	2014
Cash flows from operating activities:		
Net income (loss)	$(13,044,917)	$35,366
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	140,135	200,792
Amortization of loan costs	135,082	640,248
Gain on debt extinguishment	(184,475)	—
Unrealized currency loss on short-term investments	(17,928)	—
(Gain) loss on equipment disposal	(25,685)	24,685
Investment loss provision	1,060,834	—
Noncash compensation	96,401	496,470
Warrant issuance costs	617,776	171,116
Equity in loss of Incuron, LLC	362,137	285,542
Change in value of warrant liability	221,915	(2,662,329)
Gain on deconsolidation of Incuron, LLC	—	(14,206,555)
Changes in operating assets and liabilities:		
Accounts receivable	(414,068)	629,397
Other current assets	(286,240)	(1,243)
Other long-term assets	13,431	15,690
Accounts payable	(833,947)	459,337
Deferred revenue	(130,048)	(756,808)
Accrued expenses	209,477	213,104
Net cash used in operating activities	(12,080,120)	(14,455,188)
Cash flows from investing activities:		
Purchase of short-term investments	(16,873,917)	(1,408,169)
Sale of short-term investments	3,184,287	1,689,670
Purchase of equipment	5,910	(20,222)
Proceeds from sale of Incuron, LLC	3,000,000	—
Cash divested upon deconsolidation of Incuron, LLC	—	(2,048,023)
Decrease in restricted cash	407,097	—
Net cash used in investing activities	(10,276,623)	(1,786,744)
Cash flows from financing activities:		
Issuance of common stock, net of offering costs	27,190,292	9,697,501
Net repayment of long-term debt	(2,664,691)	(4,176,275)
Noncontrolling interest capital contribution to Incuron, LLC	—	5,152,438
Net proceeds from sale of treasury stock	417,545	—
Repayment of capital lease obligation	(7,522)	(83,634)
Net cash provided by financing activities	24,935,624	10,590,030
Effect of exchange rate change on cash and equivalents	235,574	(1,292,595)
Increase (Decrease) in cash and cash equivalents	2,814,455	(6,944,497)
Cash and cash equivalents at beginning of period	3,103,969	10,048,466
Cash and cash equivalents at end of period	$5,918,424	$3,103,969
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$517,904	$451,327
Supplemental schedule of noncash financing activities:		

Allocation of equity proceeds to fair value of warrants	$3,081,634	$2,216,593
Debt to equity conversion	1,846,200	—
Repurchase of treasury stock	906,321	—
Noncash warrant issuance costs	—	15,993

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

	Common Stock		Treasury Stock		Additional Paid-in Capital
	Shares	Amount	Shares	Amount	
Balance at December 31, 2013	2,259,818	11,299	—	—	125,723,083
Stock based compensation	3,052	12	—	—	645,488
Issuance of common stock, net of offering costs of $697,882	595,256	2,976	—	—	9,799,142
Allocation of equity proceeds to fair value of warrants	—	—	—	—	(2,216,593)
Noncontrolling interest capital contribution	—	—	—	—	1,176,982
Deconsolidation of Incuron, LLC	—	—	—	—	(2,434,114)
Net loss	—	—	—	—	—
Foreign currency translation	—	—	—	—	—
Balance at December 31, 2014	2,858,126	14,287	—	—	132,693,988
Stock based compensation	5,023	25	—	—	256,795
Issuance of common stock, net of offering costs of $1,410,011	8,122,189	40,611	—	—	28,839,862
Repurchase of Treasury Stock	—	—	264,318	(906,321)	—
Sale of Treasury Stock	—	—	(105,418)	361,468	56,077
Exercise of warrants	1,828	9	—	—	(9)
Increased ownership of Panacela Labs, Inc.	—	—	—	—	(94)
Noncontrolling interest contribution in Panacela Labs, Inc	—	—	—	—	—
Allocation of equity proceeds to fair value of warrants	—	—	—	—	(3,081,634)
Net loss	—	—	—	—	—
Unrealized gain on short-term investments	—	—	—	—	—
Foreign currency translation	—	—	—	—	—
Balance at December 31, 2015	10,987,166	$54,932	158,900	$(544,853)	$158,764,985

	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Noncontrolling Interests	Total
Balance at December 31, 2013	307,339	(135,564,666)	11,103,923	1,580,978
Stock based compensation	—	—	—	645,500
Issuance of common stock, net of offering costs of $697,882	—	—	—	9,802,118
Allocation of equity proceeds to fair value of warrants	—	—	—	(2,216,593)
Noncontrolling interest capital contribution	—	—	3,975,301	5,152,283
Deconsolidation of Incuron, LLC	245,660	—	(9,208,256)	(11,396,710)
Net loss	—	1,629,104	(1,593,738)	35,366
Foreign currency translation	(933,109)	—	(883,731)	(1,816,840)
Balance at December 31, 2014	(380,110)	(133,935,562)	3,393,499	1,786,102
Stock based compensation	—	—		256,820
Issuance of common stock, net of offering costs of $1,410,011	—	—	—	28,880,473

Repurchase of Treasury Stock	—	—	—	(906,321)
Sale of Treasury Stock	—	—	—	417,545
Exercise of warrants	—	—	—	—
Increased ownership of Panacela Labs, Inc.	(94,248)	(1,405,632)	1,499,880	(94)
Noncontrolling interest contribution in Panacela Labs, Inc	—	—	706,043	706,043
Allocation of equity proceeds to fair value of warrants	—	—	—	(3,081,634)
Net loss	—	(12,637,637)	(407,280)	(13,044,917)
Unrealized gain on short-term investments	(6,190)	—	—	(6,190)
Foreign currency translation	72,497	—	(42,472)	30,025
Balance at December 31, 2015	$(408,051)	$(147,978,831)	$5,149,670	$15,037,852

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

Cleveland BioLabs, Inc. ("CBLI" or the "Company") is an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. Our proprietary platform of Toll-like immune receptor activators has applications in radiation mitigation and immuno-oncology. 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 most advanced product candidate is entolimod, an immune-stimulatory agent, which we are developing as a radiation countermeasure and an immunotherapy for oncology and other indications. CBLI was incorporated in Delaware in June 2003 and is headquartered in Buffalo, New York. CBLI conducts business in the United States ("U.S.") and in the Russian Federation ("Russia"), through several subsidiaries including: one wholly-owned subsidiary, BioLab 612, LLC ("BioLab 612"), which began operations in 2012; Panacela Labs, Inc. ("Panacela"), which was formed by us and Open Joint Stock Company "Rusnano" ("Rusnano") our financial partner, in 2011; and, Incuron LLC ("Incuron"), which was formed by us and Bioprocess Capital Ventures ("BCV") our financial partner, in 2010. As more fully described in Note 5, "Noncontrolling Interests" our ownership in Incuron has decreased during the two years ended December 31, 2015 from being the majority shareholder until November 25, 2014, to longer being a shareholder as of June 30, 2015. Unless otherwise noted, references to the "Company," "we," "us" and "our" refer to Cleveland BioLabs, Inc. together with its subsidiaries.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements include the accounts of CBLI and the subsidiaries in which CBLI held a controlling interest as of and for the periods presented. The accounts of Incuron are included through November 25, 2014, the date at which CBLI no longer maintained a controlling interest. For the period from November 25, 2014 through April 29, 2015, the Company's interest in Incuron has been presented under the equity method of accounting, with the completed sale of our entire equity interests in Incuron recorded in the quarter ended June 30, 2015. All significant intercompany balances and transactions have been eliminated. These financial statements have been prepared on the accrual basis in accordance with accounting principles generally accepted in the United States ("GAAP").

On January 28, 2015, the Company, after receiving authorization from the Company's shareholders and board of directors, executed a reverse stock split, or Reverse Split, of the Company's common stock at the ratio of 1:20. All historical share balances and share price-related data have been adjusted based on this ratio.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Of the $5.9 million and $3.1 million of cash and cash equivalents at December 31, 2015 and December 31, 2014, respectively, $1.9 million and $0.0 million, respectively, consisted of highly liquid investments with maturities of 90 days or less when purchased. These investments consist of U.S. Treasury securities, time deposits and investments in money market funds with commercial banks and financial institutions. As of December 31, 2015, $1.2 million of the Company's cash and cash equivalents were held in Russian banks, of which $1.1 million was denominated in rubles with the remaining $0.1 million denominated in U.S. dollars.

Short-Term Investments

The Company's short-term investments are classified as available for sale. Accordingly, these investments are carried at fair market value. Short-term investments consisted primarily of U.S. Treasury securities. Unrealized gains and losses on available for-sale investments are reported as Other Comprehensive Loss, a separate component of stockholders' equity. Realized gains

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and losses, and interest and dividends on available-for-sale securities are recorded in our Consolidated Statement of Operations as "Interest and Other Income." The cost of securities sold is based on the specific identification method. All of the Company's short-term investments were held in U.S. financial institutions.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk primarily consist of cash and cash equivalents and short-term investments. The Company maintains cash balances with financial institutions in excess of insured limits. With the exception of our deposits at NOTA-Bank, discussed in "Restricted Cash" below, the Company does not believe it is exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

As of December 31, 2015, the Company held 21% of its cash and cash equivalents in accounts located outside of the United States.

As of February 12, 2016, the Russian Ruble: Dollar exchange rate increased from 72.8827 to 79.1144, resulting in a decrease of $(87.1) thousand to the Company’s cash and cash equivalents as compared to December 31, 2015.

Significant Customers and Accounts Receivable

The following table presents our revenue by customer, on a proportional basis, for the periods indicated:

	Years ended December 31,					
	2015		2014		Variance	
U.S. Department of Defense	7.9	%	0.6	%	7.3	%
Russian government agencies	59.6	%	95.2	%	(35.6	)%
Incuron, LLC	32.5	%	4.2	%	28.3	%
	100.0	%	100.0	%	—	%

Although the Company anticipates ongoing contract and grant revenue from these customers, there is no guarantee that these revenue streams will continue in the future.

The Company extends unsecured credit to its government customers under normal trade agreements and contracted terms, which generally require payment within 30 days. Accounts receivable consist of amounts due under contracts and grants from these customers, along with amounts receivable under subleases at our Buffalo, New York office facility. There were allowances for doubtful accounts of $0.2 and $0.1 million at December 31, 2015 and December 31, 2014, respectively, pertaining to accounts receivable from our subleases.

Equipment

Equipment is stated at cost, net of accumulated depreciation. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repair and maintenance costs are expensed as incurred.

Equipment is depreciated using the straight-line method over the estimated useful lives of the respective assets as follows:

Asset Category	Estimated Useful Life (in Years)
Laboratory equipment	5
Furniture and fixtures	5
Computer equipment	3

Impairment of Long-Lived Assets

Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets or related asset group may not be recoverable. Determination of recoverability is based on an

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estimate of discounted future cash flows resulting from the use of the asset. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset or asset group, the carrying amount of the asset is written down to its estimated net realizable value.

Restricted Cash

Restricted cash at December 31, 2015 includes certificates of deposit denominated in Russian rubles and posted by Panacela and BioLab 612 as collateral for performance guarantees for their contracts with the Ministry of Industry and Trade of the Russian Federation. The guarantees require Panacela and BioLab 612 to satisfactorily perform their statements of work under the contracts, after which the requirement for these deposits will be released. Both Panacela and BioLab 612 anticipate satisfactory contract performance with the release of funds processed in 2017. As a consequence, all of the Company's restricted cash is classified as a noncurrent asset.

Some of our restricted cash is on deposit at NOTA-Bank. We previously disclosed that the Bank of Russia appointed temporary management of NOTA-Bank and placed a three-month moratorium on all creditor claims. Subsequently, on November 24, 2015, the bank's license was revoked by the Bank of Russia, and on January 19, 2016, the Moscow Arbitration Court declared NOTA-Bank insolvent, noting a 70% deficiency in assets. As a result of these developments, the absence of deposit insurance coverage available to Panacela and the fact that what assets do remain will need to be settled according to priorities established by Russian law (i.e., corporate depositors are satisfied after individual depositors and state-sponsored organizations), we have written off the full value of our deposits with NOTA-Bank, aggregating $1,060,834, which was recorded as "Investment Loss Provision" on the Statement of Operations for the year ended December 31, 2015. The remaining amount of "Restricted Cash" at December 31, 2015, is on deposit with other banking institutions. If and when we recover deposits from NOTA-Bank, we will record a gain at that time.

Equity Method Investment

The Company's equity method investment, reported as of December 31, 2014, included its minority holdings in Incuron. The opening equity investment amount as of November 25, 2014, the date at which we no longer maintained a controlling interest, was determined to be $4,554,000 and represented an ownership interest in Incuron of 46.96%. This determination was made by an independent valuation expert based on the commercial potential of Incuron's drug candidates and market values assigned to other early-stage oncology drug candidates.

Under the equity method, the carrying amount of the investment is adjusted for the Company's share of earnings and losses, as well as any capital contributions to and distributions from Incuron. The Company classifies income and losses related to its equity method investments as a component of operating income or loss as Incuron is an extension of the Company's core business.

Intellectual Property

Costs related to filing and pursuing patent applications are recognized as general and administrative expenses as incurred, since the recoverability of such expenditures is uncertain. Upon marketability approval by the U.S. Food and Drug Administration ("FDA"), or a respective foreign governing body, such costs will be capitalized and depreciated over the expected life of the related patent.

Deferred Revenue

Deferred revenue represents cash received under grants and contracts in excess of the revenue recognizable through the end of the respective financial reporting period. The revenue associated with these advances will be recognized in future periods as the applicable costs are incurred.

Accrued Warrant Liability

Certain warrants are accounted for as derivative instruments in accordance with the Financial Accounting Standards Board Accounting Standards Codification (the "Codification"), on derivatives and hedging as the warrant holders, under certain change of control situations, could require settlement in cash. As such, the warrants were initially recorded as liabilities based on their fair values on the date of issuance. Subsequent changes in the value of the warrants are recorded in the Statements of Operations as "Change in value of warrant liability."

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The Company's remaining outstanding warrants were treated as equity upon issuance and continue to be treated as equity since they did not contain any mandatory redemption features or other provisions that would require a different classification of these warrant instruments outside of permanent equity.

Foreign Currency Translation

The Russian ruble is the functional currency of our foreign subsidiaries, which are all located in the Russian Federation. Assets and liabilities of these companies are translated into U.S. dollars at the period-end exchange rate. Income and expense items are translated at the average exchange rates during the period. The net effect of this translation is recorded in the consolidated financial statements as accumulated other comprehensive income (loss).

Other Comprehensive Income/(Loss)

The Company applies the Codification on comprehensive income (loss) that requires disclosure of all components of comprehensive income (loss) on an annual and interim basis. Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The following table presents the changes in accumulated other comprehensive loss for the year ended December 31, 2015.

	Unrealized loss on available-for-sale securities	Gains and losses on foreign exchange translations	Total
Beginning balance	$—	$(380,110)	$(380,110)
Other comprehensive income/(loss) before reclassifications	(6,190)	30,025	23,835
Amounts reclassified from accumulated other comprehensive loss	—	(51,776)	(51,776)
Ending balance	$(6,190)	$(401,861)	$(408,051)

Revenue Recognition

The Company generates grant and contract revenue from two different types of contractual arrangements: cost reimbursable grants and contracts and fixed-price grants and contracts. Costs consist primarily of internal labor charges, subcontractors and materials, as well as an allocation of fringe benefits, overhead and general and administrative expenses, based on the terms of the contract. Under cost reimbursable grants and contracts, revenue is recognized during the period that the associated research and development costs are incurred. Under fixed-price grants and contracts, revenue is recognized using the percentage-of-completion method. The assumptions and estimates used in determination of the percentage-of-completion are developed in coordination with the principal investigator performing the work.

Research and Development

Research and development ("R&D") costs are expensed as incurred. R&D costs primarily consist of salaries, fringe benefits, and stock-based compensation for our clinical and scientific personnel along with a ratable share of our facility expenses. Other R&D expenses include fees paid to research-oriented consultants and outside service providers, and the costs of materials used in clinical trials and other research activities.

Accounting for Stock-Based Compensation

The 2006 Equity Incentive Plan, as amended (the "Plan"), authorizes CBLI to grant (i) options to purchase common stock, (ii) restricted or unrestricted stock units, and (iii) stock appreciation rights, so long as the exercise or grant price of each are at least equal to the fair market value of the stock on the date of grant. At the 2015 annual meeting of stockholders, an amendment to increase the maximum number of shares of common stock reserved for issuance under the Plan was approved, and as of December 31, 2015, an aggregate of 650,000 shares of common stock were authorized for issuance under the Plan, of which a total of approximately 180,476 shares of common stock remained available for future awards. A single participant cannot be awarded more than 100,000 shares annually. Awards granted under the Plan have a contractual life of no more than 10 years. The

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terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Plan are specified in an award document, and approved by compensation committee of the CBLI board of directors.

The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted. Set forth below are the assumptions used in valuing the stock options granted and a discussion of the Company's methodology for developing each of the assumptions used:

	For the year ended December 31,	
	2015	2014
Risk-free interest rate	1.35-1.59%	1.59 - 1.98%
Expected dividend yield	0%	0%
Expected life	5 - 5.5 Years	5 - 6 Years
Expected volatility	75.53-76.21%	71.24 - 78.02%

"Risk-free interest rate" means the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date the option is granted.

"Expected dividend yield" means the Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.

"Expected life" means the period of time that options granted are expected to remain outstanding, based wholly on the use of the simplified (safe harbor) method. The simplified method is used because the Company does not yet have adequate historical exercise information to estimate the expected life the options granted.

"Expected volatility" means a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (implied volatility) during a period. Expected volatility is based on the Company's historical volatility and incorporates the volatility of the common stock of comparable companies when the expected life of the option exceeds the Company's trading history.

In June 2013, CBLI's stockholders approved the 2013 Employee Stock Purchase Plan ("ESPP"), which provides a means by which eligible employees of CBLI, and certain designated related corporations may be given an opportunity to purchase shares of CBLI common stock. As of December 31, 2015, there were 225,000 shares of common stock reserved for purchase under the ESPP. The number of shares reserved for purchase under the ESPP increases on January 1 of each calendar year by the lesser of (i) 10% of the total number of shares of common stock outstanding on December 31 of the preceding year, or (ii) 100,000 shares of common stock. The ESPP, when implemented, will allow employees to use up to 15% of their compensation, up to $25,000 per year, to purchase shares of common stock at an amount equal to 85% of the fair market value of the our common stock on the offering date or the purchase date, whichever is less.

Income taxes

No income tax expense was recorded for the years ended December 31, 2015, and 2014, as the Company did not have taxable income for any of the years presented. A full valuation allowance has been recorded against the Company's net deferred tax asset.

Earnings/(loss) per share

Basic net income (loss) per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net income (loss) by the weighted average number of shares outstanding for the period. Diluted net income (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Diluted net loss per share is identical to basic net loss per share as potentially dilutive securities have been excluded from the calculation of diluted net loss per common share because the inclusion of such securities would be antidilutive.

The Company has excluded the following outstanding warrants and options from the calculation of diluted net loss per share because all such securities were antidilutive for the periods presented:

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	As of December 31,	
Common Equivalent Securities	2015	2014
Warrants	2,222,155	875,304
Options	343,643	261,389
Total	2,565,798	1,136,693

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

In January 2016, the FASB issued ASU 2016-01, "Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities." The pronouncement requires equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income, requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes, requires separate presentation of financial assets and financial liabilities by measurement category and form of financial asset, and eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost. These changes become effective for the Company's fiscal year beginning January 1, 2018. The expected adoption method of ASU 2016-01 is being evaluated by the Company and the adoption is not expected to have a significant impact on the Company’s consolidated financial position or results of operations.

In May 2015, the FASB issued ASU 2015-08, Business Combinations - Pushdown Accounting - Amendment to SEC Paragraphs Pursuant to Staff Accounting Bulletin No. 115. This Update was issued to amend various SEC paragraphs pursuant to the issuance of Staff Accounting Bulletin No. 115. This ASU is not expected to have a significant impact on the Company’s financial statements.

In November 2014, the FASB issued ASU 2014-17, Business Combinations (Topic 805): Pushdown Accounting. The amendments in this Update apply to the separate financial statements of an acquired entity and its subsidiaries that are a business or nonprofit activity (either public or nonpublic) upon the occurrence of an event in which an acquirer (an individual or an entity) obtains control of the acquired entity. An acquired entity may elect the option to apply pushdown accounting in the reporting period in which the change-in-control event occurs. If pushdown accounting is not applied in the reporting period in which the change-in-control event occurs, an acquired entity will have the option to elect to apply pushdown accounting in a subsequent reporting period to the acquired entity's most recent change-in-control event. The amendments in this Update were effective on November 18, 2014. After the effective date, an acquired entity can make an election to apply the guidance to future change-in-control events or to its most recent change-in-control event. This ASU is not expected to have a significant impact on the Company’s financial statements.

In May 2014, the Financial Accounting Standards Board ("FASB"), issued Accounting Standards Update ("ASU, 2014-9"), Revenue from Contracts with Customers, which updates the principles for recognizing revenue. ASU 2014-9 also amends the required disclosures of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. ASU 2014-9 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. The Company is evaluating the potential impacts of the new standard on its existing revenue recognition policies and procedures.

In August 2014, the FASB issued ASU 2014-15, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern ("ASU 2014-15") requires that an entity’s management evaluate whether there are conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued. ASU 2014-15 is effective for annual periods beginning after December 15, 2016 and for interim periods thereafter. The Company is evaluating the potential impacts of this new standard on its quarterly reporting process.

3. Fair Value Measurements

The Company measures and records cash equivalents and warrant liabilities at fair value in the accompanying financial statements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the

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measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value include:

- Level 1 – Observable inputs for identical assets or liabilities such as quoted prices in active markets;
- Level 2 – Inputs other than quoted prices in active markets that are either directly or indirectly observable; and
- Level 3 – Unobservable inputs in which little or no market data exists, which are therefore developed by the Company using estimates and assumptions that reflect those that a market participant would use.

The following tables represent the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2015 and 2014:

	As of December 31, 2015			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$1,885,826	$—	$—	$1,885,826
Short-term investments	13,701,273	—	—	13,701,273
Total assets	$15,587,099	$—	$—	$15,587,099
Liabilities:				
Accrued warrant liability	$—	$—	$4,048,900	$4,048,900

	As of December 31, 2014			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Accrued warrant liability	$—	$—	$862,074	$862,074
Compensatory stock options not yet issued (1)	—	—	132,295	132,295
Total liabilities	$—	$—	$994,369	$994,369

(1) Included in accrued expenses in the accompanying consolidated balance sheets.

The Company has certain warrants that could require settlement in cash if a fundamental transaction occurs, as defined in the respective agreements. These agreements specify the amount due to warrant holders is based on the Black-Scholes pricing model. The following are the assumptions used to measure the accrued warrant liability at December 31, 2015 and 2014, which were determined in a manner consistent with that described for grants of options to purchase common stock as set forth in Note 2, "Summary of Significant Accounting Policies:"

	December 31, 2015	2014
Stock Price	$3.49	$5.60
Exercise Price	$ 3.00 - 100.00	$ 10.10 - 100.00
Term in years	0.48 - 5.60	0.46 - 6.04
Volatility	64.00 - 114.74%	70.69 - 100.08%
Annual rate of quarterly dividends	0 %	0 %
Discount rate- bond equivalent yield	.31 - 1.86%	.12 - 1.65%

The following table sets forth a summary of changes in the fair value of the Company's Level 3 fair value measurements for the years ended December 31, 2015 and 2014:

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	Year Ended December 31, 2015	
	Accrued Warrant Liability	Compensatory Stock Options Issued After Year End
Beginning Balance	$862,074	$132,295
Total (gains) or losses, realized and unrealized, included in earnings (1)(2)	221,915	(51,569)
Issuances	3,636,260	—
Settlements	(671,349)	(80,726)
Balance at, December 31, 2015	$4,048,900	$—

	Year Ended December 31, 2014	
	Accrued Warrant Liability	Compensatory Stock Options Issued After Year End
Beginning Balance	$1,241,311	$309,450
Total (gains) or losses, realized and unrealized, included in earnings (1)(2)	(2,572,035)	(21,055)
Issuances	2,283,092	132,295
Settlements	(90,294)	(288,395)
Balance at, December 31, 2014	$862,074	$132,295

(1) Unrealized gains or losses related to the accrued warrant liability were included as change in value of accrued warrant liability. For the years ended December 31, 2015 and 2014 we realized gains of $671,349 and $90,294, respectively, in connection with the elimination of the Series B warrants issued to an investor in the January 2014 equity investment transaction.

(2) Expenses recorded for compensatory stock options not yet issued are included in "Research and Development" expense and "General and Administrative" expense in the Statements of Operations.

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis, as documented above, from those measured at fair value on a nonrecurring basis. As of December 31, 2015 and 2014, the Company had no assets or liabilities that were measured at fair value on a nonrecurring basis.

The Company considers the accrued warrant liability and compensatory stock options not yet issued to be Level 3 because some of the inputs into the measurements are neither directly or indirectly observable. The compensatory stock options not yet issued use management’s estimate for the expected term, which is based on the safe harbor method as historical exercise information over the term of each security is not readily available. The following table summarizes the unobservable inputs into the fair value measurements:

	December 31, 2015			
Description	Fair Value	Valuation Technique	Unobservable Input	Range in years
Accrued warrant liability	$4,048,900	Black-scholes pricing model	Expected term	0.48 - 5.60

Management believes the value of the accrued warrant liability and compensatory stock options are more sensitive to changes in the Company’s stock price at the end of the respective reporting period as opposed to changes in the expected term. At December 31, 2015, a 10% increase in the expected term of the Company’s warrants measured using the Black-Scholes pricing model would increase the warrant liability by approximately 2%, while a 10% decrease in the expected term would decrease the warrant liability by approximately 2%. A 10% increase in the Company’s stock price would result in an increase in the accrued warrant liability of approximately 13%, while a 10% decrease in the stock price would decrease the warrant liability by approximately 12%.

The carrying amounts of the Company's remaining financial instruments, which include cash, short-term investments, accounts receivable and accounts payable, approximate their fair values due to their short maturities.

4. Equipment

The following table summarizes the Company's gross equipment costs for the years ended December 31, 2015 and 2014:

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	As of December 31,	
	2015	2014
Lab equipment	$298,772	$1,062,679
Computer equipment	1,023,795	293,663
Furniture	494,188	528,807
	1,816,755	1,885,149
Less accumulated depreciation	(1,693,797)	(1,640,612)
Equipment, net	$122,958	$244,537

As part of the sublease income received from Buffalo BioLabs, Inc. mentioned in Note 9, Significant Alliances and Related Parties, the Company leases lab equipment to Buffalo BioLabs, Inc. The original cost and net book value of that equipment as of December 31, 2015 was $989,149 and $62,501, respectively. The monthly income we receive from Buffalo BioLabs, Inc. for this equipment is $4,500 and is cancellable upon 90 days notice.

5. Noncontrolling Interests

On May 31, 2012, BCV contributed approximately 194.0 million Russian rubles (approximately $5.9 million) to Incuron, which increased its ownership percentage to 40.78% and decreased CBLI’s ownership percentage to 59.22%, which was the ownership percentage at December 31, 2013. On June 20, 2014, BCV contributed 100.0 million Russian rubles (approximately $2.9 million) to Incuron, which increased its ownership interest from 40.78% to 46.06% and decreased CBLI’s ownership percentage from 59.22% to 53.94%. The effect of this change in CBLI’s ownership interest in Incuron on CBLI’s equity is shown on the consolidated statement of stockholders’ equity. On August 5, 2014, BCV contributed an additional 79.9 million Russian rubles (approximately $2.3 million) to Incuron which increased its ownership interest from 46.06% to 49.98%. On November 25, 2014, BCV exercised their rights under Amendment 1 to the Participation Agreement and purchased 3.05% of Incuron from us for a nominal amount. As a result, effective November 25, 2014 CBLI no longer maintained control of Incuron, owning 46.96%, and deconsolidated Incuron. The Company’s consolidated income statement for the year ended December 31, 2014 includes revenue, research and development, and general and administrative expenses recognized by Incuron through November 25, 2014 in the amounts of $1,000,770, $1,664,094 and $907,643, respectively.

Beginning on November 25, 2014, CBLI accounted for its ownership interest in Incuron using the equity method of accounting, and recognized its share of equity method losses in the amount of $285,542 by December 31, 2014. The gain on deconsolidation of Incuron amounted to $14,206,555, and was determined based on comparison of the fair value of CBLI’s retained investment in Incuron of $4,554,000 and the carrying amount of the non-controlling interest on the deconsolidation date of $9,797,083, less the carrying amount of the net assets of Incuron on the deconsolidation date of $144,528.

The fair value of Incuron at the date of deconsolidation was determined by an independent valuation. This fair value is categorized within Level 3 of the fair value hierarchy. The value was determined by weighting a market approach and an income approach (Risk adjusted debt-free discounted cash flow) using equal weights of 50% and adjusted for uncertainties associated with the Russian capital markets. The unobservable input of the market approach was a 0.5 multiple of market value to invested capital. The unobservable input to the income approach was a discount rate based upon a weighted average cost of capital of 22%.

On April 29, 2015, CBLI entered into an agreement to sell its equity stake in Incuron to Dr. Mikhail Mogutov, Chairman of Incuron’s Board of Directors and founder of BCV and/or his designee. The transaction was split into two tranches, with 75% of the Company’s equity stake in Incuron being sold for approximately $3 million on April 29, 2015, and an option being given to Dr. Mogutov to purchase CBLI’s remaining ownership interest in Incuron for approximately $1 million, which was exercised by his affiliate, BCV, on June 30, 2015. The purchase price was paid in the form of (i) $2 million in cash received in April 2015, (ii) the transfer of 264,318 shares of CBLI’s common stock (the "Mogutov Shares"), to escrow which were to be sold with the net proceeds provided to CBLI, and (iii) $1 million in cash paid in July 2015. Consequently, CBLI's remaining cost basis of $906,321, that resulted from the independent valuation discussed above, was initially recorded as a reduction in equity in the form of treasury stock. By December 31, 2015, 105,418 Mogutov Shares had been sold leaving 158,900 Mogutov Shares with CBLI's escrow agent. As

such, $417,545, representing CBLI's net cash proceeds from the sale of these shares of stock have reduced the treasury stock balance at December 31, 2015. In addition, CBLI assigned its remaining intellectual property relating to Curaxin CBL0137 to Incuron in exchange for a 2% royalty on the future commercialization, licensing or sale of the Curaxin CBL0137 technology.

We anticipate that CBLI will continue to provide services to Incuron in a related party capacity following the date of deconsolidation to assist in furthering the development of CBL137. Since the date of the deconsolidation, the Company recognized $881,732 and

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$154,687 of revenues associated with executed services contracts for the years ended December 31, 2015 and 2014, respectively. At December 31, 2015 the Company held $135,989 in accounts receivable from Incuron.

In 2011 Rusnano, and certain other third-party technology providers formed Panacela to develop and commercialize early-stage drug candidates for the treatment of oncological, infectious or other diseases. CBLI invested $3.0 million, certain third-party owners, assigned and/or provided exclusive licenses, and Rusnano invested $9.0 million, with an additional $17.0 million available for investment. $1.5 million of the $17.0 million was invested in the form of a convertible loan (the “Panacela Loan”), discussed in Note 6, “Debt.”

By the fourth quarter of 2015 Panacela owed approximately $2.1 million to Rusnano under the Panacela Loan, approximately $0.4 million in trade payables to CBLI and approximately $0.4 million to third-party vendors, for total obligations of approximately $2.9 million. CBLI issued 256,215 shares of common stock to Rusnano, at an agreed-upon valuation of $4.45 per share for an aggregate value of approximately $1.1 million in partial settlement of the obligations due under the Panacela Loan. Then, through a combination of debt-to-equity conversions and cash investment, an additional $1.8 million of equity capital was provided to Panacela in order to retire the remaining obligations. As a result, the Panacela Loan was fully retired, Rusnano’s proportionate equity position remained constant and CBLI’s grew from 60.47% to 66.77% at December 31, 2015. CBLI issued the 256,215 shares of common stock to Rusnano on December 18, 2015 when the stock closed at a price of $3.73 per share, or $0.72 below the $4.45 per share agreed-upon value, resulting in a gain on debt extinguishment of approximately $184,000 which has been recorded as Interest Other Income in the Statement of Operations for the year ended December 31, 2015.

6. Debt

On September 30, 2013, CBLI and BioLab 612 entered into a Loan and Security Agreement (the "Hercules Loan "), with Hercules Technology II, L.P. ("Hercules"), pursuant to which we issued a $6.0 million note and received net proceeds of $5.9 million. During 2015, the Hercules Loan was fully retired. The Hercules Loan bore interest at 10.45% per annum and matured on January 1, 2017, requiring interest-only payments for the initial 12 months and principal and interest payments in 27 monthly installments thereafter. In June 2014, CBLI repaid $4.0 million of the Hercules Loan primarily using net proceeds from a sale of equity intended for this purpose. Between June 2014 and August 2015 CBLI repaid the remaining principal and interest in accordance with the provisions of the Hercules Loan. In August 2015, CBLI fully paid the remaining obligations of the Hercules Loan along with a prepayment penalty of approximately $28,000 and expensed approximately $76,000 in deferred charges. In connection with the Hercules Loan, CBLI granted a first priority lien in substantially all of CBLI’s assets (exclusive of intellectual property) to Hercules. Upon full repayment this lien was cancelled.

Additional features of the Hercules Loan, all of which were recorded as debt issuance costs and loan discounts in non-current assets, include: $102,000 related to legal fees and a $100,000 facility fee both of which were paid in cash. A $550,000 “end-of-term charge” which was due and paid upon full repayment of the loan and was included in long-term liabilities. And a 5-year warrant to purchase 7,813 shares of CBLI common stock. The warrant had an initial exercise price of $32.00 per share, which was subsequently lowered to $10.10 per share in accordance with its terms. The Black-Scholes pricing model yielded $117,999 as the fair value of the warrant upon issuance which was recorded as equity. CBLI amortized the loan discounts and debt issuance costs to interest expense during the term the loan was outstanding using the effective interest rate method, which approximated 16.6%.

On September 3, 2013, Panacela entered into the Panacela Loan with Rusnano and CBLI pursuant to which Panacela issued a $1,530,000 note to Rusnano. During 2015 and as noted in Note 5, "Noncontrolling Interests," the Panacela Loan was fully retired. The Panacela Loan bore interest at a rate of 16.3% per annum and matured in September 2015, which was extended into the fourth quarter of 2015. In connection with the Panacela Loan, CBLI issued Rusnano a warrant to purchase shares of CBLI's common stock in the event Panacela defaulted on the Panacela Loan. This warrant was cancelled upon retirement of the Panacela Loan.

For the years ended December 31, 2015 and 2014, we recognized interest expense of $532,049 and $1,340,639 for these loans, respectively. Included in interest expense was $75,907 and $401,803 recognized as non-cash reductions of debt issuance costs associated with loan prepayments for the years ended December 31, 2015 and 2014, respectively.

7. Stockholders’ Equity

On January 27, 2015, the Company's stockholders approved the Reverse Split of one share for each twenty shares outstanding (1:20). The Reverse Split became effective as of the open of trading on the NASDAQ Capital Market on January 28, 2015. All shares of Common Stock, warrants, options, per share data and exercise prices included in these financial statements and notes

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for all periods presented have been retroactively adjusted to reflect the Reverse Split with respect to the Company's shares of Common Stock.

As discussed in Note 5, "Noncontrolling Interests," CBLI issued 256,215 shares of common stock to Rusnano, at an agreed-upon value of $4.45 per share for an aggregate value of approximately $1.1 million in partial settlement of the obligations due under the Panacela Loan. The issuance of these shares were recorded at market on the date of issuance, which was $3.73 per share.

On July 9, 2015, the Company sold 6,459,948 shares of the Company's common stock to David Davidovich, a venture capital investor, for an aggregate purchase price of $25.0 million, or $3.87 per share.

On February 4, 2015, CBLI entered into a Securities Purchase Agreement with certain institutional investors providing for the issuance and sale of 572,205 registered shares, or the Shares, of the Company's common stock, at an offering price of $3.00 per share, or the Share Offering, and Series B pre-funded warrants, or the Pre-Funded Warrants, to purchase an aggregate of 594,688 registered shares of its common stock, or the Pre-Funded Warrants Offering. The Share Offering and the Pre-Funded Warrants Offering are referred to collectively as the Offerings.

In a concurrent private placement, or the Private Placement Transaction, and, together with the Offerings, CBLI sold to the purchasers of the Shares and Pre-Funded Warrants, 717.4 shares of our Series A Convertible Preferred Stock, stated value of $1,000 per share, or the Preferred Stock, which are convertible into 239,134 shares of our common stock. Gross proceeds from the Offerings amounted to approximately $4.2 million before deducting placement agent fees and expenses. In addition, Series A warrants, or the Series A Warrants, were issued to purchase one share of our common stock for each share of common stock purchased or prefunded in the Offerings and each share of Series A Convertible Preferred Stock purchased in the Private Placement Transaction. The Series A Warrants cover, in the aggregate, 1,406,028 shares of common stock and became exercisable on the six month anniversary of the date of issuance at an exercise price of $3.64 and expire 6 years from the date they become exercisable.

The Series A Warrants and Pre-Funded Warrants contain provisions that could require CBLI to settle the warrants in cash, and also provide for price or share issuance adjustments in the event of a subsequent qualified issuance of common stock at a price below $3.64 for the Series A Warrants or $3.00 for the Pre-Funded Warrants, and accordingly have been classified as a liability. As of February 6, 2015, the closing date, the fair value of the Preferred Stock and the Pre-Funded Warrants amounted to $3,636,260 and was determined based on the assumptions using the Black-Scholes valuation model listed below.

During 2015, the Pre-Funded Warrants and the Preferred Stock had fully converted into common stock and as such, no balances other than stockholders' equity remain for these securities.

On June 20, 2014, the Company completed a sale of units that were immediately separable into an aggregate of 308,370 shares of the Company's common stock and warrants to purchase up to 154,186 additional shares of the Company's common stock issuable upon the exercise of a warrant. Each unit was sold for $11.35, which qualified as an "at market" transaction as determined by NASDAQ, resulting in net proceeds of approximately $3.4 million after deducting for placement agent fees and offering expenses. In connection with the sale, the Company issued 1,324 warrants to the placement agent. Each warrant has an exercise price of $11.20 per share, and will expire 5 years from the date of issuance. The sale also triggered a reduction in the exercise price of 228,891 of the Company's warrants to $10.10.

On January 16, 2014, the Company completed a public offering of 286,886 shares of the Company's common stock at a price of $24.40 per share, resulting in net proceeds of approximately $6.4 million after deducting for placement agent fees and offering expenses. In connection with the offering, the Company issued Series A warrants for 143,445 shares of common stock and Series B warrants for 143,445 shares of common stock to the purchasers. Each Series A warrant has an exercise price of $24.40 per share, and expire five years from the date of issuance. Each Series B warrant has an exercise price of $24.40 per share, and expire 18 months from the date of issuance. In addition to the warrants issued to the purchasers, the Company also issued Series A warrants for an aggregate of 4,306 shares of common stock and Series B warrants for an aggregate of 4,306 shares of common stock to the placement agent as compensation for completing the offering. The warrants to the placement agent have the same terms, including exercise price, as the warrants issued to investors. The offering also triggered a reduction in the exercise price of 221,078 of the Company's warrants to $24.40.

The January 2014 Series A and B warrants contain provisions that could require the Company to settle the warrants in cash, and accordingly, have been classified as a liability. The fair value of the January Series A and B warrants amounted to $2,283,092 and was determined based on the assumptions using the Black-Scholes valuation model listed below.

The following table sets forth the Black-Scholes valuation model assumptions used to value the warrants noted above at the dates indicated:

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	February 6, 2015				January 16, 2014	
	Series A		Pre-Funded			
Stock price	$3.16		$3.16		$24.60	
Exercise price	$3.64		$3.00		$24.40	
Term in years	6.5		1.00		.75 - 2.50	
Expected volatility	0.83	%	0.88	%	43.06 - 79.86	
Expected dividend yield	0	%	0	%	0	%
Risk-free interest rate	1.48	%	0.26	%	0.09% - 0.58%	

On September 4, 2014, the Company and certain investors in the January 16, 2014 public offering discussed above amended the Securities Purchase Agreement to remove restrictions on the Company's ability to issue securities involving a variable rate transaction, as therein defined. In addition, the same investors returned January 2014 Series B warrants to purchase, in the aggregate, 102,460 shares of the Company's common stock for cancellation. In exchange for these concessions, the Company agreed to extend the expiration dates from January 16, 2019 to January 16, 2021 for Series A warrants to purchase 102,460 shares of the Company's common stock, and reduced the exercise price from $24.40 to $20.40.

On September 29, 2014, the Company and certain investors amended a Securities Purchase Agreement, dated as of February 13, 2009, to remove restrictions on the Company's ability to issue securities involving a variable rate transaction, as therein defined. In exchange, the Company agreed to extend the expiration dates from February 13, 2016 to March 30, 2018 on Series D warrants to purchase 174,307 shares of the Company's common stock, and revised the anti-dilution provision in the Series D warrants to include variable rate transactions.

On January 9, 2015, the Company and certain investors amended a Securities Purchase Agreement, dated as of February 25, 2010, to remove restrictions on the Company's ability to issue securities involving a variable rate transaction, as therein defined. In exchange, the Company agreed to extend the expiration dates from March 2, 2015 to March 2, 2017 on warrants to purchase shares of the Company's common stock, and revised the anti-dilution provision to include variable rate transactions.

The following table sets forth the changes in the number of warrants outstanding for the periods presented:

	Number of Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2013	526,752	$54.00
Granted	451,012	19.85
Forfeited, Canceled	(102,460)	24.40
Outstanding at December 31, 2014	875,304	33.72
Granted	1,406,028	3.64
Exercised	(5,077)	3.00
Forfeited, Canceled	(54,100)	36.71
Outstanding at December 31, 2015	2,222,155	13.98

Equity Incentive Plan

The following is a summary of option award activity under the Plan for the year ended December 31, 2015:

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	Year Ended December 31, 2015			
	Total Stock Options Outstanding	Weighted Average Exercise Price per Share	Nonvested Stock Options	Weighted Average Grant Date Fair Value per Share
December 31, 2014	261,389	$67.89	21,287	$22.31
Granted	131,500	3.19	90,750	2.02
Vested	—	—	(51,287)	10.06
Exercised	—	—	—	—
Forfeited, Canceled	(49,246)	43.72	(18,750)	3.14
December 31, 2015	343,643	46.60	42,000	1.99

The following is a summary of outstanding stock options under the Plan as of December 31, 2015:

	Stock Options Outstanding	Non-Vested Stock Options
Quantity	343,643	42,000
Weighted-average exercise price	$46.60	$3.15
Weighted Average Remaining Contractual Term (in Years)	6.72	9.32
Intrinsic value	$—	$—

For the years ended December 31, 2015, and 2014, the Company granted 131,500, and 49,550 stock options, respectively, with a weighted-average grant date fair value of $2.01, and $7.60, respectively. For the years ended December 31, 2015, and 2014, the total fair value of options vested was $515,904, and $267,382, respectively. The total intrinsic value of options exercised for the years ended December 31, 2015, and 2014 was $0, and $0, respectively.

As of December 31, 2015, total compensation cost not yet recognized related to non-vested stock options was $25,529. The Company expects to recognize this cost over a weighted average period of 0.23 years.

8. Significant Alliances and Related Parties

Roswell Park Cancer Institute

The Company has entered into several agreements with Roswell Park Cancer Institute, or RPCI, including: various sponsored research agreements, an exclusive license agreement and clinical trial agreements for the conduct of the Phase 1 entolimod oncology study and the Phase 1 CBL137 intravenous administration study. Additionally, the Company's Chief Scientific Officer, Dr. Andrei Gudkov, is the Senior Vice President of Basic Research at RPCI.

The Company incurred $970,260, and $1,042,859 in expense to RPCI related to research grants and agreements for the years ended December 31, 2015, and 2014, respectively. The Company had $0 and $208,092 included in accounts payable owed to RPCI at December 31, 2015 and 2014, respectively. In addition, the Company had $183,877 and $324,194 in accrued expenses payable to RPCI at December 31, 2015 and 2014, respectively.

The Cleveland Clinic

CBLI entered into an exclusive license agreement, or the License, with The Cleveland Clinic pursuant to which CBLI was granted an exclusive license to The Cleveland Clinic's research base underlying our therapeutic platform and certain product candidates in development by Panacela. CBLI has the primary responsibility to fund all newly developed patents; however, The Cleveland Clinic retains ownership of those patents covered by the agreement. CBLI also agreed to use commercially diligent efforts to bring one or more products to market as soon as practical, consistent with sound and reasonable business practices and judgments. In consideration for the License, CBLI agreed to issue The Cleveland Clinic common stock and make certain milestone, royalty and sublicense royalty payments. Milestone payments, which may be credited against future royalties, amounted to $0, and $0 for the years ended December 31, 2015, and 2014, respectively. No royalty or sublicense royalty payments were made to The Cleveland Clinic during the two-year period ended December 31, 2015.

The Company also recognized $9,700, and $0 as research and development expense to CCF for the years ended December 31, 2015, and 2014, respectively. The Company had $9,700 and $0 included in accrued expenses payable at December 31, 2015 and 2014, respectively.

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Buffalo BioLabs, et. al.

Our Chief Scientific Officer, Dr. Andrei Gudkov has business relationships with several entities with which we transact business, the most significant of which is Buffalo BioLabs ("BBL"), where Dr. Gudkov was a founder and currently serves as their Principal Scientific Adviser. Pursuant to a master services agreement we have with BBL, the Company recognized $1,405,261, and $1,494,464 as research and development expense for the years ended December 31, 2015, and 2014, respectively, and included $0 and $54,353 in accounts payable at December 31, 2015 and 2014. In addition, the Company had $87,690 and $9,716 in accrued expenses payable to BBL at December 31, 2015 and 2014. We also recognized $101,667, and $230,398 from BBL for sublease and other income for the years ended December 31, 2015, and 2014, respectively. Pursuant to our real estate sublease and equipment lease with BBL, we had gross and net accounts receivable of $215,414 and $0 at December 31, 2015 and gross and net accounts receivables of $198,124 and $88,363 at December 31, 2014, respectively.

9. Income Taxes

The Company accounts for income taxes using the asset and liability method. Deferred taxes are determined by calculating the future tax consequences attributable to differences between the financial accounting and tax bases of existing assets and liabilities. A valuation allowance is recorded against deferred tax assets when, in the opinion of management, it is more likely than not that the Company will not be able to realize the benefit from its deferred tax assets.

The Company files income tax returns, as prescribed by the national, state and local jurisdictions in which it operates. The Company’s uncertain tax positions are related to tax years that remain subject to examination and are recognized in the financial statements when the recognition threshold and measurement attributes are met. Interest and penalties related to tax deficiencies and uncertain tax positions are recorded as income tax expense.

Income (loss) from continuing operations consists of the following:

	For the Year Ended December 31,	
	2015	2014
US operations	$(9,988,875)	$6,234,092
Foreign operations	(3,056,042)	(6,198,726)
	$(13,044,917)	$35,366

The provision for income taxes charged to continuing operations is $0 for all periods presented.

Deferred tax assets (liabilities) were comprised of the following as of the periods presented below:

	As of December 31,	
	2015	2014
Deferred tax assets:		
Operating loss carryforwards	$51,710,000	$48,643,000
Accrued expenses	8,932,000	8,916,000
Tax credit carryforwards	3,618,000	3,449,000
Intellectual property	3,902,000	3,214,000
Outside tax basis difference in affiliate	—	3,948,000
Equipment	330,000	365,000
Other	—	—
Total deferred tax assets	68,492,000	68,535,000
Deferred tax liabilities:	—	—
Net deferred tax asset	68,492,000	68,535,000
Valuation allowance	(68,492,000)	(68,535,000)
	$—	$—

The provision for income taxes differs from the amount of income tax determined by applying the applicable U.S. statutory federal income tax rate to the pretax loss from continuing operations as a result of the following differences:

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	For the Year Ended December 31,	
	2015	2014
Tax at the U.S. statutory rate	$(4,435,000)	$12,000
Change in value of warrant liability	75,000	(905,000)
Valuation allowance	3,335,000	5,717,000
Deconsolidation of Incuron	—	(4,830,000)
Gain on sale of Incuron	1,020,000	—
Other	5,000	6,000
	$—	$—

At December 31, 2015, the Company had U.S. federal net operating loss carryforwards of approximately $128,665,000, which begin to expire if not utilized by 2023, and approximately $3,750,000 of tax credit carryforwards which begin to expire if not utilized by 2024. The Company also has state net operating loss carryforwards of approximately $118,097,000, which begin to expire if not utilized by 2027 and state tax credit carryforwards of approximately $336,000, which begin to expire if not utilized by 2022. The purchase of 6,459,948 shares of common stock by Mr. Davidovich on July 9, 2015 resulted in Mr. Davidovich owning 60.2% of the Company, at that time. We therefore believe it highly likely that this transaction, more fully described in Note 7, "Stockholders' Equity," will be viewed by the U.S. Internal Revenue Service as a change of ownership as defined by Section 382 of the Internal Revenue Code. Consequently, our ability to utilize $124,662,000 of U.S. federal net operating loss carryforwards, $3,642,000 of U.S. tax credit carry forwards, $114,094,000 of state net operating loss carryforwards, and $336,000 of state tax credit carryforwards, all of which occurred prior to July 9, 2015, are limited. As such, a significant portion of these carryforwards will likely expire before they can be utilized, even if the Company is able to generate taxable income that, except for this transaction, would have been sufficient to fully utilize these carryforwards.

The Company files U.S. federal tax returns, along with various state and foreign income tax returns. All federal, state and foreign tax returns for the years ended December 31, 2014, 2013 and 2012 are still open for examination.

The following presents a roll-forward of the unrecognized tax benefits and the associated interest and penalties:

	Unrecognized Tax Benefits	Interest and Penalties
Balance at January 1, 2014	$445,000	$—
Prior year tax position	—	—
Current year tax position	—	—
Deferred tax position	8,000	—
Settlements with tax authorities	—	—
Expiration of the statute of limitations	—	—
Balance at December 31, 2014	453,000	—
Prior year tax position	—	—
Current year tax position	—	—
Deferred tax position	15,000	—
Settlements with tax authorities	—	—
Expiration of the statute of limitations	—	—
Balance at December 31, 2015	$468,000	$—

CBLI received New York State incentive tax credit refunds of $119,200, and $0 during 2015, and 2014, respectively. These refundable tax credits were based on the Company's research and development activities, real estate tax payments, employment levels and equipment purchases. Since there is no state tax liability or refund of prior year tax payments, these refundable tax credits were recorded against operating expenses in the year of receipt, instead of being recorded as an income tax benefit.

10. Employee Benefit Plan

CBLI maintains an active defined contribution retirement plan for its employees, referred to herein as the Benefit Plan. All employees satisfying certain service requirements are eligible to participate in the Benefit Plan. The Company makes matching cash contributions each payroll period, up to 4% of employees' salaries. The Company's expense relating to the Benefit Plan was $76,668, and $79,737 for the years ended December 31, 2015, and 2014, respectively.

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11. Commitments and Contingencies

The Company has entered into various agreements with third parties and certain related parties in connection with the research and development activities of its existing product candidates as well as discovery efforts on potential new product candidates. These agreements include fixed obligations to sponsor research and development activities, minimum royalty payments for licensed patents and additional amounts that may be required upon the achievement of scientific, regulatory and commercial milestones, including milestones such as the submission of an IND to the FDA and the first commercial sale of the Company's products in various countries. As of December 31, 2015 the Company is uncertain as to whether any of these contingent events will become realized. There were no milestone payments or royalties on net sales accrued for any of these agreements as of December 31, 2015 and 2014 as none were due.

From time-to-time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues for liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. For all periods presented, the Company was not a party to any pending material litigation or other material legal proceedings.

The Company has entered into agreements with substantially all of our employees who, if terminated by the Company without cause as described in these agreements, would be entitled to severance pay.

As of December 31, 2015, the Company had unconditional purchase obligations totaling $977,860 for goods and services, substantially all of which the Company anticipates to incur during 2016.

Capital Lease

In December 2011, the Company entered into a capital lease for scientific equipment in the amount of $304,673. The terms of the lease required an upfront payment of $82,983 and monthly payments of $7,616 for 36 months once the lease term began in March 2012. Principal payments under the capital lease obligation were $7,522, and $83,634; and, interest payments were $90, and $7,707 for the years ended December 31, 2015, and 2014, respectively. As of December 31, 2015, accumulated depreciation for the leased equipment was $55,423.

Operating Leases

The Company leases laboratory facilities and office facilities at various locations with expiration dates ranging from 2015 to 2019. The Company recognizes rent expense on a straight-line basis over the term of the related operating leases. For the years ended December 31, 2015, and 2014, total rent expense related to the Company's operating leases was $395,461, and $511,029, respectively. In addition, the Company has subleased some of its facilities.

As of December 31, 2015, future minimum payments under operating leases are as follows:

2016	$372,420
2017	365,565
2018	376,532
2019	191,048
2020	—
Total minimum lease payments	$1,305,565

Item 9: Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A: Controls and Procedures

Effectiveness of Disclosure

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), as of December 31, 2015. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the

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evaluation of our disclosure controls and procedures as of December 31, 2015, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective to assure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the periods specified in the SEC's rules and forms, and (2) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

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

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during our fourth fiscal quarter ended December 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B: Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Management and Corporate Governance Matters" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our Proxy Statement for the 2016 Annual Meeting of Stockholders.

Item 11. Executive Compensation

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Executive Officer and Director Compensation," and "Management and Corporate Governance" in our Proxy Statement for the 2016 Annual Meeting of Stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in our Proxy Statement for the 2016 Annual Meeting of Stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Certain Relationships and Related Person Transactions" and "Management and Corporate Governance" in our Proxy Statement for the 2016 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Independent Registered Public Accounting Firm" in our Proxy Statement for the 2016 Annual Meeting of Stockholders.

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PART IV

Item 15. Exhibits, Financial Statement Schedules

The following documents are filed as part of this report:

(1) Financial Statements, included in Part II, Item 8. “Financial Statements and Supplementary Data”:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2015 and 2014

Consolidated Statements of Operations for the years ended December 31, 2015 and 2014

Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2015 and 2014

Consolidated Statements of Cash Flows for the years ended December 31, 2015 and 2014

Consolidated Statement of Stockholders’ Equity as of December 31, 2015 and 2014

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules:

None.

(3) Index to Exhibits: The exhibits listed in the following Exhibit Index are filed with this report or, as noted, incorporated by reference here.

Exhibit No.	Identification of Exhibit
3.1	Restated Certificate of Incorporation filed with the Secretary of State of Delaware on March 18, 2010 (Incorporated by reference to Exhibit 3.1 to Form 10-K for the year ended December 31, 2009, filed on March 22, 2010).
3.2	Certificate of Amendment to the Restated Certificate of Incorporation, filed with the Secretary of State of Delaware on June 20, 2013 (Incorporated by reference to Exhibit 3.1 to Form 10-Q for the period ended June 30, 2013, filed on August 9, 2013).
3.3	Certificate of Amendment of Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Form 8-K filed on January 27, 2015).
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on February 9, 2015).
3.5	Certificate of Amendment of Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 to Form 8-K filed on February 9, 2015).
3.6	Second Amended and Restated By-Laws (Incorporated by reference to Exhibit 3.1 to Form 8-K filed on December 5, 2007).
3.7	Amendment to Second Amended and Restated By-Laws of Cleveland BioLabs, Inc. (Incorporated by reference to Exhibit 3.1 to Form 8-K filed on May 18, 2015).
4.0	Form of Common Stock Purchase Warrant (Series D Transaction) (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on March 30, 2009).
4.1	Form of Common Stock Purchase Warrant (Private Placement closed on March 2, 2010) (Incorporated by reference to Exhibit 4.1 to Form 8-K/A filed on February 26, 2010).
4.2	Form of Series F Warrants (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on June 21, 2011).
4.3	Form of Warrant Agreement by and between Cleveland BioLabs, Inc. and Continental Stock Transfer & Trust Company (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on October 22, 2012).
4.4	Warrant Agreement, dated September 30, 2013, between Cleveland BioLabs, Inc. and Hercules Technology II, L.P. (Incorporated by reference to Exhibit 4.2 to Form 10-Q for the period ended September 30, 2013, filed on November 8, 2013).

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Exhibit No.	Identification of Exhibit
4.5.1	Form of Series A Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on January 15, 2014).
4.5.2	Amendment to Series A Common Stock Purchase Warrant, dated September 4, 2014, by and between Cleveland BioLabs, Inc.,Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (Incorporated by reference to Exhibit 4.1 and Exhibit 4.2 to Form 8-K filed on September 8, 2014).
4.6	Form of Series J Warrant Agreement (Incorporated by reference to Exhibit 4.1 Form 8-K filed on June 20, 2014).
4.7	Form of Series A Warrant to Purchase Common Stock, as amended to date (Incorporated by reference to Exhibit 4.2 to Form 8-K filed on February 9, 2015).
10.0	Amendment No. 1 to Securities Purchase Agreement and Series D Warrants, dated September 29, 2014, by and among Cleveland BioLabs, Inc. and the parties on the signature pages thereto (Incorporated by reference to Exhibit 10.1 Form 8-K filed on October 2, 2014).
10.1	Amendment No. 1 to Securities Purchase Agreement, dated February 25, 2010, by and among Cleveland BioLabs, Inc., and the Purchasers set forth therein (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on January 13, 2015).
10.2	Registration Rights Agreement, dated June 17, 2014, by and among Cleveland BioLabs, Inc., and the purchasers on Exhibit A thereto (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on June 20, 2014).
10.3	Securities Purchase Agreement, dated February 4, 2015, by and among Cleveland BioLabs, Inc. and the Purchasers set forth therein, as amended to date (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on February 9, 2015).
10.4	Registration Rights Agreement, dated February 4, 2015, by and among Cleveland BioLabs, Inc. and the Purchasers set forth therein (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on February 9, 2015).
10.5	Securities Purchase Agreement dated June 24, 2015 by and between Cleveland BioLabs, Inc. and David Davidovich (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 24, 2015).
10.6	Registration Rights Agreement dated June 24, 2015 by and between Cleveland BioLabs, Inc. and David Davidovich (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on June 24, 2015).
10.7	Stock Subscription Agreement, dated as of December 18, 2015, between Cleveland BioLabs, Inc. and Open Joint Stock Company “Rusnano” (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on December 24, 2015).
10.8	Stock Subscription Agreement, dated as of December 18, 2015, between Panacela Labs, Inc. and Cleveland BioLabs, Inc. (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on December 24, 2015).
10.9	Stock Subscription Agreement, dated as of December 18, 2015, between Panacela Labs, Inc. and Open Joint Stock Company “Rusnano” (Incorporated by reference to Exhibit 10.3 to Form 8-K filed on December 24, 2015).
10.10	Acknowledgement Agreement, dated as of December 18, 2015, among Cleveland BioLabs, Inc., Panacela Labs, Inc. and Open Joint Stock Company “Rusnano” (Incorporated by reference to Exhibit 10.4 to Form 8-K filed on December 24, 2015).
10.11	Exclusive License Agreement by and between The Cleveland Clinic Foundation and Cleveland BioLabs, Inc., effective as of July 1, 2004 (Incorporated by reference to Exhibit 10.8 to Amendment No. 1 to Registration Statement on Form SB-2 filed on April 25, 2006 (File No. 333-131918)).
10.12†	Second Amendment to Exclusive License Agreement, dated September 22, 2011, by and between The Cleveland Clinic Foundation and the registrant (Incorporated by reference to Exhibit 10.3 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).†
10.13	

	Library Access Agreement by and between ChemBridge Corporation and Cleveland BioLabs, Inc., effective as of April 27, 2004 (Incorporated by reference to Exhibit 10.5 to Amendment No. 1 to Registration Statement on Form SB-2 filed on April 25, 2006 (File No. 333-131918)).
10.14	Restricted Stock and Investor Rights Agreement between Cleveland BioLabs, Inc. and ChemBridge Corporation, dated as of April 27, 2004 (Incorporated by reference to Exhibit 10.6 to Amendment No. 1 to Registration Statement on Form SB-2 filed on April 25, 2006 (File No. 333-131918)).
10.15	Process Development and Manufacturing Agreement between Cleveland BioLabs, Inc. and SynCo Bio Partners B.V., effective as of August 31, 2006 (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on October 25, 2006).
Exhibit No.	Identification of Exhibit

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10.16	Sponsored Research Agreement between Cleveland BioLabs, Inc. and Roswell Park Cancer Institute Corporation, effective as of January 12, 2007 (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on January 12, 2007).
10.17	Investment Agreement, dated September 19, 2011, by and among Panacela Labs, Inc., the Registrant and Open Joint Stock Company Rusnano (Incorporated by reference to Exhibit 10.1 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).
10.18†	Exclusive License and Option Agreement, dated September 23, 2011, by and between Children's Cancer Institute Australia for Medical Research and Panacela Labs, Inc (Incorporated by reference to Exhibit 10.2 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).†
10.19†	Exclusive License and Option Agreement, dated September 23, 2011, by and between Health Research, Inc., Roswell Park Institute Division, Roswell Park Cancer Institute Corporation, and Panacela Labs, Inc (Incorporated by reference to Exhibit 10.4 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).†
10.20	Amended and Restated Exclusive Sublicense Agreement, dated September 23, 2011, by and between the registrant and Panacela Labs, Inc. (Incorporated by reference to Exhibit 10.5 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).
10.21	Assignment Agreement, dated September 23, 2011, by and between Panacela Labs, Inc. and the registrant (Incorporated by reference to Exhibit 10.7 to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).
10.22	Master Services Agreement, dated October 14, 2014, between Buffalo BioLabs, LLC and Cleveland BioLabs, Inc. (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on October 18, 2013).
10.23	Cooperative Research and Development Agreement by and between the Uniformed Services University of the Health Sciences, the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., the Cleveland Clinic Foundation, and Cleveland BioLabs, Inc., dated as of August 1, 2004 (Incorporated by reference to Exhibit 10.9 to Form 10-Q for the period ended September 30, 2010, filed on November 15, 2010).
10.24	Award/Contract W81XWH-15-C-0101 dated September 1, 2015 issued by USA Med Research ACQ Activity (Incorporated by reference to Exhibit 10.4 to Form 10-Q filed on November 9, 2015).
10.25	Award/Contract W81XWH-15-1-0570 dated September 30, 2015 by issued by USA Med Research ACQ Activity (Incorporated by reference to Exhibit 10.5 to Form 10-Q filed on November 9, 2015).
10.26	Master Purchase Agreement dated April 29, 2015 by and among Cleveland BioLabs, Inc., Mikhail Mogutov and Incuron LLC (Incorporated by reference to Exhibit 2.1 to Form 8-K filed on May 4, 2015).
10.27	Option Agreement dated April 29, 2015 by and between Cleveland BioLabs, Inc. and Mikhail Mogutov (Incorporated by reference to Exhibit 2.2 to Form 8-K filed on May 4, 2015).
10.28	Royalty Agreement dated April 29, 2015 by and between Cleveland BioLabs, Inc. and Incuron LLC (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 4, 2015).
10.29*	Employment Agreement, dated August 4, 2011, between the Company and C. Neil Lyons (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on August 4, 2011).
10.30*	Employment Agreement dated July 9, 2015 by and between Cleveland BioLabs, Inc. and Langdon Miller (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on July 10, 2015).
10.31*	Employment Agreement dated July 9, 2015 by and between Cleveland BioLabs, Inc. and Andrei Gudkov (Incorporated by reference to Exhibit 10.3 to Form 8-K filed on July 10, 2015).
10.32*	Employment Agreement dated July 9, 2015 by and between Cleveland BioLabs, Inc. and Yakov Kogan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on July 10, 2015).
10.33*	Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Appendix A to Proxy Statement on Schedule 14A filed on April 1, 2008).
10.34*	First Amendment to Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Exhibit 99.1 to Form 8-K filed on June 9, 2010).

10.35*	Second Amendment to Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Exhibit 99.1 to Form 8-K filed on June 15, 2012).
10.36*	Third Amendment to Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on April 17, 2015).
10.37*	Form of Stock Award Grant Agreement (Incorporated by reference to Exhibit 99.2 to Form 8-K filed on June 15, 2012).
10.38*	Form of Non-Qualified Stock Option Agreement (Incorporated by reference to Exhibit 99.3 to Form 8-K filed on June 15, 2012).
Exhibit No.	Identification of Exhibit

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10.39*	Cleveland Biolabs, Inc. 2013 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 20, 2013).
10.40*	First Amendment to Cleveland BioLabs, Inc. Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on April 17, 2015).
10.41*	2012 Long-term Executive Compensation Plan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 15, 2012).
10.42*	Severance Benefit Plan (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 13, 2014).
21.1	Subsidiaries
23.1	Consent of Meaden & Moore, Ltd.
31.1	Rule 13a-14(a)/15d-14(a) Certification of Yakov Kogan
31.2	Rule 13a-14(a)/15d-14(a) Certification of C. Neil Lyons
32.1	Section 1350 Certification.
101.1	The following financial statements and supplementary data are filed as a part of this annual report on Form 10-K for the quarter and year ended December 31, 2015: (i) Consolidated Balance Sheets at December 31, 2015 and 2014; (ii) Consolidated Statements of Operations for years ended December 31, 2015 and 2014; (iii) Consolidated Statements of Stockholders' Equity for years ended December 31, 2015 and 2014; (iv) Consolidated Statements of Cash Flows for years ended December 31, 2015 and 2014; and (v) Notes to Consolidated Financial Statements as blocks of text.

† Confidential treatment has been requested from the Securities and Exchange Commission as to certain portions of this document.

* Indicates management contract or compensatory plan required to be filed as an Exhibit.

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SIGNATURES

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

CLEVELAND BIOLABS, INC.

Dated: February 23, 2016

By: /s/ YAKOV KOGAN
Yakov Kogan
Chief Executive Officer

CLEVELAND BIOLABS, INC.

Dated: February 23, 2016

By: /s/ C. NEIL LYONS
C. Neil Lyons
Chief Financial Officer

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

Signature	Title	Date
/S/ Yakov Kogan Yakov Kogan	Chief Executive Officer and Director (principal executive officer)	February 23, 2016
/S/ C. Neil Lyons C. Neil Lyons	Chief Financial Officer (principal financial and accounting officer)	February 23, 2016
/S/ Richard McGowan Richard McGowan	Director	February 23, 2016
/S/ James J. Antal James J. Antal	Director	February 23, 2016
/S/ Anthony Principi Anthony Principi	Director	February 23, 2016
/S/ Randy Saluck Randy Saluck	Director	February 23, 2016
/S/ Andrei Gudkov Andrei Gudkov	Director	February 23, 2016
/S/ Anna Evdokimova Anna Evdokimova	Director	February 23, 2016