CLEVELAND BIOLABS INC
Form 10-K
March 18, 2013

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, 2012

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[x] No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
[ ] Yes [x] No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. [x] Yes [ ] No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). [x] Yes [ ] No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

| | |
|---|---|
| Large accelerated filer [ ] | Accelerated filer [x] |
| Non-accelerated filer [ ] | Smaller reporting company [ ] |

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates, computed by reference to the price at which the common equity was last sold or the average bid and asked price of such common equity, as of the last business day of the registrant’s most recently completed second fiscal quarter was $50,916,786. There were 44,837,315 shares of common stock outstanding as of March 15, 2013.

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant’s 2013 Annual Meeting of Stockholders is incorporated by reference in Part III to the extent described therein.

Cleveland BioLabs, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2012

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

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

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

PART I

Item 1. Business

GENERAL OVERVIEW

We are a clinical-stage biotechnology company with a focus on oncology drug development. Our lead drug Entolimod™ (previously known as CBLB502) is being developed for dual indications under (a) the U.S. Food & Drug Administration's ("FDA's") Animal Efficacy Rule (21 CFR §314.610 drugs; §601.91 biologics), commonly referred to as the "Animal Rule", as a radiation countermeasure, and (b) under the FDA's traditional drug approval pathway as a targeted cancer treatment. CBLI is a Delaware corporation and was founded in 2003. Since our inception, we have pursued the research, development and commercialization of products that have the potential to treat cancer, reduce death from total body irradiation, and counteract the genotoxic effects of radio- and chemotherapies for oncology patients. Presently, nine product candidates are under development directly by our wholly-owned subsidiary, BioLab 612, LLC ("BioLab 612"), and our majority-owned subsidiaries, Incuron, LLC ("Incuron") and Panacela Labs, Inc. ("Panacela"). An illustration of our product pipeline follows:

| Product Candidate | Indication | Description | Development Stage |
|---|---|---|---|
| Entolimod™* | Radiation Countermeasure | Radioprotectant and mitigating agent targeting increased survival from lethal exposure | Pivotal stage |
| Entolimod™ | Targeted Cancer Treatment | TLR5 agonist inducing innate immune response to targeted tumor types and liver metastases | Phase 1 |
| CBLB612 | Neutropenia/HSCT** | Hematopoietic stem cell inducer and mobilizer to peripheral blood | Pre-clinical |
| Incuron Product Candidates | | | |
| CBL0102 | Hepatocellular Carcinoma | Quinacrine | Phase 1 |
| CBL0137 | Cancer Treatment | Small molecule targeting FACT*** | Phase 1 |
| Panacela Product Candidates | | | |
| Revercom | Cancer Treatment | Chemotherapy adjuvant | Pre-clinical |
| Mobilan | Cancer Treatment | Immunotherapy | Pre-clinical |
| Arkil | Targeted Cancer Treatment | Inhibitor of Androgen receptor | Pre-clinical |
| Antimycon | Targeted Cancer Treatment | Inhibitor of Myc oncogene | Pre-clinical |
| Xenomycins | Anti-Infective | Small molecules targeting FACT*** | Pre-clinical |

* We currently intend to rely on the Animal Rule in seeking marketing approval for this indication. Under the Animal Rule, if human efficacy trials are not ethical or feasible, the FDA can approve drugs or biologics used to treat or prevent serious or life threatening conditions caused by exposure to lethal or permanently disabling toxic chemical, biological, radiological, or nuclear substances based on human clinical data demonstrating safety and evidence of efficacy from appropriate animal studies and any additional supporting data. For more information about the Animal Rule, see "Government Regulation — Animal Rule."
** HSCT means hematopoietic stem cell transplant

*** FACT means chromatin remodeling complex named Facilitates Chromatin Transcription

We have successfully negotiated contracts and grants with the U.S. government totaling $85.9 million for the development and procurement of our lead compound, Entolimod™, for biodefense application as a radiation countermeasure. Of this $85.9 million, we have received development funding of approximately $44.2 million, of which we have recognized approximately $42.3 million in revenue through December 31, 2012. As of December 31, 2012, the federal government has the potential to fund an additional $41.7 million under our existing contracts and grants, including a $30 million procurement option that becomes exercisable upon FDA approval. We have performed extensive safety and efficacy studies in non-human primates ("NHPs") and rodents and have evaluated Entolimod™'s safety profile in 150 healthy human volunteers. We have submitted a proposal to the Biomedical Advanced Research and Development Agency ("BARDA") of the Department of Health and Human Services ("HHS") to fund the remaining work necessary to complete a dossier of information needed to submit a Biologic License Application, or BLA, to the FDA for marketing approval. This remaining work includes: animal efficacy trials, human safety trials and biostatistical data needed to confirm proper dose conversion between NHPs and humans.

A Phase 1 trial evaluating the safety and pharmacokinetic and pharmacodynamic profile of Entolimod in refractory patients with advanced cancers, many of whom evidence liver metastases is underway at Roswell Park Cancer Institute ("RPCI"). Evaluation of the effect that Entolimod has on metastasized tumor lesions in the liver is a secondary endpoint.

CBLB612, an inducer and mobilizer of hematopoietic stem cells, or HSCs, is also actively being developed and is currently undergoing formal pre-clinical safety assessment and cGMP-manufacturing development. In mid-2012, we received a contract valued at 139 million rubles (approximately $4.6 million) from the Ministry of Industry and Trade of the Russian Federation for development of CBLB612.

In December 2009, we entered into a Participation Agreement with BioProcess Capital Partners, LLC ("BCP"), a Russian Federation venture capital fund, to create a joint venture, Incuron, to develop our Curaxin line of anti-cancer product candidates: specifically CBL0102, a nonproprietary molecule originally used to combat the effects of malaria, which we identified as having cancer treatment properties; and CBL0137, a new, proprietary molecule optimized to better target similar mechanisms of action in combating cancer. Incuron is our majority owned subsidiary, with approximately 59.2% of its equity interests held by us at December 31, 2012. Our Curaxin research is supported by a 150 million ruble (approximately $4.9 million) grant from the Russian Federation Government initiative "Skolkovo", which was awarded in late 2011.

CBL0102 is currently undergoing a Phase 1 safety and tolerability study in patients with liver metastases of solid tumors of epithelial origin, or primary advanced hepatic carcinoma for which standard therapy has failed or does not exist in the Russian Federation.

In October 2012, dosing was started with the oral formulation of CBL0137 in a multi-center, single agent, dose escalation study in subjects with advanced solid tumors that are resistant or refractory to standard of care treatment in the Russian Federation.

In September 2011, we entered into an Investment Agreement with Open Joint Stock Company "Rusnano", or Rusnano, a multi-billion Russian Federation fund, governing the creation of Panacela, a joint venture company formed to develop five separate product candidates, all of which were in pre-clinical development at the end of 2012. Panacela is a majority-owned subsidiary, with 54.6% of its shares held by us at December 31, 2012. In late 2012, Panacela received a contract valued at 146 million rubles (approximately $4.8 million) from the Ministry of Industry and Trade of the Russian Federation for the development of a family of anti-infective compounds known as Xenomycins.

Additionally, we leverage close development relationships with RPCI, Cleveland Clinic Foundation ("CCF") and Children's Cancer Institute Australia ("CCIA"). Together, our team of legal entities, financial partners and other collaborators engage in the collective development efforts necessary to advance all of our product candidates towards marketing approval and commercialization.

Further information regarding our revenue and research and development expenditure for each of the last three fiscal years are presented under the headings "Revenue" and "Research and Development Expenses" in Part II, Item 7 of this Form 10-K, and incorporated by reference herein.

Our common stock is listed on the NASDAQ Capital Market under the symbol "CBLI."

MARKETS

Biodefense

Awareness of the need for biodefense countermeasures grew dramatically following the September 11, 2001 terrorist attacks and the subsequent use of anthrax in a biological attack within the United States. Terrorist activities have not abated in the intervening dozen years and the possibility of a chemical, biological, radiation and nuclear ("CBRN") attack continues to represent a global threat.

The U.S. government provides funding to conduct biodefense research and support the development of drugs and vaccines as medical countermeasures ("MCM") to mitigate a potential terrorist event. Additionally, the U.S. government has appropriated funds to procure biodefense countermeasures that are critical to national preparedness and response.

The U.S. government makes substantial development funding available, primarily through two federal agencies and their subdivisions:

- Department of Defense ("DoD"):
  - Joint Program Executive Office ("JPEO"): Chemical Biological Medical Systems ("CBMS") and the Joint Vaccine Acquisition Program ("JVAP")
  - The Defense Threat Reduction Agency ("DTRA")

- Department of Health and Human Services ("HHS"):
  - National Institutes of Health ("NIH")/National Institutes of Allergy and Infectious Disease Health ("NIAID")
  - Biomedical Advanced Research and Development Agency ("BARDA")

The Pandemic and All-Hazards Preparedness Act ("PAHPA"), originally enacted in 2006, established BARDA as the primary agency within HHS responsible for awarding advanced development and procurement contracts for biomedical countermeasures against chemical, biological, radiological and nuclear threats and emerging infectious diseases. NIH/NIAID is responsible for basic research and early stage development of biomedical products, which includes drugs such as Entolimod. Annual congressional appropriations provide funding to BARDA and NIH/NIAID for these activities. DoD funding authority is separate from PAHPA and is through Congressional appropriation.

Both HHS and DoD procure and maintain medical stockpiles to respond to bioterrorist and emerging infectious disease outbreaks. The Project BioShield Act ("Project BioShield") was enacted in 2004 with $5.6 billion to procure medical countermeasures against biological, chemical, radiological and nuclear attacks over ten years. HHS procures countermeasures under Project Bioshield for the Strategic National Stockpile, a national repository of medical assets and countermeasures designed to provide federal, state and local public health agencies with medical supplies needed to treat and protect those affected by terrorist attacks, natural disasters, industrial accidents and other public health emergencies. Since 2005, HHS has procured more than $2.6 billion of medical countermeasures for the Strategic National Stockpile, mostly for anthrax, smallpox and other infectious diseases.

HHS also provides significant funding for civilian biodefense programs, which includes funding to states and localities through various programs to enhance their emergency preparedness activities and to better enable them to respond to large-scale, natural, or manmade public health emergencies, such as acts of bioterrorism or nuclear or radiological accidents.

On March 13, 2013, President Obama signed a bill to reauthorize PAHPA into law. This legislation is considered important because the authorization for BARDA grant and contract programs and the monies for Project BioShield expire on September 30, 2013. This legislation re-authorizes PAHPA and Project BioShield, however both initiatives require funding through Congressional appropriations. There is a risk to both CBLI and the MCM market generally if funding is not included in an appropriations bill or continued resolution by October 1, 2013 or if insufficient funds are appropriated.

Biodefense countermeasures are developed in a context that is a major departure from the traditional biotechnology business model employed for drugs and vaccines:

- Most biodefense countermeasures cannot ethically be studied for efficacy in humans. As a result, the FDA published a possible development route, termed the Animal Rule, whereby efficacy is determined in animal models under conditions in which the results are predictive of the human response, with safety trials conducted in healthy human subjects (see "Government Regulation –Animal Rule"); and
- Under specific circumstances, a state of emergency may be determined by the Secretary of Health and Human Services enabling procurement of countermeasures for the Strategic National Stockpile under an Emergency Use Authorization prior to FDA approval.

In addition to the U.S. government, we believe there are other potential markets for the sale of biodefense countermeasures, which include:

- State and local governments;
- Allied foreign governments, including both defense and public health agencies;
- Non-governmental organizations and multinational companies, transportation and security companies;
- Healthcare providers, hospitals and clinics; and

- Nuclear power facilities.

Medical

According to the National Cancer Institute, cancer is the leading cause of death in developed countries and the second leading cause of death in developing countries. Deaths from cancer worldwide are projected to continue rising, with an estimated 12 million deaths in 2030.

In 2011, estimated annual sales of all cancer drugs worldwide totaled approximately $110 billion. In recent years targeted therapies have become the preferred and most desired cancer treatment category. Improved patient outcomes combined with significant market value and improved reimbursement, are the primary reasons for interest in this oncology category. In 2011, this category represented over $60 billion in sales, or approximately 60% of the global estimated cancer market. Chemotherapy is the second largest and second fastest growing drug category for oncology, with a market size of approximately $20 billion worldwide, as of 2011.

Stem cell mobilization is also a significant therapeutic category within oncology. Stem cell mobilization is mostly represented by granulocyte colony stimulating factor (“G-CSF”) products for treatment of cancer patients with neutropenia (a compromised immune system).

STRATEGIES AND OBJECTIVES

Our strategy is to leverage our resources to achieve commercialization of our most advanced product candidate, Entolimod, as a radiation countermeasure, while we establish our position as a leading developer of a broad range of oncology therapeutics. Key elements of our strategy include:

- Commercializing Entolimod as a radiation countermeasure. Our most advanced drug candidate, Entolimod, offers the potential to improve survival from total body irradiation and is being developed under the Animal Rule for this indication. Moreover, because Entolimod demonstrates the potential to address an unmet medical need and is intended to treat a serious or life-threatening condition, Entolimod has been granted Fast Track and Orphan Drug status by the FDA. Due to the Fast Track designation of Entolimod, we are eligible to engage in early and frequent communications with the FDA and our BLA filing will be eligible for priority review, which could result in an abbreviated review time of six months (see "Government Regulation – Fast Track Designation"). Due to the Orphan Drug designation, we may be eligible for preferential tax treatment and a period of marketing exclusivity (see "Government Regulation – Orphan Drug Designation").

- Utilizing U.S and other government initiatives to fund development and target initial markets. Through a multi-targeted, international approach we have leveraged governmental funding sources to further our development activities. We have successfully negotiated contracts that have provided $44.2 million in development funding from the U.S. government, with the potential to provide an additional $41.7 million, including a $30 million procurement option for Entolimod as a radiation countermeasure. And, in October 2012 we submitted a proposal to BARDA to fund the remaining activities necessary to complete the dossier of data needed for BLA submission. For more information see "Products in Development – Protectans – Entolimod – Government Funding." In addition, we received a $4.9 million award for development of Curaxins from the Russian government through a Skolkovo Foundation grant, as well as awards of $4.6 million for development of CBLB612 and $4.8 million for development of Xenomycins from the Russian Ministry of Industry and Trade, collectively referred to as "the Russian Grants." A table summarizing our U.S. and Russian grants and contracts is presented in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations.

- Creating a corporate structure that enables us to fund and develop multiple product candidates simultaneously and cost-effectively. CBLI's scientists possess many of the core competencies needed to further development of our pipeline candidates. As such, CBLI's expertise is a compelling value-added proposition for our subsidiaries. Each subsidiary, using its respective funding sources, maintains a separate management team to guide development and contract needed services from CBLI, clinical/research sites and others. CBLI's executive management is able to remain focused on the development of its core and wholly-owned product candidates and leverage key skill sets across the entire platform including a coordinated world-wide business development effort and key scientific skills. For more information on our development efforts with our subsidiaries see "Our Joint Venture Partnerships."

- Capitalizing on our knowledge and connections in the Russian Federation to expedite clinical data and, licensing of our pipeline compounds. Our familiarity with the Russian Federation enables us to capitalize on four key efficiencies: (1) access to private funding as evidenced by our financial partners in Incuron and Panacela, (2) access to public economic development funds targeted for biomedical research and product development for the Russian Federation as evidenced by the award of approximately $14.3 million in three separate grants, (3) access to patients through eight currently active clinical sites in the Russian Federation. Of note, there is less competition for eligible patients in the Russian Federation as compared with the U.S. and Europe. Consequently we can expeditiously enroll patients. And (4) Phase 3 studies in the Russian Federation are generally smaller and significantly less complex than Phase 3 studies in the U.S. and Europe, which provide for a more expedited drug application process. Finally, we are leveraging two drug development strategies. For CBL0137 we are in parallel development in both the Russian Federation and the U.S. In the Russian Federation we are using an oral delivery formulation, while in the US we are using an intravenous delivery. With our Panacela compounds we intend to develop proof-of-concept

data more expeditiously, primarily given the less competition for patients, after which we intend to commence more targeted development in the U.S.

- Pursuing collaborations with large pharmaceutical and biopharmaceutical partners. We are actively marketing our entire pipeline of drug candidates with large, established pharmaceutical companies. Drug development collaborations can provide attractive sources of significant capital and drug development expertise. Oncology collaborations represented 24% of total collaborations in the Pharma/biotech sector in 2012.

- Leveraging our relationship with leading research and clinical development institutions. We are able to leverage our in-house R&D capabilities as well as those of RPCI, CCF and CCIA through our collaborative relationships to further the research and development of our current product candidates, to determine new indications for our current products and to potentially develop new product candidates. For more information on our collaborative relationships see "Intellectual Property – License Agreements and Collaborations."

Founding Technological Principle

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 (temporary loss of blood flow), such as cerebral stroke, heart attack and acute renal failure. In addition, apoptotic loss of cells of the hematopoietic ("HP") system and gastrointestinal ("GI") tract is largely responsible for both the acute lethality of high dose radiation exposure and the adverse side effects of radio- and chemotherapies. 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 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 categorized as Protectans; and
(b) Reactivation of apoptosis in tumor cells to eliminate cancer using compounds categorized as Curaxins.

Protectans, including Entolimod and CBLB612, are engineered derivatives of natural apoptosis-suppressing factors produced by microbes that are part of the human microflora. The activity of these microbial products and the related Protectans derives from their ability to bind to and stimulate a particular class of cell surface receptors called Toll-like receptors ("TLRs"). TLRs are major components of the innate immune system that evolved to provide the body's first response to the invasion of various pathogens. Signaling through these TLRs leads to activation of the pro-survival NF-kB pathway. Activation of the NF-kB pathway drives expression of numerous genes, including those encoding inhibitors of apoptosis, scavengers of reactive oxygen species, anti-microbial proteins and cytokines. Due to differences in the cellular signaling pathways (including NF-kB) of tumor and normal cells, Protectans prevent apoptosis in normal cells, yet have no effect on the death of tumor cells, which occurs through non-apoptotic mechanisms.

The particular TLRs targeted by Entolimod and CBLB612 (TLR5 and TLR2, respectively) are expressed on a unique subset of cell types and mobilize unique downstream pathways. This leads to biological effects that are highly desirable from a therapeutic standpoint. Importantly, stimulation of these representatives of the TLR class of receptors is not accompanied by potentially dangerous acute inflammatory responses that are known to be induced by some other TLR and NF-kB activators. Although initially conceived of as suppressors of apoptosis, Protectans have exhibited the potential to act as multi-purpose therapeutic agents with a broader, multi-faceted mechanism of action

involving modulation of immune response and multiple mechanisms of tissue regeneration. Thus, we believe Protectans may have a wide range of potential applications including reduction of the lethality of high dose radiation exposure (biodefense), amelioration of the negative side effects of radiation and chemotherapy, prevention of ischemia-induced tissue damage, stimulation of proliferation and mobilization of hematopoietic stem cells and, notably, induction of anti-tumor immune responses.

Curaxins, including CBL0102 and CBL0137, are small molecules that have no effect on normal cells, yet induce apoptosis in a broad range of human tumor cells and sensitize tumor cells to the apoptosis-inducing effects of other cancer treatments. Curaxins have been shown to have a mechanism of action involving modulation of the FACT (facilitates chromatin transcription) complex. Curaxins sequester FACT such that it is not able to perform its normal function in opening up chromatin structure to allow transcription of certain genes.

Notably, the gene expression programs that are blocked in Curaxin-treated cells include several that are known to be critical for tumor cell survival (e.g., HIF-1a-, HSF1- and NF-kB-regulated genes) (Gasparian, et al., 2011. Curaxins: anti-cancer compounds that simultaneously suppress NF-kB and activate p53 by targeting FACT. Sci Transl Med. PubMed PMID: 21832239). The multi-targeted nature of Curaxins suggests that they may be useful for treatment of many different types of cancer with greater efficacy and substantially lower risk of development of drug resistance. In addition, since we believe that Curaxins will not cause DNA damage, we anticipate that Curaxins may be much safer than many conventional chemotherapeutics.

Therefore, our original paradigm surrounding therapeutic modulation of apoptosis resulted in identification of lead compounds for both tissue protection and anti-cancer treatment. However, we now know the mechanisms of action of these compounds actually extend beyond regulation of apoptosis per se, thus presenting potential applications outside of what was originally envisioned. Our basic science research efforts focus in part on discovering these potential applications. We currently have a number of anti-cancer and anti-infective compounds with diverse mechanisms of action in different early stages of development.

OUR JOINT VENTURE PARTNERSHIPS

Incuron

In December 2009, we entered into our Incuron joint venture with BCP to develop our Curaxin compounds for treatment of oncological diseases. According to the terms of the agreement, we transferred the aforementioned rights of Curaxin molecules to the new joint venture and BCP will contribute an aggregate of 549,497,000 Russian rubles (approximately $17.7 million based on the current exchange rate) to support development of the compounds. As of December 31, 2012, we received from BCP payments of 369,570,000 Russian rubles (approximately $11.7 million). BCP will make the balance of its contribution of 179,927,000 Russian rubles (approximately $5.9 million) upon the achievement of predetermined development milestones. As of December 31, 2012, we had a 59.2% ownership interest in Incuron. After remaining contractual investments, we may ultimately own less than 50.1% of the membership interest of Incuron, but will retain the right to appoint a majority of the members of its board of directors.

Panacela

In October 2011, we entered into our Panacela joint venture with Rusnano to carry out a complete cycle of development, research, performance of clinical trials, production and sales of a line of pharmaceutical drugs for the treatment of oncological, infectious or other diseases. We invested $3.0 million in Panacela preferred shares and warrants, and, together with certain third-party owners, assigned and/or provided exclusive licenses, as applicable, to Panacela in respect of certain intellectual property relating to the Panacela product candidates in exchange for Panacela common shares. Rusnano invested $9.0 million in Panacela preferred shares and warrants, with additional amounts of up to $17.0 million to be provided by Rusnano upon the achievement of certain development milestones as set forth in the Investment Agreement. As of December 31, 2012, we have an ownership stake of approximately 54.6% in Panacela. If Rusnano invests additional amounts upon the achievement of certain development milestones, our ownership stake will be diluted. However, we have an option to maintain an ownership stake of approximately 51% which, if we choose to exercise, would require additional investment in Panacela.

PRODUCTS IN DEVELOPMENT

Protectans

CBLI’s Protectan technology evolved from our recognition of a strong connection between a variety of acute pathologies and apoptosis (programmed cell death). Apoptosis was found to be the primary cause of massive cell loss in sensitive tissues following exposure of mammals to severe stresses such as radiation, chemotherapeutic drugs or ischemia. We proposed to develop pharmacological agents capable of temporarily and reversibly suppressing apoptotic cell death under such stress conditions in order to reduce tissue damage and improve organism survival. Since tumor cells commonly lose apoptotic mechanisms as part of their progression towards unconstrained growth, such agents, including Entolimod, would be expected to selectively protect only normal cells and, therefore, be useful to prevent side effects of cancer therapies without altering their anti-tumor efficacy.

In a search for apoptosis suppressors, we took advantage of natural products of microorganisms that are part of the human microflora. Having coexisted with humans in symbiotic relationships for millions of years, these

microorganisms have developed mechanisms to suppress apoptosis of their host cells as part of their survival strategy. By screening factors produced by various representatives of the human microflora, we identified a series of compounds that were capable of inhibiting apoptosis by activating NF-kB pathway, a powerful anti-apoptotic/pro-survival signal transduction pathway that also controls all aspects of immunity. Our subsequent R&D efforts have been predominantly focused on two drug candidates (which we refer to as Protectans): Entolimod and CBLB612. These compounds are injectable biologics that act via stimulation of specific mammalian cell surface receptors that regulate innate immunity, Toll-like receptors 5 and 2 (TLR5 and TLR2), respectively.

TLRs act as molecular sensors to detect the presence of pathogens and induce an appropriate innate immune response. Different TLR family members are activated by different microbial products and induce distinct downstream consequences. TLR5 is specifically activated by flagellins, members of an evolutionarily conserved family of proteins that polymerize to form the flagella of bacteria. TLR2 can be activated by a number of biological molecules, including lipopeptides that are essential components of the cell wall of mycoplasma. Therefore, Entolimod is a pharmacologically optimized derivative of the Salmonella flagellin protein and CBLB612 is a synthetic lipopeptide that mimics properties of mycoplasma products.

A shared feature of all TLRs is that upon binding of their ligand (activator or agonist), they become activated and transmit a signal into the interior of the cell that results in activation of NF-kB. Activated NF-kB triggers expression of a large number of genes encoding a variety of defense factors, such as cytokines, scavengers of reactive oxygen species, anti-apoptotic factors and anti-microbial factors. Activation of NF-kB in general, as well as activation of various TLRs in particular, has been previously explored for clinical immunological applications (e.g., improvement of vaccination). We believe that the uniqueness of our approach lies not only in our use of TLR agonists for a new indication (tissue protection), but also in our specific focus on targeting TLR5 and TLR2 which differ from other members of TLR family members in their favorable safety profiles and useful properties.

We demonstrated that Protectans are capable, within safe dose ranges, of protecting mammalian organisms from lethal doses of radiation (Singh, et al., 2012. CBLB613: a TLR 2/6 agonist, natural lipopeptide of Mycoplasma arginini, as a novel radiation countermeasure. Radiat Res. PubMed PMID: 22175300); (Shakhov, et al., 2012. Prevention and mitigation of acute radiation syndrome in mice by synthetic lipopeptide agonists of Toll-like receptor 2 (TLR2). PLoS One. PubMed PMID: 22175300); (Krivokrysenko, et al., 2012. Identification of granulocyte colony-stimulating factor and interleukin-6 as candidate biomarkers of CBLB502 efficacy as a medical radiation countermeasure. J Pharmacol Exp Ther. PubMed PMID: 22837010).

The ability of TLR5 and TLR2 (as compared to other TLRs) to stimulate powerful tissue protective effects without being prohibitively toxic (due to acute inflammation, the main challenge of using NF-kB-stimulating agents) is explained by specific molecular signaling mechanisms mediating the downstream effects of these TLRs and, even more importantly, by the pattern of expression of TLR5 and TLR2 on only certain cell types within certain tissues.

Our studies have shown that Protectans were not only found to prevent tissue damage when administered before exposure to an assault (e.g, irradiation), but they were also found to be powerful mitigators of tissue injury when administered long after assault. This mitigative capacity of Protectans involves stimulation of multiple mechanisms of tissue recovery and regeneration mediated by a broad spectrum of Protectan-induced bioactive factors (e.g., cytokines, chemokines, endogenous antibiotics and antioxidants. These properties allowed us to define additional potential applications for Protectans as strong prospective candidates for use in cancer treatment, hematopoietic stem cell amplification and mobilization and protection from ischemia-reperfusion injuries. We have filed a number of patent applications in respect of Protectans.

Entolimod™

Entolimod is an engineered derivative of the Salmonella flagellin protein that was designed to retain its specific TLR5-activating capacity while increasing its stability, reducing its immunogenicity and enabling high-yield production. Our studies have shown that Entolimod has in vivo tissue protective effects in animal models of a number of tested scenarios, including (a) protection against death following acute high-dose radiation exposure, (b) protection of healthy tissues (but not tumors) from radiation and chemotherapy in cancer treatment models, and (c) alleviation of ischemia-reperfusion-induced acute kidney injury.

We also believe that Entolimod has the potential to treat cancer, which appears to result from induction of a strong innate immune response (and, subsequently, an adaptive anti-tumor response), which is consistent with the known

roles of TLR5 and NF-kB as regulators of immune responses.

We have demonstrated that liver hepatocytes show a rapid, primary NF-kB activation response following in vivo administration of Entolimod in mice and NHPs. The response of these cells was shown to be essential for Entolimod's efficacy in protecting the HP system against radiation damage. In addition, studies showed that Entolimod protected the liver itself in several experimental models of hepatotoxicity. Therefore, we believe that protection of liver tissue under different hepatotoxic conditions is another potential application for Entolimod.

In summary, we believe that Entolimod induces a broad-reaching, multi-faceted molecular pathway (NF-kB) that impacts death/survival pathways, immune responses and tissue regenerative mechanisms in the desired directions for protection of normal cells and killing of tumor cells, and it accomplishes this in a manner that we believe is generally safe for the organism as a whole. Our success in solving the crystal structure of flagellin bound to TLR5 revealed the structural basis of Entolimod-induced TLR5 signaling (Yoon, et al., 2012. Structural Basis of TLR5-Flagellin Recognition and Signaling. Science. PubMed PMID: 22344444), which should allow future precise manipulation of the activity of Entolimod.

Entolimod's Biodefense Application: Reduction of Death from Total Body Irradiation

Acute high-dose whole body or significant partial body radiation exposure induces massive apoptosis of cells of the HP system and GI tract, which leads to Acute Radiation Syndrome ("ARS"), a fatal disease for which there are currently no FDA-approved treatments. The threat of ARS is limited to emergency/defense scenarios; however, this threat is significant given the possibility of nuclear/radiological accidents, warfare or terrorist incidents, the scale of possible exposure (number of people affected) and the current lack of approved treatments to deal with such an event. Therefore, development of medical radiation countermeasures, such as Entolimod, has benefitted from the priority placed on this need by the U.S. government and associated development funding, as outlined below. In addition, since it is not feasible or ethical to test the efficacy of Entolimod as a radiation countermeasure in humans, development of the compound for this indication is guided by the Animal Rule (see "Government Regulation – Animal Rule").

The efficacy of Entolimod as a radiation countermeasure has been primarily assessed in mice and NHPs (Rhesus macaques). These studies demonstrated that a single injection of Entolimod given either before or after lethal total body irradiation led to significant improvement in animal survival. For example, survival of NHPs was increased from 20% in the control group to 70% to 80% in Entolimod -treated groups when injections were administered between 1 and 48 hours after irradiation.

We believe that an important advantage of Entolimod, over any other radiation countermeasure known to us, is its broad spectrum of effects across doses of radiation linked to so-called HP and GI radiation sub-syndromes of ARS, which are induced by different doses of radiation and largely account for the lethality of ARS. At the lower end of the spectrum of lethal radiation doses, HP syndrome results from radiation-induced apoptosis of blood cells and their progenitors and can ultimately lead to death from hemorrhage, anemia and/or infection. GI syndrome is induced by higher doses of radiation and is the more difficult component of ARS to protect against/mitigate. In GI syndrome, massive apoptosis in the intestinal epithelium and endothelium leads to disintegration of the intestinal wall and death from intestinal bleeding and sepsis. These morbidities are exacerbated by the compromised immunity and coagulation caused by coincident HP syndrome. We have directly shown that Entolimod both reduces radiation damage to HP and GI tissues and improves their regeneration through detailed histopathological analysis of the morphology of tissue samples collected in our NHP studies. Our studies have shown that Entolimod has the following features relevant to its strong potential as a radiation countermeasure:

- Significant improvement of survival following lethal irradiation;
- Efficacious as a single injection given over a very broad time window, including administration as late as 72 hours post-irradiation;
- Significant reduction of radiation damage to both HP and GI tissues and improves tissue regeneration;
- Stability, storage and administration characteristics consistent with requirements for stockpiling and emergency civilian or military field use; and
- High-yield manufacturing process.

Regulatory Status of Entolimod for Biodefense Applications

Entolimod's development for use as a medical radiation countermeasure is guided by the Animal Rule (see "Government Regulation – Animal Rule"). The Animal Rule authorizes the FDA to rely on evidence 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 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, evidence of safety derived from studies in healthy human subjects and any additional supporting data.

We believe that we are well-positioned to meet the requirements of the Animal Rule for submission of a BLA for the use of Entolimod as a radiation countermeasure. Extensive pre-clinical studies related to safety, pharmacology, assay development and efficacy have been performed in two animal species that appear to accurately model human total body irradiation.

In June 2012, we announced survival results in a Good Laboratory Practice ("GLP") study of Entolimod in 179 NHPs exposed to lethal radiation that killed 72.5% of the control group. Entolimod delivered 70-75% survival in the experimental group when administered 25 hours after irradiation as a single intramuscular injection. The design of this study has since been accepted by the FDA as a pivotal efficacy study for purposes of licensure. We announced receipt of an Advice Letter from the FDA in September 2012 indicating agreement with the design of proposed pivotal animal efficacy studies for the development of Entolimod as a radiation countermeasure.

The mechanism of action of Entolimod is well understood and dose-dependent biomarkers of Entolimod efficacy that are relevant to its mechanism of action have been identified and agreed to by the FDA. A framework has been established to use the response of these biomarkers to convert the experimentally established NHP efficacious dose to a predicted human efficacious dose.

Two clinical studies that involved administration of a range of doses of Entolimod in 150 healthy human subjects have been completed. Both studies demonstrated that administration of Entolimod is not associated with irreversible harm at any of the doses studied. Transient (lasting approximately 24 hours), mild-moderate flu-like syndrome is the most common adverse event linked to up-regulation of cytokines (including biomarkers of efficacy). Transient changes in blood pressure and laboratory parameters also observed, without clinical complications. An additional FDA Advice Letter in October 2012 provided specific guidance on the structure of remaining clinical studies, including two primary study outcomes: generation of additional biomarker information for dose conversion as an initial study focus and then subsequent generation of extended safety data using the projected efficacious dose defined by the initial dose conversion study.

In July 2010, the FDA granted our application for Fast Track status in respect of Entolimod (see "Government Regulation – Fast Track Designation"). Fast Track status allows us to have additional interactions with the FDA, including extra in-person meetings and faster review of our BLA filing, which we anticipate should expedite implementation of the Entolimod development plan and preparation and approval of the BLA.

Entolimod was also granted Orphan Drug status by the FDA in November 2010 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"). Orphan Drug status qualifies Entolimod for tax credits, financial assistance for development costs, a possible exemption from the FDA-user fee and assistance in clinical trial protocol design.

As part of the process to receive FDA licensure for Entolimod, we have established a high-yield cGMP compliant manufacturing process. The process that we developed gives us the ability to manufacture up to three million estimated doses within a couple of months without a need for any additional scale-up. We currently have drug substance corresponding to over one million projected human doses.

Prior to our submission for FDA licensure for Entolimod for biodefense applications, we will need to complete several remaining steps, including:

- Conducting remaining pivotal animal efficacy studies in accordance with FDA guidelines.
- Performing additional clinical studies as advised by the FDA; and
- Filing a BLA.

Government Funding of Entolimod for Biodefense Applications

Entolimod is a candidate for procurement by the DoD, HHS/BARDA and governments of other countries/territories. The HHS opportunity is particularly attractive for us, as the agency's mandate is to protect the U.S. civilian population in the event of a radiological emergency, including stockpiling radiation countermeasures for mass distribution. We believe that our development contract awards from the DoD and BARDA are evidence of the government's focus on acquiring adequate protection against nuclear and radiation threats for military and civilian populations. Upon FDA approval, we believe that Entolimod will be well positioned to fulfill both of these needs due to its demonstrated unprecedented efficacy and survival benefits, unique ability to address both HP and GI damage, broad time window relative to radiation exposure for effective administration and suitability for projected military and civilian delivery scenarios. We believe that Entolimod is the only radiation countermeasure in advanced development that has these characteristics and can be administered without the need of additional supportive care in a battlefield or civilian community settings.

CBLI has received multiple grants and contracts for development funding for Entolimod's biodefense application from various U.S. government agencies, including a conditional purchase option, from the DoD. The following table is a summary itemizing these grants and contracts:

| Agency | Title | Contract Value | Period of Performance |
|---|---|---|---|
| DoD | Advanced Development of a Medical Radiation Countermeasure | $ 48,322,695* | 09/2010 - 09/2013 |
| HHS | CBLB502 as a therapy for Hematopoietic Syndrome, Bone Marrow Stromal Cell Loss, and Vascular Injury Resulting From Acute Exposure to Ionizing Radiation | 15,800,136 | 09/2008 - 02/2011 |
| DoD | Development of CBLB502 as Medical Radiation Countermeasure | 8,346,083 | 05/2008 - 09/2010 |
| NIH | Mechanisms of Mitigation of Radiation Damage of GI Tract by Protectan CBLB502 | 5,329,543 | 09/2009 - 09/2011 |
| DoD | CBLB502: Mechanism of Action and Therapeutic Optimization as Medical Countermeasure | 2,359,548 | 01/2011 - 10/2013 |
| Various | Various | 5,790,905 | Various |
| | | | |
| | Total U.S. Federal Government funding | $ 85,948,910 | |

* Our DoD contract granted in September 2010 (the "2010 DoD Contract") is valued at up to $48.3 million, including all options provided thereunder. Under the terms of the contract, CBMS-JPEO may initiate funding of up to $18.3 million, including all options, for the advanced development of Entolimod through the receipt of approval from the FDA. Selected tasks related to the advanced development of Entolimod under the 2010 DoD Contract include, among others, conducting pilot animal model studies to support approval under the Animal Rule, performing an International Conference on Harmonization-compliant stability testing program, scaling up manufacturing processes to achieve a cGMP-compliant large-scale manufacturing process for lyophilized product formulation and performing other activities in preparation for the submission of a BLA for gastrointestinal sub-syndrome ARS. In addition, the 2010 DoD Contract includes options for the purchase of an aggregate of up to 37,500 troop-equivalent doses, in pre-determined increments, for $30,000,000. The 2010 DoD Contract requires us to provide the DoD with periodic status reports and to maintain, to the maximum extent possible, the employment of certain key personnel during the duration of the program. We anticipate that the tasks currently funded under the 2010 DoD Contract will be completed in September 2013. As a government contractor subject to the Federal Acquisition Regulation, we will be permitted to retain title to any patentable invention or discovery made while performing the contract. The U.S. government, in return, will receive a non-exclusive, non-transferable, irrevocable, paid-up license to the subject inventions throughout the world. In addition, the U.S. government will also have unlimited rights in the technical data produced in the performance of the 2010 DoD Contract. Furthermore, the DoD has the right to terminate the 2010 DoD Contract at any time. In certain instances, the 2010 DoD Contract also limits our ability to engage in certain activities, such as subcontracting a portion of the work, without prior approval from the DoD.

In October 2012, we announced the submission of a proposal to BARDA for funding of the remaining development steps needed for FDA licensure of Entolimod as a medical radiation countermeasure. The scope of the proposal is based on feedback received from the FDA regarding the pivotal animal efficacy and clinical programs and animal-to-human dose conversion. There is no guarantee that BARDA will fund the proposal.

Medical Applications of Entolimod

Targeted Cancer Treatment

Entolimod is being developed as a targeted cancer therapy. We have demonstrated this effect in a number of models of transplanted tumors grown in mice and rats, including colon and lung cancer and lymphoma. In one of the animal models of transplanted colon cancer, Entolimod treatment resulted in complete tumor regression with no recurrence of the disease in a large percentage of the animals. The animal data that we have obtained indicate that the effect of Entolimod involves tissue-specific activation of innate immune responses via interaction of Entolimod with its receptor, TLR5. Entolimod's anti-tumor effect depends upon the TLR5 expression status of the tumor. A companion assay has been created to identify TLR5-expressing tumors. Interestingly, in our animal experiments of tumors residing in the liver, which has been identified as a natural primary target organ of Entolimod, tumors are effectively suppressed by the Entolimod -induced immune response regardless of their TLR5 status. This indicates that Entolimod may also be effective in treating liver metastases and primary tumors located in the liver.

Supportive Care in Oncology: Reduction of the Adverse Side Effects of Radio-/Chemotherapy

Entolimod may also be used as an adjuvant to standard radiation and chemotherapy, the efficacy of which is frequently limited by collateral damage to HP and GI tissues. For this application, it is critical that Entolimod specifically protects only normal cells and does not affect the killing of tumor cells by the applied radiation or chemotherapy. We have conducted multiple in vitro and in vivo experiments that have shown Entolimod -mediated protection is limited to normal, non-cancerous cells. Entolimod did not reduce, but in fact, somewhat enhanced, radiation-induced shrinkage of tumors. At the same time, the compound prevented radiation toxicity, resulting in improved animal survival and recovery from radiation-induced dermatitis and oral mucositis (Burdelya, et al., 2012. Toll-like receptor 5 agonist protects mice from dermatitis and oral mucositis caused by local radiation: implications

for head-and-neck cancer radiotherapy. Internat J Radiat Oncol Biol Phys. PubMed PMID: 22000579). Entolimod was also shown to reduce the toxicity of chemotherapeutic drugs in preliminary animal studies.

Prevention of Tissue Damage Caused by Ischemia-Reperfusion Injury

Temporary loss of blood flow (ischemia) causes tissue damage in a number of medical conditions, such as cerebral stroke, heart attack and acute renal failure. This damage results from induction of apoptotic cell death. In a study performed in collaboration with investigators from CCF, we found that a single injection of Entolimod effectively prevented acute renal failure and subsequent death in a mouse model of ischemia-reperfusion renal injury (Fukuzawa, et al., 2011. A TLR5 agonist inhibits acute renal ischemic failure. J Immunol. PubMed PMID: 21890657).

Based on this scientific foundation, the DoD awarded a $1 million grant to CCF in 2008 to conduct pre-clinical studies on Entolimod for use in tourniquet and other ligation-reperfusion battlefield injuries where blood flow is stopped and then restored after a prolonged period of time. The studies performed under this grant demonstrated that Entolimod treatment accelerated limb recovery in an animal model of tourniquet-mediated injury. Administration of Entolimod within 30 minutes of tourniquet removal resulted in a marked reduction in the severity of injury, including reduced tissue edema, pro-inflammatory cytokine production and leukocyte infiltration, which led to accelerated recovery of limb function.

Development/Regulatory Status of Entolimod for Oncology

An IND application for clinical testing of Entolimod in oncology patients was opened with the FDA in October 2011. In March 2012, we initiated dosing of a Phase 1 trial evaluating Entolimod in advanced cancer patients. Up to forty-eight patients are expected to be enrolled in multiple cohorts to determine the safety, tolerability and maximum tolerated dose of repeated administrations of Entolimod. Evaluations for evidence of activity of Entolimod in these patients will also be performed. We plan to initiate additional studies with Entolimod as a targeted cancer therapy before the ongoing trial concludes.

In contrast to the biodefense application of Entolimod as a radiation countermeasure, other applications of Entolimod are subject to the traditional FDA approval process, including performance of human clinical trials to determine efficacy for each proposed indication.

For example, in order for us to receive final FDA licensure for use of Entolimod as a targeted cancer treatment, we expect to complete various tasks, including:

- Performing one or two initial human efficacy studies on a small number of cancer patients;
- Performing additional efficacy studies on a larger number of cancer patients; and
- Filing a BLA with the FDA.

CBLB612

Our second lead Protectan, CBLB612, is a proprietary compound based upon a natural activator of another tissue-specific component of the innate immune system, the TLR2/TLR6 heterodimeric receptor. CBLB612 is a pharmacologically optimized synthetic molecule that structurally mimics naturally occurring lipopeptides of Mycoplasma (a genus of parasitic bacteria). Like Mycoplasma lipopeptides, CBLB612 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. As in the case of Entolimod, this event triggers a number of molecular and cellular pathways including those involved in suppressing cell death, stimulating the immune system and promoting tissue protection and regeneration.

CBLB612 demonstrated significant in vivo radioprotective and radiomitigative efficacy in mice against lethal doses of radiation that induce the HP component of acute radiation syndrome, but not the higher doses that induce the GI component. The improved survival of CBLB612-treated animals was associated with accelerated recovery of bone marrow and spleen cellularity and amelioration of thrombocytopenia (reduction in platelet levels). CBLB612 injection resulted in strong transient induction of multiple cytokines with known roles in hematopoiesis, including G-CSF, keratinocyte chemoattractant and interleukin-6 (Shakhov, et al., 2012. Prevention and Mitigation of Acute Radiation Syndrome in Mice by Synthetic Lipopeptide Agonists of Toll-Like Receptor 2 (TLR2). PLoS One. PubMed PMID: 22479357).

The key property of CBLB612 underlying its beneficial effects on the HP system and animal survival following radiation exposure is its ability to stimulate proliferation of HSCs and induce their mobilization from the bone marrow

to the peripheral blood. HSCs are critical for maintaining homeostasis of the blood and lymphoid systems and restoring these systems following injuries that cause their depletion such as exposure to radiation. Therefore, the potent efficacy of CBLB612 as a HSC stimulator has focused our development efforts on its potential use in various medical scenarios that require stem cell protection, stimulation and/or mobilization including (a) acceleration of recovery from myelosuppression (depletion of stem and progenitor cells in the bone marrow) and cytopenias (reduced circulating levels of blood cells) during chemotherapy, and (b) preparation of donors for isolation of HSCs to be used for bone marrow transplantation. The potential usefulness of CBLB612 for the latter application was demonstrated by our finding that a small amount of peripheral blood from CBLB612-treated donor mice successfully rescued mice with radiation-induced bone marrow stem cell deficiency. Therefore, we believe that CBLB612 has the potential to simplify transplantation procedures by eliminating the need for surgical harvesting of donor bone marrow or HSC isolation from peripheral blood using aphaeresis. We believe that such a simplified procedure could even allow for creation of individual HSC stocks for the general population.

Preclinical studies have shown that the efficacy of CBLB612 exceeds that of G-CSF (Amgen's Neupogen®), the market leading drugs used for stimulation of white blood cell regeneration. CBLB612's HSC stimulatory activity outweighed that of G-CSF when the drugs were administered either as monotherapies or in combination with Plerixafor (Genzyme's Mozobil®, a chemokine receptor antagonist approved by the FDA as an HSC mobilizer) in either mice or NHPs. However, the highest degree of HSC mobilization, a 12-fold greater than that induced by the current clinical standard of G-CSF+Plerixafor, was observed when CBLB612 was used in combination with both G-CSF and Plerixafor. The strong synergistic effect of this triple drug combination provides further support for development of CBLB612 as a valuable stem cell mobilizing agent.

Development/Regulatory Status of CBLB612

CBLB612 is currently undergoing formal pre-clinical safety assessment and cGMP-manufacturing development. Efficacy studies in mobilization of HSC and mitigation of neutropenia and thrombocytopenia and non-GLP safety studies of CBLB612 have been completed in mice and NHPs. A currently available batch of CBLB612 (non-cGMP manufactured) is sufficient to support remaining pre-clinical toxicology studies. An initial Phase 1 clinical trial is expected to be performed in healthy subjects, following the release of a cGMP batch and allowance of an IND application, with the primary objective of determining safety/tolerability of CBLB612. In addition, the planned study would allow us to assess levels of various HP stem and progenitor cell types in order to gain a preliminary estimate of the drug's HSC stimulatory efficacy.

In order for us to receive final FDA approval for CBLB612, we expect to complete several interim steps, including:

- Conducting IND-enabling GLP animal safety studies;
- Submitting an IND application and receiving allowance from the FDA to conduct clinical trials;
- Performing a Phase 1 dose-escalation human safety study;
- Performing human efficacy studies using the dose of CBLB612 selected from the previous studies as being safe in humans; and
- Filing an NDA.

In July 2012, we were awarded a contract valued at 139 million rubles, or approximately $4.6 million (based on current exchange rates), with the Ministry of Industry and Trade of the Russian Federation for development of CBLB612. The contract provides matching funding over a period of approximately three years, to further development of CBLB612 in the Russian Federation and the United States, which will be used to support preclinical and clinical studies.

Curaxins

Based on our understanding of mechanisms by which tumor cells escape apoptosis (e.g., inactivation of the p53 tumor suppressor pathway and/or constitutive activation of the pro-survival NF-κB pathway), we set out to identify compounds capable of targeting these mechanisms to reactivate apoptotic pathways in tumor cells and eliminate cancer. We succeeded in isolating several classes of such compounds (termed "Curaxins") by screening a library of small molecules using a read-out that was specifically designed to select molecules capable of activating p53 without inducing DNA damage. While DNA damage is a major natural activator of p53 and is involved in the mechanisms of action of many chemotherapeutic drugs, we wished to identify new drugs with non-genotoxic (not causing DNA damage) mechanisms of action that would be safer for clinical use. Notably, the "hit" molecules identified in our library screen not only activated p53, but also inhibited NF-kB. This multi-targeted mechanism of action suggested that Curaxins might be useful for treatment of many different types of cancer with greater efficacy and substantially lower risk of development of drug resistance than conventional chemotherapeutic agents. These expectations have now been confirmed in experimental models: as predicted from their effects on the p53 and NF-kB pathways, Curaxins have been shown to be efficacious against a broad range of in vivo mouse xenograft tumor models, including models of colon cancer, renal cell carcinoma and melanoma.

We determined that the anti-tumor effects of Curaxins derive from a mechanism of action involving modulation of the FACT complex (Gasparian, et al., 2011. Curaxins: anti-cancer compounds that simultaneously suppress NF-kB and activate p53 by targeting FACT. Sci Transl Med. PubMed PMID: 21832239). The FACT complex is normally required for opening up chromatin to allow transcription of certain classes of inducible genes and has also been implicated in other DNA-related cellular processes and our work is the first evidence linking this complex to cancer. Notably, the FACT-dependent transcriptional programs that are blocked in Curaxin-treated cells include several that are associated with cancer. Thus, our studies have shown that, in addition to inhibition of NF-kB-dependent

transcription, Curaxins block expression of genes regulated by Heat Shock Factor 1 (HSF1) and Hypoxia-Inducible Factor 1a (HIF-1a) two other pro-survival pathways that are commonly active in cancer.

In addition to strengthening our intellectual property position, this mechanistic knowledge provided additional rationale for the use of Curaxins as cancer agents either alone or in combination with other drugs that target pathways impacted by Curaxins. For example, the cellular heat shock response controlled by HSF-1-induced genes is a pro-survival pathway that is frequently activated in tumor cells due to proteotoxic stress (accumulation of misfolded or unfolded proteins). HSF-1 induces expression of heat shock proteins (HSPs) that help cells deal with this stress by refolding proteins or targeting them for degradation. Therefore, compounds that enhance proteotoxic stress or block heat shock response have been explored as potential anti-cancer treatments. Since Curaxins block HSF-1-mediated induction of HSPs, we believe that the efficacy of such treatments may be enhanced by applying them in combination with Curaxins. We have validated this concept in preliminary animal studies.

Our Curaxin program has already brought two molecules to advanced stages of development. These include an old anti-malaria drug quinacrine (CBL0102), which was found to act as a Curaxin, and CBL0137, a representative of a new generation of Curaxins with proprietary structure and significantly improved anti-tumor activity.

Moreover, we completed a study that provides proof of principle for expansion of Curaxins into antiviral applications (Gasparian, et al., 2010. Inhibition of encephalomyocarditis virus and poliovirus replication by quinacrine: implications for the design and discovery of novel antiviral drugs. J Virol. PubMed PMID: 20631142). This work has led to the recognition of a new avenue for Curaxin development into a new subclass of drugs, named Xenomycins, which are being developed through our Panacela subsidiary for anti-bacterial and anti-infective applications (see below).

CBL0102

CBL0102 is a member of a class of Curaxins that includes relatives of 9-aminoacridine, a compound that is the core structure of many existing drugs. CBL0102 was found to be a Quinacrine, a compound with a long history of use in humans as a treatment for malaria, osteoarthritis and autoimmune disorders. Quinacrine was not, however, previously used as cancer agent.

Development/Regulatory Status of CBL0102

Based upon Quinacrine's historical safety record and our extensive basic research and pre-clinical studies with CBL0102 and other Curaxins (including demonstration of CBL0102's efficacy in suppressing growth of human tumor cells transplanted into primates), we filed an IND application for the application of the CBL0102 as a cancer treatment. The first human anti-cancer trial with this drug was a Phase 2 study performed in 2008 in 31 patients with late stage, hormone refractory (androgen-independent) prostate cancer that had not responded to or relapsed following previous hormonal therapy and/or chemotherapy. The study results showed that one patient had a partial response, while 50% of the patients exhibited a decrease or stabilization in the rate of prostate cancer progression. CBL0102 was well-tolerated and there were no serious adverse events attributed to the drug. Therefore, the trial provided indications of anti-cancer activity and demonstrated remarkable safety for CBL0102 treatment in the group of cancer patients who were subject to the trial.

In November 2010, the first patient was dosed in a multi-center clinical trial of CBL0102 in cancer patients in the Russian Federation. The study is an open-label, dose escalation, Phase 1 safety and tolerability study in patients with liver metastases of solid tumors of epithelial origin, or primary advanced hepatic carcinoma for which standard therapy has failed or does not exist. The primary objective of the study is to determine the maximum tolerated dose and dose limiting toxicity in patients receiving CBL0102. Secondary objectives include describing the pharmacokinetics and response to CBL0102. The study includes a dose escalation arm divided into several cohorts, with an additional six patients enrolled at the selected therapeutic dose. Dosing in this study is currently ongoing.

In October 2012, CBL0102 was granted Orphan Drug status by the FDA for treatment of hepatocellular carcinoma.

We anticipate that additional clinical efficacy studies will be required before we are able to apply for licensure of CBL0102.

CBL0137

CBL0137 is our lead second generation Curaxin, demonstrating reproducible anti-tumor effects in animal models of colon, breast, renal, pancreatic, head and neck and prostate cancers, melanoma, non-small cell lung cancer, glioblastoma, lymphoma, leukemia and neuroblastoma.

Our tests indicate that CBL0137 may have favorable pharmacological characteristics, including suitability for oral and intravenous administrations and the lack of genotoxicity (DNA-damaging or mutagenic activity).

Development/Regulatory Status of CBL0137

In October 2012, dosing was started in a multi-center, single agent, dose escalation Phase 1 study of the oral formulation of CBL0137 in subjects with advanced solid tumors that are resistant or refractory to standard of care treatment in the Russian Federation.

A companion diagnostic has been created to measure FACT expression in tumors, making them potentially more responsive to CBL0137 treatment. This diagnostic is also being used to measure patient response to CBL0137 in ongoing trials.

Other Compounds

In addition to moving forward with development of product candidates that arose from our original concept of therapeutic modulation of apoptosis (Protectans and Curaxins), we are continually developing new concepts for drug development. As a result of such efforts, we currently have number of oncology and anti-infective compounds with diverse mechanisms of action in various early stages of development. Currently, these product candidates are being developed by Panacela and are described below.

Revercom

Revercom is a cancer drug candidate comprised of a liposome-packaged proprietary small molecule named Reversan. Reversan is a small molecule inhibitor of the multi-drug transporter MRP1, which is associated with development of tumor resistance to chemotherapy. Early studies have shown that Reversan sensitizes tumor cells to conventional chemotherapeutic drugs. Therefore, Reversan is being developed as an adjuvant to conventional chemotherapy for use in treatment of a broad range of cancers (e.g., head & neck, bladder, melanoma, breast, prostate, non-small cell lung carcinoma). Revercom is in the pre-clinical stage of development.

Mobilan

Mobilan is a nanoparticle-formulated recombinant non-replicating adenovirus that directs expression of TLR5 and its agonistic ligand, flagellin. In pre-clinical studies, delivery of Mobilan to tumor cells results in constitutive autocrine TLR5 signaling and strong activation of the innate immune system with subsequent development of adaptive anti-tumor immune responses. Mobilan is in the pre-clinical stage of development as a universal anti-cancer therapy.

Arkil

Arkil is a prospective treatment for prostate cancer (both androgen-dependent and androgen-independent/refractory forms). This proprietary small molecule compound has been shown to cause selective degradation of androgen receptor, thereby eliminating the constant AR signaling pathway activity that is essential for growth and viability of the majority of prostate cancers, including those that have lost their dependence on androgen. Arkil is in the pre-clinical stage of research and development, currently undergoing hit-to-lead optimization.

Antimycon

Antimycon is a proprietary small molecule lead compound generated to selectively target and inactivate oncoproteins of the Myc family, which are frequently upregulated in tumor cells. The Myc transcription factor has long been recognized as a highly attractive target for anti-cancer treatment. Potential indications for Antimycon include treatment of a broad range of solid tumors (breast, prostate, colon, non-small cell lung carcinoma, etc.) and hematological malignancies (various types of leukemia and lymphoma). Antimycon is in the pre-clinical stage of development, currently undergoing hit-to-lead optimization.

Xenomycins

The Xenomycin family of compounds has a broad range of potential applications as antimicrobial and, particularly, anti-fungal agents. Animal studies demonstrated efficacy of the compounds against parasites causing candidiasis, malaria, trypanosomiasis and Chagas disease including those with demonstrated resistance to other drugs. The mechanism(s) of antimicrobial action of these compounds are currently under investigation. Xenomycins are in the pre-clinical stage of development, currently undergoing hit-to-lead optimization.

In November 2012, we received a contract valued at 146 million rubles, or approximately $4.8 million (based on current exchange rates), from the Ministry of Industry and Trade of the Russian Federation for development of Xenomycins. The contract provides matching funding over a period of approximately three years, which will be used to support preclinical and clinical studies.

INTELLECTUAL PROPERTY

Our policy is to seek patent protection for the inventions that we consider important to the development of our business. As of December 31, 2012, we owned or held exclusive licenses to U.S., Patent Cooperation Treaty ("PCT") and foreign patents and patent applications relating to our product candidates. 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 EU, or similar mechanisms in other countries or territories. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

Our patent portfolio includes patents and patent applications with claims directed to compositions of matter, pharmaceutical formulations and methods of use. The following are the patent positions relating to our product candidates as of December 31, 2012.

Patents Relating to Protectans

Entolimod

As of December 31, 2012, we owned one PCT patent application and one foreign patent application, co-owned and exclusively licensed one U.S. patent, two U.S. patent applications and seven foreign patent applications, and held exclusive licenses to five U.S. patents, two U.S. patent applications, 26 foreign patents and twelve foreign patent applications relating to our product candidate Entolimod. The issued patents and the patents that may be issued based on these patent applications are scheduled to expire between 2024 and 2032.

CBLB612

As of December 31, 2012, we owned one foreign patent, one U.S. patent application and 15 foreign patent applications and held exclusive licenses to one U.S. patent, one U.S. patent application, nine foreign patents and nine foreign patent applications relating to our product candidate CBLB612. The issued patents, and the patents that may be issued based on these patent applications, are scheduled to expire between 2026 and 2028.

Patents Relating to Curaxins

As of December 31, 2012, we owned three foreign patents, one U.S. patent application and seventeen foreign patent applications, co-owned and exclusively licensed one U.S. patent application and five foreign patent applications and exclusively licensed one foreign patent, one U.S. patent application and three foreign patent applications relating to our Curaxin product candidates. The issued patents and the patents that may be issued based on these patent applications are scheduled to expire between 2026 and 2029.

Patents Relating to Panacela Product Candidates

As of December 31, 2012, we co-owned and exclusively licensed one U.S. provisional patent application, three U.S. patent applications and 40 foreign patent applications and exclusively licensed one U.S. patent, ten foreign patents, one U.S. patent application and 17 foreign patent applications to the Panacela product candidates. The issued patents and the patents that may be issued based on patent applications are scheduled to expire between 2026 and 2032.

License Agreements and Collaborations

We have entered into several significant license and collaboration agreements for our research and development programs, as further outlined below. These agreements typically provide for the payment by us or to us of license fees, milestone payments and royalties on net sales of product candidates developed and commercialized under these agreements.

Cleveland Clinic Foundation

We entered into an exclusive license agreement with CCF effective as of July 1, 2004, pursuant to which we were granted an exclusive license to CCF's research base underlying our therapeutic platform (the CBLC100, CBLB500 and CBLB600 series). In consideration for obtaining this exclusive license, we agreed to issue CCF common stock and make certain milestone, royalty and sublicense royalty payments. Under this agreement, CCF 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. As each patent covered by this license agreement expires, the license agreement will terminate as to such patent.

In August 2004, we entered into a cooperative research and development agreement ("CRADA"), with (a) the Uniformed Services University of the Health Sciences, which includes the Armed Forces Radiobiology Research Institute, (b) the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., and (c) CCF, to evaluate one of our radioprotective product candidates and its effects on intracellular and extracellular signaling pathways. As a collaborator under this agreement, we were able to use the laboratories of the Armed Forces Radiobiology Research Institute to evaluate radioprotection efficacy of Entolimod and perform analysis of HP stem cell mobilization in NHPs. This agreement expires in August 2015, but may be unilaterally terminated by any party upon 30 days prior written notice with or without cause.

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
- an asset transfer and clinical trial agreement entered into in December 2011.

In December 2007, CBLI entered into an agreement with RPCI pursuant to which we have an option to exclusively license any technological improvements to our foundational technology developed by RPCI for the term of the agreement. Pursuant to this agreement, we have exercised our option to exclusively license certain rights relating to CBL0102. In consideration for this option and exclusive license, we agreed to make certain milestone, royalty and sublicense royalty payments. 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 to exclusively license certain rights to our Mobilan, Antimycon, Arkil and Revercom technologies and to non-exclusively license certain know-how relating to the aforementioned product candidates and Xenomycin for the limited purposes of research and development and regulatory, export and other government filings. In consideration for obtaining these licenses, Panacela agreed to make certain milestone, royalty and sublicense royalty payments. Under these agreements, Panacela has a right to exclusively license (a) any technological improvements to the Mobilan, Antimycon, Arkil, Revercom and Xenomycin technologies developed by RPCI before September 2016, and (b) any technology jointly developed by Panacela and RPCI. 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). The licenses in respect of know-how will terminate after 20 years, and the licenses with respect of each patent will terminate as each patent expires.

We have entered into a number of sponsored research agreement with RPCI pursuant to which both parties have sponsored research to be conducted by the other party. Under the sponsored research agreement granted by RPCI to us, 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, 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 granted by us to 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 RPCI's ownership in any invention developed under such sponsored research agreements that are owned by RPCI. Such sponsored research agreements with RPCI expire in 2013, 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. Either party may terminate this agreement upon 30 days' notice to the other party.

Children’s Cancer Institute Australia

In September 2011, Panacela entered into an agreement with CCIA to exclusively license certain rights to our Antimycon technology. In consideration for this exclusive license, Panacela agreed to make certain milestone, royalty and sublicense royalty payments. Under this agreement, Panacela has the right to exclusively license any inventions developed by CCIA relating to the Panacela compounds. CCIA 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. The license does not have a specified term, however, the royalty term is 20 years.

MANUFACTURING

We do not intend to establish or operate facilities to manufacture our product candidates, and therefore will be dependent upon third parties to do so. As we develop new products or increase sales of any existing product, we must establish and maintain relationships with manufacturers to produce and package sufficient supplies of our finished pharmaceutical products. We have established a relationship with SynCo Bio Partners B.V., a leading biopharmaceutical manufacturer, to produce Entolimod under cGMP specifications in sufficient amounts for clinical trials and a commercial launch. The yields from the established manufacturing process at SynCo Bio Partners B.V. have been very high and the current process is expected to handle up to several million estimated human doses per year without need for any additional scale up and/or process improvements. For CBLB612, we have contracted with AmbioPharm in North Augusta, South Carolina to manufacture sufficient amounts for preclinical and clinical trials. For CBL0102, we have contracted with Regis Technologies, Inc., based in Illinois, and Aptuit, Inc., based in Missouri, to manufacture sufficient amounts for clinical programs. For CBL0137, we have contracted with Aptuit, Inc., based in Missouri and Glasgow, Scotland, to manufacture sufficient amounts for clinical trials. For our other potential products, we have entered into various manufacturing contracts to manufacture substance for pre-clinical testing.

COMPETITION

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and intense competition. This competition comes both from biotech and major pharmaceutical companies. Many of these companies have substantially greater financial, marketing and human resources than we do including, in some cases, substantially greater experience in clinical testing, manufacturing and marketing of pharmaceutical products. Our product candidates' competitive position among other biotechnology and biopharmaceutical companies will be based on, among other things, patent position, product efficacy, safety, reliability, availability, patient convenience, delivery devices and price, as well as the development and marketing of new competitive products. We can also experience competition from universities and other research institutions for product candidates.

Some of our competitors are actively engaged in R&D in areas where we also are developing product candidates. The competitive marketplace for our product candidates is somewhat dependent upon the timing of entry into the market and targets to address important unmet medical needs. Early entrants may have an advantage in gaining product acceptance and market share contributing to the product's eventual success and profitability. Accordingly, in some cases, the relative speed with which we can develop products, complete the testing, receive approval and supply commercial quantities of the product to the market is vital towards establishing a strong competitive position.

Biodefense

In the area of radiation countermeasures, various companies, such as Cellerant Therapeutics, Aeolus Pharmaceuticals, Neumedicines, Inc., Onconova Therapeutics, Inc., Soligenix, Inc., Pluristem Therapeutics, Araim Pharmaceuticals, Inc., RxBio, Inc., Exponential Biotherapies Inc., ImmuneRegen BioSciences, Inc. and Humanetics Corporation are developing biopharmaceutical products that potentially directly compete with Entolimod, even though their approaches to such treatment are different.

Our ability to sell to the government also can be influenced by indirect competition from other providers of products and services. For instance, a major breakthrough in an unrelated area of biodefense could cause a reallocation of government funds away from radiation countermeasures. Likewise, an outbreak or threatened outbreak of some other form of disease or condition may also cause a reallocation of funds away from the condition that Entolimod is intended to address.

Medical Applications

The number of cancer therapies is extremely large, numbering in the thousands. In recent years targeted therapies have become the preferred and most desired oncology category. Targeted therapies such as Herceptin® (Genentech) for HER-2 positive tumors, Gleevec® (Novartis) for Philadelphia chromosome tumor mutations, Erbitux® (Eli Lilly) and Iressa® (AstraZeneca) for EGRF expressing tumors and most recently Zelboraf® (Genentech) for BRAF mutated tumors, drive significant interest and value for cancer companies developing these treatments for cancer patients.

A subset of these targeted therapies are gaining market share as preferred by clinicians and insurers, such as therapies with companion diagnostics. These diagnostic tests allow clinicians to select patients who will most benefit from that specific drug. Insurers are more willing to reimburse for these drugs because there is a greater likelihood that the price of the drug will provide a benefit to the patient.

Chemotherapy is the second largest cancer drug category. These treatments are the foundation for treatment of all cancer types and used in most combination regimens. Drugs in this category include, among others, irinotecan, carboplatin, taxanes and doxorubicin. These drugs act on various cell division pathways and ultimately cause cell death. This cell division pathway may not always be specific to the cancer cell but often effects normal cells such as red blood cells, white blood cells and other healthy tissues. Although these drugs as a treatment category in general carry higher toxicities than targeted therapies, they are none the less an important drug category for improving patient survival.

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

GOVERNMENT REGULATION

Government authorities in the U.S. at the federal, state and local level, as well as 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 most medical products. The process of obtaining regulatory approvals in the U.S. and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

U.S. Drug Development Process

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

- Completion of non-clinical laboratory studies, animal studies and formulation and manufacturing studies according to GLP or other applicable regulations;
- Submission of an IND application to the FDA, which must be allowed before human clinical trials may begin;
- Performance of adequate and well-controlled human clinical trials according to GLP in the case of clinical trials and according to GLP in the case of animal efficacy studies under the Animal Rule and other applicable requirements to establish the safety and efficacy of the proposed drug for its intended use;
- Submission to the FDA of an NDA or BLA;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities in which the drug is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity or to meet standards designed to ensure the biologic's continued safety, purity and potency;
- Satisfactory completion of FDA inspections of clinical trial sites as well, in the case of the Animal Rule, of the animal testing facility(-ies) in which the drug is tested for pivotal efficacy; and
- FDA review and approval of the NDA or BLA.

As part of the IND, the sponsor must submit to the FDA the results of pre-clinical 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. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a "clinical hold" because of safety concerns or perceived procedural deficiencies. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials may begin. A clinical hold may be imposed by the FDA at any time during the life of an IND and may affect one or more specific studies or all studies conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice regulations. An institutional review board ("IRB") at each institution participating in the clinical trial must also review and approve each new clinical protocol and patient informed consent form prior to commencement of the corresponding clinical trial. Each new clinical protocol must be submitted to the IND for FDA

review and to the IRBs for approval. 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.

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

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

- Phase 2: Involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide, if appropriate, an adequate basis for product labeling.

During the development of a new drug, sponsors are given an opportunity to meet with the FDA at certain points. These meetings typically occur prior to submission of an IND, at the end of Phase 2 and before an NDA is submitted. 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.

On occasion, the FDA may suggest, or the sponsor of a clinical trial may decide, to use an independent data monitoring committee to provide advice regarding the continuing safety of trial subjects and the continuing validity and scientific merit of a trial. In 2006, the FDA published a final Guidance for Clinical Trial Sponsors on the Establishment and Operations of Clinical Trial Data Monitoring Committees in which it describes the types of situations where the use of a data monitoring committee is appropriate and suggests how a data monitoring committee should be established and operated. Data monitoring committees evaluate data that may not be available to the sponsor during the course of the study to perform interim monitoring of clinical trials for safety and/or effectiveness and consider the impact of external information on the trial. They often make recommendations to the sponsor regarding the future conduct of the trial.

Progress reports of work performed in support of IND studies must be submitted at least annually to the FDA and reports of serious and unexpected adverse events must be submitted to the FDA and the investigators in a timely manner. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the study participants are being exposed to an unacceptable health risk. Similarly, an IRB may suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirement or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies may complete additional animal studies, develop additional information about the chemistry and physical characteristics of the drug, and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and sponsors must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

With regard to an NDA or BLA, the FDA may deny or delay approval of an application that does not meet applicable regulatory criteria. For example, if the FDA determines that the pre-clinical or clinical data or the manufacturing information does not adequately establish the safety, purity and potency (including efficacy) of the drug candidate, it may deny or delay approval. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the data submitted in its NDA or BLA. The FDA can request additional information, seek clarification regarding information already provided in the submission or ask that clinical trials be conducted, all of which can delay approval. The FDA also may, at any time, require the submission of product samples and testing protocols for lot-by-lot confirmatory review or testing, known as lot release, by the FDA prior to commercial distribution. This means a specific lot of a drug cannot be released for commercial distribution until the FDA has authorized such release. Similar types of regulatory processes will be encountered as efforts are made to market any

drug product internationally. We will be required to assure product performance and manufacturing processes from one country to another.

If the FDA approves a product, the approved uses for the product are limited to what is described in the product labeling, including contraindications, warning statements or precautions. The FDA may also require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescription or dispensing in the form of a risk evaluation and mitigation strategy, or "REMS", or otherwise limit the scope of any approval or limit labeling. Once it approves a BLA, the FDA may revoke or suspend the product approval if compliance with post-market regulatory standards is not maintained or if problems occur after the product reaches the marketplace.

Animal Rule

In 2002, the FDA amended its requirements applicable to BLAs 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 trial 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 evidence 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 agent. Under these requirements, and with the FDA's prior agreement, drugs used to reduce or prevent the toxicity of chemical, biological, radiological or nuclear substances may be approved for use in humans based on evidence of effectiveness derived from appropriate animal studies and any additional supporting data. Products evaluated for effectiveness under this rule are evaluated for safety under preexisting requirements for establishing the safety of new drug and biological products. Under certain circumstances, a single animal species may be acceptable if that animal model is sufficiently well-characterized for predicting a response in humans. 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. Products approved under the Animal Rule are subject to additional requirements including post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

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

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

Project Bioshield Act

Under the Project BioShield Act, the Secretary of HHS may, with the recommendation of either the Secretary of Homeland Security or the Secretary of Defense, contract to use unapproved medical countermeasures in specified circumstances related to national defense and public health preparedness under an Emergency Use Authorization. To be eligible for purchase under these provisions, the Secretary of HHS must receive a recommendation from the FDA that there is sufficient and satisfactory clinical results or research data, including data, if available, from pre-clinical and clinical trials, to support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years. Entolimod may be eligible both for consideration for procurement into the Strategic National Stockpile and for use in the event of an emergency once the FDA agrees that Entolimod meets the criteria for an Emergency Use Authorization.

Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act, or PREP Act, provides immunity for manufacturers from all claims under state or federal law for “loss” arising out of the administration or use of a “covered countermeasure.” However, injured persons may still bring a suit for “willful misconduct” against the manufacturer under some circumstances. “Covered countermeasures” include security countermeasures and “qualified pandemic or epidemic products”, including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines, as well as treatments intended to address conditions caused by such products. For these immunities to apply, the Secretary of HHS must issue a declaration in cases of public health emergency or “credible risk” of a future public health emergency. Since 2007, the Secretary of HHS has issued 8 declarations and six amendments under the PREP Act to protect countermeasures that are necessary to prepare the nation for potential pandemics or epidemics from liability.

Regulations Regarding Government Contracting

The status of an organization as a government contractor in the United States and elsewhere means that the organization is also subject to various statutes and regulations, including the Federal Acquisition Regulation, which governs the procurement of goods and services by agencies of the United States. These governing statutes and regulations can impose stricter penalties than those normally applicable to commercial contracts, such as criminal and civil damages liability and suspension and debarment from future government contracting. In addition, pursuant to various statutes and regulations, government contracts can be subject to unilateral termination or modification by the government for convenience in the United States and elsewhere, and government contracts have detailed auditing requirements, statutorily controlled pricing, sourcing and subcontracting restrictions and statutorily mandated processes for adjudicating contract disputes.

Fast Track Designation

Entolimod has been granted Fast Track designation by the FDA for reducing the risk of death following total body irradiation during or after a radiation disaster. 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.

Orphan Drug Designation

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

If an orphan drug-designated product subsequently receives the first FDA approval for the disease for which it was designed, the product will be entitled to seven years of 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.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA or BLA.

Market exclusivity provisions under the Federal Food, Drug, and Cosmetic Act can delay the submission or the approval of certain applications. The Federal Food, Drug, and Cosmetic Act provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (“ANDA”) or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The Federal Food, Drug, and Cosmetic Act also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

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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.

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

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

EMPLOYEES

As of March 15, 2013, we had 85 employees, 66 of whom are located in the U.S. and 19 of whom are located outside of the U.S.

ENVIRONMENT

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

AVAILABLE INFORMATION

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

Item 1A. Risk Factors

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL FINANCING

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

We incurred net losses of approximately $22.4 million, $5.2 million and $26.7 million for the years ended December 31, 2012, 2011 and 2010, respectfully. We expect significant losses to continue for the next few years as we spend substantial additional 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, Entolimod;
- our ability to bring to market other proprietary drugs that are progressing through our development process;
- our R&D efforts, including the timing and cost of clinical trials; and
- our ability to enter into favorable alliances with third-parties who can provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales, marketing and distribution.

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

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

We are and will continue to be dependent on our ability to raise money through the issuance of additional equity or debt securities, or by entering into other financial arrangements, including relationships with corporate and other partners, in order to cover our operational costs, including the costs of product development and clinical testing.

Depending upon market conditions and subject to limitations imposed by the terms of our outstanding securities and contractual obligations, we may not be successful in raising sufficient additional capital for our long-term requirements. Over the past several years, the capital and credit markets have reached unprecedented levels of volatility and disruption, and if such adverse conditions continue, our ability to obtain financing may be significantly diminished. In addition, the decline in the market price of our common stock could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. Our internal sources of liquidity may prove to be insufficient, and in such case, we may not be able to successfully obtain financing on favorable terms, or at all. If we fail to raise sufficient additional financing and on terms and dates acceptable to us, we may not be able to continue our operations and the development of our product candidates, and may be required to reduce staff, reduce or eliminate R&D, slow the development of our product candidates, outsource or eliminate several business functions or shut down operations. Even if we are successful in raising such additional financing, we may not be able to successfully complete pre-clinical studies or clinical trials, development, and marketing of all, or of any, of our product candidates. Additionally, funds raised through debt financing would require us to make periodic payments of interest and principal and might impose restrictive covenants on the conduct of our business. 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.

Our R&D expenses are subject to uncertainty.

We are highly dependent on the success of our R&D efforts and, ultimately, upon regulatory approval and market acceptance of our products under development. Our ability to complete our R&D on schedule is, however, subject to a number of risks and uncertainties. Because we expect to expend substantial resources on R&D, our success depends in large part on the results as well as the costs of our R&D. R&D expenditures are uncertain and subject to much fluctuation. Factors affecting our R&D expenses include, but are not limited to:

- the number and outcome of pre-clinical studies and clinical trials we are planning to conduct; for example, our R&D expenses may increase based on the number of pivotal animal studies and clinical trials that we may be required to conduct;
- the number of products entering into development from late-stage research; for example, there is no guarantee that internal research efforts will succeed in generating sufficient data for us to make a positive development decision or that an external drug candidate will be available on terms acceptable to us and some promising product candidates may not yield sufficiently positive pre-clinical results to meet our stringent development criteria;
- in-licensing activities, including the timing and amount of related development funding or milestone payments; for example, we may enter into agreements requiring us to pay a significant up-front fee for the purchase of in-process R&D that we may record as R&D expense; or
- future levels of revenue; R&D expenses as a percentage of future potential revenues can fluctuate with the changes in future levels of revenue and lower revenues can lead to less spending on R&D efforts.

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

As of December 31, 2012, we had federal net operating loss carryforwards, or NOLs, of $94.1 million to offset future taxable income, which expire if not utilized by 2023. Under the provisions of the Internal Revenue Code, substantial changes in our ownership, in certain circumstances, will limit the amount of NOLs that can be utilized annually in the future to offset taxable income. In particular, section 382 of the Internal Revenue Code imposed limitations on a company's ability to use NOLs if a company experiences a more than 50% ownership change over a three-year period. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to utilize our NOLs fully.

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

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

- pre-clinical study or clinical trial results may show the product to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;
- we fail to receive the necessary regulatory approvals or there is a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or an NDA or BLA preparation, discussions with the FDA, an FDA request for additional pre-clinical or clinical data or unexpected safety or manufacturing issues;

- they fail to conform to a changing standard of care for the diseases they seek to treat;
- they are less effective or more expensive than current or alternative treatment methods;
- of manufacturing costs, pricing or reimbursement issues, or other factors that make the product not economically feasible; or
- proprietary rights of others and their competing products and technologies may prevent our product from being commercialized.

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

We anticipate substantial reliance upon strategic collaborations for marketing and commercialization of our product candidates and we may rely even more on strategic collaborations for R&D of our other product candidates. Our business depends on our ability to sell drugs to both government agencies and to the general pharmaceutical market. Offering our product candidates for non-medical applications to government agencies does not require us to develop new sales, marketing or distribution capabilities beyond those already existing in the company. Selling oncology and anti-infective drugs, however, requires a more significant infrastructure. We plan to sell oncology and anti-infective 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 collaborations with third parties capable of providing these services. In addition, we have not yet marketed or sold any of our product candidates or entered into successful collaborations for these services in order to ultimately commercialize our product candidates. We also rely on third-party collaborations with our manufacturers. Manufacturers producing our product candidates must follow current Good Manufacturing Practice (“cGMP”) regulations enforced by the FDA and foreign equivalents.

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

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

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

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

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

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

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

- we may decide, or regulators may require us, to conduct additional pre-clinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our pre-clinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable safety risks;
    - regulators or IRBs may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or if it is believed that the clinical trials present an unacceptable safety risk to the patients enrolled in our clinical trials;
        - the cost of our clinical trials or animal studies could escalate and become cost prohibitive;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials or certain animals used in our animal studies or facilities conducting our studies may not be available at the time that we plan to initiate a study; and
- the effects of our product candidates may not be the desired effects, may include undesirable side effects, or the product candidates may have other unexpected characteristics.

Even if we or our collaborators complete our animal studies and clinical trials and receive regulatory approval, it is possible that a product may be found to be ineffective or unsafe due to conditions or facts that arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such product from the market. To the extent that our success will depend on any regulatory approvals from government authorities outside of the U.S. that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist.

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

As of December 31, 2012, we owned 59.2% of the equity interests in Incuron and 54.6% of the equity interests in Panacela. Although these subsidiaries are majority-owned by us and are consolidated in our results, they have significant non-controlling interest holders, each of which are funds regulated by the Russian Federation government. As such, we share ownership and management of our subsidiaries with one or more parties who may not have the same goals, strategies, priorities, or resources as we do.

In each of our majority-owned subsidiaries, both we and our co-owners have certain rights in respect of such subsidiaries. Our majority-owned subsidiaries provide the right to each party to designate certain of the board members and certain decisions in respect of these subsidiaries may not be made without a supermajority vote of the equity holders or the consent of all of the equity holders. The right to transfer ownership interests in our majority-owned subsidiaries is restricted by provisions such as rights of first refusal and tag along and drag along rights. In addition, the use of funds and other matters are subject to monitoring and oversight by both groups of equity holders. Furthermore, we are required to pay more attention to our relationship with our co-owners as well as with the subsidiary, and if a co-owner changes, our relationship may be materially adversely affected.

The co-owners of our majority-owned subsidiaries are required to make additional payments to the subsidiaries to finance their operations. Such additional contributions are dependent on the satisfaction of various developmental milestones by our majority-owned subsidiaries. In the case of Panacela, we are required to meet the milestones within set time periods. As of December 31, 2012, Incuron and Panacela were potentially entitled to $5.9 and $17 million of future milestone-based payments, respectively (in the case of Incuron, based on an exchange rate of 30.3727 Rubles/USD as of December 31, 2012). The financing of our future subsidiaries may also be dependent on the satisfaction of similar milestones. The failure to satisfy the contractual requirements that we have with our co-owners in respect of obtaining additional financing from them may result in a material adverse effect in our business, financial

condition and results of operations.

These various restrictions may lead to additional organizational formalities as well as time-consuming procedures for sharing information and making decisions. In addition, the benefits from a successful joint venture are shared among the co-owners, so that we would not receive all the benefits from our successful joint ventures. Our future subsidiaries may also have significant non-controlling interest holders and the agreements with our co-owners may contain terms similar to those described above.

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 clinical supplies and commercial quantities of any products or product candidates that we market or may supply to our collaborators. Our dependence on third parties for the manufacture of our product candidates may adversely affect our ability to develop and commercialize any product candidates on a timely and competitive basis.

To date, our product candidates have only been manufactured in quantities sufficient for pre-clinical studies and clinical trials. We rely on one collaborator to produce Entolimod, one collaborator to produce CBL0102 and one collaborator to produce CBL0137. For a variety of reasons, dependence on any single manufacturer may adversely affect our ability to develop and commercialize our product candidates on a timely and competitive basis. In addition, our current contractual arrangements alone may not be sufficient to guarantee that we will be able to procure the needed supplies as we complete clinical development and/or enter commercialization.

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

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

- Contract manufacturers may encounter difficulties in achieving volume production, quality control and quality assurance and also may experience shortages in qualified personnel and obtaining active ingredients for our product candidates.
- If, for any circumstance, we are required 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.
- Contract manufacturers are subject to ongoing periodic, unannounced inspection by the FDA and state and foreign agencies or their designees to ensure strict compliance with cGMP and other governmental regulations and corresponding foreign standards. We do not have control over compliance by our contract manufacturers with these regulations and standards. Our contract manufacturers may not be able to comply with cGMP and other FDA requirements or other regulatory requirements outside the United States. Failure of contract manufacturers to comply with applicable regulations could result in delays, suspensions or withdrawal of approvals, seizures or recalls of product candidates and operating restrictions, any of which could significantly and adversely affect our business.
- Contract manufacturers may breach the manufacturing agreements that we have with them because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient to us.

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

RISKS RELATING TO REGULATORY APPROVAL

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

The testing, marketing and manufacturing of any product for use in the 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. Pre-clinical studies and clinical trials may reveal that one or more products are ineffective or unsafe, in which event, further development of such products could be seriously delayed, terminated or rendered more expensive. Moreover, obtaining approval for certain products may require testing on human subjects of substances whose effects on humans are not fully understood or documented.

In addition, we expect to rely on an FDA regulation known as the "Animal Rule" to obtain approval for Entolimod for biodefense applications. The Animal Rule permits the use of animal efficacy studies together with human clinical safety and immunogenicity trials to support an application for marketing approval of products when human efficacy studies are neither ethical nor feasible. These regulations are relatively new and we have limited experience in the application of these rules to the product candidates that we are developing. In fact, to date no new pharmaceuticals have been approved under the Animal Rule. As such the FDA is setting rule-making precedent given our advanced stage of development and, consequently, we cannot predict the time required for them to confirm the relevant rules, or the scope thereof. The FDA may decide that our data are insufficient for 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 biodefense applications, 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 for biodefense applications 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 seven meetings with DMIP during 2011-2012 to review the product mechanisms of action, safety profile and preliminary estimation of an effective human dose. While (i) DMIP has agreed on the scope and design of the proposed pivotal animal efficacy program, 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, and (ii) gave advice on the design of the remaining clinical program, we are still in the process of reaching an agreement with FDA on the certain elements of the design of our remaining clinical studies for Entolimod. There can be no guarantee that we will reach a satisfactory agreement in a timely manner, or at all, or that DMIP may request any additional information related to our preclinical or clinical programs.

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

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

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

We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any or all of the countries or regulatory jurisdictions in which we desire to market our product candidates. At this time, other countries do not have an equivalent to the Animal Rule and, as a result, such countries do not have established criteria for review and approval for this type of product outside their normal review process.

Specifically, because such other countries do not have an equivalent to the Animal Rule, we may not be able to file for or receive regulatory approvals for Entolimod for biodefense applications 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 for biodefense applications. However, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw our Fast Track designation if the FDA believes that the designation is no longer supported by data from our clinical development program. Our Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the FDA’s expedited review procedures or that any application that we may submit to the FDA for regulatory approval will be accepted for filing or ultimately approved.

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

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

After FDA approval of a product, the discovery of problems with a product or its class, or the failure to comply with requirements may result in restrictions on a product, manufacturer, or holder of an approved marketing application. These include withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay or prevent further marketing. Newly discovered or developed safety or effectiveness data, including from other products in a therapeutic class, may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Also, the FDA may require post-market testing and surveillance to monitor the product's safety or efficacy, including additional clinical studies, known as Phase 4 trials, 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, physicians and 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 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. GOVERNMENT CONTRACTS AND GRANTS

If we lose our funding from R&D contracts and grants, or 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 2012, we received 34.8% of our revenues from government contract and grant development work in connection with grants from the DoD, NIH and BARDA. In 2011 and 2010, we received 87.6% and 100% of our revenues from government contract and grant development work.

These revenues have funded some of our personnel and other R&D and General and Administrative costs and expenses. However, it is possible that awards that have been granted will not be funded in their entirety or that the funding will be delayed. It is also the case that we may not be able to procure new grants and contracts that provide sufficient funding, or at all. In addition, the finalization of new contracts and grants may require a significant time from the initial request and negotiations for such contracts and grants are subject to a significant amount of uncertainty.

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

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

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

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

- the need to devote substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;
- the risk that the government will issue a request for proposal to which we would not be eligible to respond;
- the risk that third parties may submit protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal;
- the expenses that we might incur and the delays that we might suffer if our competitors protest or challenge contract awards made to us pursuant to competitive bidding and the risk that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in termination, reduction or modification of the awarded contract; and
- the risk that review of our proposal or award of a contract or an option to an existing contract could be significantly delayed for reasons including, but not limited to, the need for us to resubmit our proposal or limitations on available funds due to government budget cuts.

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

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

We have entered into contracts with various U.S. government agencies. For the near future, substantially all of our revenue may be derived from government contracts and grants. In contracting with government agencies, we will be 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 and modification by the government at its sole discretion, which subjects us to additional risks. These risks include the ability of the U.S. government to unilaterally:

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

- reduce the scope and value of our existing contracts;
- audit and object to our contract-related costs and fees, including allocated indirect costs;
- control and potentially prohibit the export of our products; and
- change certain terms and conditions in our contracts.

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.

Furthermore, in most government contracts, including those awarded to us, much of the award amounts are not provided to the recipient until the underlying contract options are exercised. Such options may be exercised at the option of the government and, as a result, there is no guarantee that the government will exercise such options. If the U.S. government chooses not to exercise the options under the contracts it has with us, we will not be able to realize the full value of the awarded contracts, which may result in a material and adverse effect on our business, financial condition and results of operations.

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 (the "DCAA"). These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. The DCAA also reviews the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, which such costs already reimbursed must be refunded.

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

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

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

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

for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others.

Our technology may be found in the future to infringe upon the rights of others or be infringed upon by others. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief which could effectively block our ability to further develop, commercialize and sell products. In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our products so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology and the technology exclusively licensed by us or developed with our collaborative partners. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

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

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

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

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

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

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

We also rely on a combination of trade secrets, know-how, technology and nondisclosure and other contractual agreements and technical measures to protect our rights in the technology. However, trade secrets are difficult to protect and we rely on third parties to develop our products and thus must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements will typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. If any trade secret, know-how or other technology not protected by a patent or intellectual property right were disclosed to, or independently developed by, a competitor, our business, financial condition and results of operations could be materially adversely affected.

RISKS RELATING TO OUR INDUSTRY AND OTHER EXTERNAL FACTORS

The biopharmaceutical market in which we compete is highly competitive.

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

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

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

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

We have limited experience in filing and prosecuting regulatory applications to obtain marketing approval from the FDA or other regulatory authorities. The loss of services of one or more of our key employees or consultants could have a negative impact on our business or our ability to expand our research, development and clinical programs. We depend on our scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial and marketing personnel, particularly as we expand our activities in clinical trials, the regulatory approval process, external partner solicitations and sales and manufacturing. We routinely enter into consulting agreements with our scientific and clinical collaborators and advisors, opinion leaders and heads of academic departments in the ordinary course of our business. We also enter into contractual agreements with physicians and institutions who recruit patients into our clinical trials on our behalf in the ordinary course of our business. Notwithstanding these arrangements, 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 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, which could involve our directors and officers as defendants. We currently have D&O insurance to cover such risk exposure for our directors and officers. Our bylaws require us to indemnify our current and past directors and officers from reasonable expenses related to the defense of any action arising from their service to us. Our certificate of incorporation and by-laws include provisions to indemnify the directors and officers to the fullest extent permitted by the Delaware General Corporation Law, including circumstances under which indemnification is otherwise discretionary. If our D&O insurance is insufficient to cover all such expenses for all directors and officers, we would be obligated to cover any shortfall, which may be substantial. Such expenditure could have a material adverse effect on our results of operation, financial condition and liquidity. Further, if D&O insurance becomes prohibitively expensive to maintain in the future, we may be unable to renew such insurance on economic terms or unable renew such insurance at all. The lack of D&O insurance may make it difficult for us to retain and attract talented and skilled directors and officers to serve our company, which could adversely affect our business.

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

We use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. As appropriate, we store these materials and wastes resulting from their use at our laboratory facility pending their ultimate use or disposal. We contract with a third party to properly dispose of these materials and wastes. We are 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 to comply with environmental laws and regulations adopted in the future.

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

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

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

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

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

Our business is subject to changing regulations for corporate governance and public disclosure that has increased both our costs and the risk of noncompliance.

Each year, under Section 404 of the Sarbanes-Oxley Act, we are required to evaluate our internal controls systems in order to allow management to report on our internal controls as required by and to permit our independent registered public accounting firm to attest to our internal controls. As a result, we have incurred and will continue to incur additional expenses and divert our management's time to comply with these regulations. In addition, if we cannot continue to comply with the requirements of Section 404 in a timely manner, we might be subject to sanctions or investigation by regulatory and quasi-governmental authorities, such as the SEC, the Public Company Accounting Oversight Board, or The NASDAQ Stock Market. Any such action could adversely affect our financial results and the market price of our common stock.

In addition, stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business.

RISKS RELATING TO OUR SECURITIES

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 2012 through December 2012, the market price of our common stock, which is listed on the NASDAQ Capital Market, fluctuated from a high of $4.06 per share in the first quarter of 2012 to a low of $1.15 in the second quarter of 2012. 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 CCF, RPCI or our other collaborators;
- 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 80,000,000 shares of common stock and 10,000,000 of preferred stock. As of December 31, 2012, we had 44,730,445 shares of our common stock and 0 shares of our preferred stock issued and outstanding and warrants exercisable into 10,377,995 shares and 5,016,916 options outstanding. To the extent the shares of common stock are issued or options and warrants are exercised, holders of our common stock will experience dilution.

In the event of any future issuances of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution. Furthermore, our outstanding warrants contain provisions that, in certain circumstances, could result in the number of shares of common stock issuable upon the exercise of such warrants 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. If we issue preferred stock in the future that has 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. Any provision permitting the conversion of any such preferred stock into our common stock could result in significant dilution to the holders of our common stock.

We also consider from time to time various strategic alternatives that could involve issuances of additional common stock, including but not limited to acquisitions and business combinations, but do not currently have any definitive plans to enter into any of these transactions.

We have no plans to pay dividends on our common stock and investors may not receive funds without selling their common stock.

We have not declared or paid any cash dividends on our common stock, nor do we expect to pay any cash dividends on our common stock for the foreseeable future. We currently intend to retain any additional future earnings to finance our operations and growth and, therefore, we have no plans to pay cash dividends on our common stock at this time. Any future determination to pay cash dividends on our common stock will be at the discretion of our board of directors and will be dependent on our earnings, financial condition, operating results, capital requirements, any contractual restrictions, regulatory and other restrictions on the payment of dividends by our subsidiaries to us and other factors that our board of directors deems relevant.

Accordingly, investors may have to sell some or all of their common stock in order to generate cash from your investment. Investors may not receive a gain on your investment when they sell our common stock and may lose the entire amount of their investment.

Provisions in our charter documents and Delaware law may inhibit a takeover or impact operational control of our company, which could adversely affect the value of our common stock.

Our certificate of incorporation and bylaws, as well as Delaware corporate law, contain provisions that could delay or prevent a change of control or changes in our management that a stockholder might consider favorable. These provisions include, among others, prohibiting stockholder action by written consent, advance notice for raising business or making nominations at meetings of stockholders and the issuance of preferred stock with rights that may be senior to those of our common stock without stockholder approval. These provisions would apply even if a takeover offer may be considered beneficial by some of our stockholders. If a change of control or change in management is delayed or prevented, the market price of our common stock could decline.

RISKS RELATED TO CONDUCTING BUSINESS IN THE RUSSIAN FEDERATION

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. Prospective investors in our common stock should note that emerging markets are subject to rapid change and that the information set out in this Annual Report on Form 10-K about our operations in Russia may become outdated relatively quickly.

Future deterioration in the international economic situation may cause financial instability in Russia and could adversely affect our business.

The Russian economy is vulnerable to market downturns and economic slowdowns elsewhere in the world, has experienced periods of considerable instability and has been subject to abrupt downturns. 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. More recently, the negative trends of the global economy and volatility in the financial markets, partially due to the recent debt crisis in Europe, have resulted in a decreased growth outlook for those countries dependent on Western Europe for trade. The Russian government has taken certain anti-crisis measures including using the “stabilization fund” and hard currency reserves to soften the impact of the global economic downturn on the Russian economy and support the value of the Russian ruble. Should global economic conditions deteriorate significantly, it is possible that the Russian economy could continue to decline in the near future. Further economic instability in Russia where we operate through our consolidated subsidiaries and any future deterioration in the international economic situation could materially adversely affect our business, financial condition and results of operations.

Inflation in Russia and government efforts to combat inflation may contribute significantly to economic uncertainty in Russia and could materially adversely affect our financial condition and results of operations.

The Russian economy has periodically experienced high rates of inflation. According to The World Bank and Bloomberg, the annual inflation rate in Russia, as measured by the consumer price index, was 6.9% in 2010 and 8.4% in 2011. 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 subsidiaries to conduct business operations, including any outsourced product testing costs.

Political and governmental instability in Russia could materially adversely affect our business and operations in these countries.

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. Since the breakup of the U.S.S.R. in 1991, the political and economic situation in Russia has generally become more stable. However, there is still a risk of significant changes to the political and economic environment, potential changes in the direction of the reforms or reversal of the reforms. 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. Any disruption or reversal of reform policies could lead to political or governmental instability or the occurrence of conflicts among powerful economic groups, which could materially adversely affect our business and operations in Russia.

A deterioration in political and economic relations between Russia and the United States could materially adversely affect our business and operations in Russia and generally.

Political and economic relations between Russia and the United States, two of the jurisdictions in which we operate, are complex. Political, ethnic, religious, historical and other differences have, on occasion, given rise to tensions. The emergence of new or escalated tensions could further exacerbate tensions between Russia and the United States and/or the European Union (EU) where we have manufacturing or other partners, which may have a negative effect on their economy. Any of the foregoing circumstances could materially adversely affect our business and operations in Russia and generally.

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.

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 (VAT), corporate property tax and other taxes with new legislation. 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 can 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. Our Russian subsidiaries' 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 Arbitration 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 systems in Russia impose 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 tax laws are unclear 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 these countries. This could materially adversely affect our financial condition and results of operations.

We may be exposed to liability for actions taken by our subsidiaries.

Under the laws of Russia, we may be jointly and severally liable for obligations of our subsidiaries. We may also incur secondary liability and, in certain cases, liability to creditors for obligations of our subsidiaries in certain instances involving bankruptcy or insolvency. This type of liability could result in significant obligations and could materially adversely affect our financial condition and results of operations.

Our majority-owned Russian subsidiaries can be forced into liquidation on the basis of formal noncompliance with certain legal requirements.

Our majority-owned subsidiaries operate in Russia primarily through Incuron and the wholly-owned Russian subsidiary of Panacela, both of which were organized under the laws of the Russian Federation. 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 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.

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. This space serves as the corporate headquarters and primary research facilities for us and U.S. corporate headquarters for Incuron and Panacela. In addition, (a) we have leased approximately 2,500 square feet of office space located at 9450 W. Bryn Mawr Rd., Rosemont, Illinois, 60018 through August 2013, which is utilized as a satellite office by both CBLI and Panacela; and (b) we have less than 3,600 square feet under lease outside of the United States expiring at varying times through December 2015. We do not own any real property.

Item 3. Legal Proceedings

We are not a party to any litigation or other legal proceeding and management is not aware of any contemplated proceedings by any governmental authority against us. However, in the normal course of business, we may become involved in a variety of lawsuits, claims and legal proceedings, including commercial and contract disputes, employment matters, product liability claims, environmental liabilities and intellectual property disputes.

Item 4. Mine Safety Disclosure

None.

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 2012 and 2011. On March 15, 2013, the last reported sale price of our common stock was $1.64 per share.

| 2012 | High | Low |
|---|---|---|
| First Quarter | $4.06 | $2.45 |
| Second Quarter | $2.57 | $1.15 |
| Third Quarter | $2.95 | $1.31 |
| Fourth Quarter | $2.76 | $1.23 |

| 2011 | High | Low |
|---|---|---|
| First Quarter | $9.60 | $6.35 |
| Second Quarter | $8.46 | $3.17 |
| Third Quarter | $3.46 | $2.10 |
| Fourth Quarter | $3.29 | $2.23 |

Stockholders

As of December 31, 2012, there were approximately 40 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.

Unregistered Sale of Securities

During 2012, as consideration for consulting services provided, we issued an aggregate of 75,000 shares of our common stock to various consultants without registration in reliance on the exemptions afforded by Section 4(2) of the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

We made no repurchases of our securities during the year ended December 31, 2012.

Item 6: Selected Financial Data

The following selected financial data has been derived from our audited financial statements. The information below is not necessarily indicative of the results of future operations and should be read in conjunction with Item 7,

"Management's Discussion and Analysis of Financial Condition and Results of Operations," and Item 1A, "Risk Factors," of this Form 10-K and the financial statements and related notes thereto included in Item 8 of this Form 10-K, in order to fully understand factors that may affect the comparability of the information presented below:

SELECTED FINANCIAL DATA

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| (in thousands, except per share data) | 2012 | 2011 | 2010 | 2009 | 2008 |
| Consolidated statement of operations data: | | | | | |
| Revenues: | | | | | |
| Government contract or grant | $3,571 | $8,790 | $15,332 | $12,696 | $4,586 |
| Commercial | - | - | - | 1,650 | 120 |
| Total revenues | 3,571 | 8,790 | 15,332 | 14,346 | 4,706 |
| Operating expenses (1) | 33,617 | 33,895 | 26,069 | 20,729 | 19,051 |
| Loss from operations | (30,047) | (25,105) | (10,737) | (6,383) | (14,345) |
| Other income (expense): | | | | | |
| Change in value of warrant liability | 7,702 | 19,822 | (16,012) | (6,268) | - |
| Other income (expense) | (70) | 53 | 77 | (175) | 319 |
| Total other income (expense) | 7,632 | 19,875 | (15,935) | (6,443) | 319 |
| Net loss | (22,415) | (5,230) | (26,672) | (12,826) | (14,026) |
| Net loss attributable to noncontrolling interests | 4,180 | 1,216 | 306 | - | - |
| Net loss attributable to Cleveland BioLabs, Inc. | (18,234) | (4,014) | (26,366) | (12,826) | (14,026) |
| Dividends on convertible preferred stock | - | - | - | 616 | 1,182 |
| Net loss available to common stockholders | $(18,234) | $(4,014) | $(26,366) | $(13,442) | $(15,208) |
| Net loss per share, basic and diluted | $(0.49) | $(0.12) | $(1.01) | $(0.82) | $(1.13) |

| | December 31, | | | | |
|---|---|---|---|---|---|
| (in thousands) | 2012 | 2011 | 2010 | 2009 | 2008 |
| Consolidated balance sheet data: | | | | | |
| Cash and cash equivalents | $25,652 | $22,873 | $10,919 | $963 | $300 |
| Short-term investments | 2,634 | 5,520 | 459 | - | 1,000 |
| Total current assets | 29,406 | 31,010 | 17,751 | 4,735 | 2,864 |
| Total assets | 32,010 | 32,127 | 19,887 | 6,554 | 4,706 |
| Capital leases (current & noncurrent) | 169 | - | - | - | - |
| Long-term debt | - | - | - | - | - |
| Stockholder's equity (deficit) | 20,486 | 22,245 | (12,500) | (6,800) | 538 |

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

This management’s discussion and analysis of financial condition and results of operations and other portions of this filing contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking information. Factors that may cause such differences include, but are not limited to, availability and cost of financial resources, results of our R&D efforts and clinical

trials, product demand, market acceptance and other factors discussed in this annual report under the heading “Risk Factors” and the Company’s other Securities and Exchange Commission (“SEC”) filings. The following discussion should be read in conjunction with our financial statements and the related notes included elsewhere in this filing.

OVERVIEW

We are a clinical-stage biotechnology company with a focus on oncology drug development whose lead drug candidate, Entolimod, is being developed for dual indications: under an FDA regulation commonly referred to as the “Animal Rule” as a radiation countermeasure; and under the FDA’s traditional drug approval pathway as a targeted cancer treatment. Since our inception we have pursued the research, development and commercialization of products that have the potential to treat cancer, reduce death from total body irradiation and counteract the genotoxic effects of radio- and chemotherapies for oncology patients. Presently, nine product candidates are under development directly by us and our majority-owned subsidiaries. See “Business” for more information on our product candidates.

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. ("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 research and development. We based 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, 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 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 grants to determine levels of accomplishments throughout the life of the grant.

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: (a) the closing price of our common stock; (b) the expected remaining life of the warrants; (c) the expected volatility using a weighted-average of historical volatilities of CBLI and a group of comparable companies; and (d) the risk-free market rate.

As of December 31, 2012, we held approximately $13.0 million in money market funds, classified as a Level 1 security, and held approximately $4.1 million in accrued expenses, classified as a Level 3 security, related to 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.

Recently Issued Accounting Pronouncements

In October 2012, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2012-04, “Technical Corrections and Improvements” in Accounting Standards Update No. 2012-04. The amendments in this update cover a wide range of Topics in the Accounting Standards Codification. These amendments include technical corrections and improvements to the Accounting Standards Codification and conforming amendments related to fair value measurements. The amendments in this update will be effective for fiscal periods beginning after December 15, 2012. The adoption of ASU 2012-04 is not expected to have a material impact on our financial position or results of operations.

In July 2012, the FASB issued ASU 2012-02, “Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment” in ASU No. 2012-02. This update amends ASU 2011-08, Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment and permits an entity first to assess qualitative factors to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired as a basis for determining whether it is necessary to perform the quantitative impairment test in accordance with Subtopic 350-30, Intangibles - Goodwill and Other - General Intangibles Other than Goodwill. The amendments are effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. The adoption of ASU 2012-02 is not expected to have a material impact on our financial position or results of operations.

Components of Our Results of Operations

The following table sets forth our statement of operations data for the years ended December 31, 2012, 2011 and 2010 and should be read in conjunction with our financial statements and the related notes appearing elsewhere in this annual report on Form 10-K:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Revenues | $3,570,710 | $8,790,209 | $15,331,567 |
| Operating expenses | 33,617,316 | 33,895,380 | 26,068,765 |
| Other income (expense) | 7,631,966 | 19,875,446 | (15,934,659) |

| | | | |
|---|---|---|---|
| Net loss | $(22,414,640) | $(5,229,725 ) | $(26,671,857) |

Revenue

Our revenue originates from grants and contracts from both U.S. federal and state government sources and Russian government sources. Federal grants and contracts are provided to advance research and development for product candidates that are of interest for potential sale to DoD and BARDA, as medical radiation countermeasures to be added to the Strategic National Stockpile. State grants are usually designed to stimulate economic activity. Russian government contracts are provided to develop the biotechnology and pharmaceutical industries in Russia.

Research and Development Expenses

Research and development, or 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 contract research organizations; drug product manufacturing and formulation; and a pro-rata share of facilities expense and other overhead items.

General and Administrative Expenses

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

YEAR ENDED DECEMBER 31, 2012 COMPARED TO YEAR ENDED DECEMBER 31, 2011

Revenue

Revenue decreased by $5.2 million to $3.6 million for the year ended December 31, 2012 from $8.8 million for the year ended December 31, 2011, representing a decrease of 59%. This decrease consisted of a reduction in $4.1 million of U.S. government contracts and grant revenues and $2.3 million of revenue from the NY State/RPCI Sponsored Research Agreement. These decreases were partially offset by an increase of $1.2 million in revenues from our Russian government grants.

The following table sets forth details regarding the sources of our government grant and contract revenue:

| Funding Source | Program | 2012 | 2011 | Variance |
|---|---|---|---|---|
| DoD | CBMS-MITS Contract | $ 1,113,830 | $ 3,684,142 | $ (2,570,312) |
| Russian Federation Ministry of Industry & Trade | CBLB612 Pre-clinical (1) | 888,686 | - | 888,686 |
| DoD | DTRA Contract | 130,149 | 1,462,417 | (1,332,268) |
| NY State/RPCI | Sponsored Research Agreement | - | 2,317,218 | (2,317,218) |
| HHS | BARDA Contract | - | 237,748 | (237,748) |
| | | 2,132,665 | 7,701,525 | (5,568,860) |
| Russian Federation Ministry of Industry & Trade | Xenomycins Pre-clinical (1) | 949,264 | - | 949,264 |
| Skolkovo Foundation | Curaxin research (1) | 488,781 | 1,088,684 | (599,903) |
| | | $ 3,570,710 | $ 8,790,209 | $ (5,219,499) |

(1)

The grants received from Russian government entities are denominated in Russian Rubles (RUR). 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 mainly from government grants and contracts. We plan to submit or have submitted proposals for additional government grants and contracts to funding sources that have awarded grants and contracts to us in the past, but there can be no assurance that we will receive future funding awards. The following table sets forth information regarding our currently active contracts:

| Funding Source | Program | Total Award Value | Funded Award Value | As of December 31, 2012 Cumulative Revenue Recognized | Funded Backlog |
|---|---|---|---|---|---|
| DoD | CBMS-MITS Contract (1) | $ 48,322,695 | $ 6,933,761 | $ 5,421,948 | $ 1,511,813 |
| Russian Federation Ministry of Industry & Trade | CBLB612 Pre-clinical (2) | 4,556,553 | 3,101,199 | 888,686 | 2,212,513 |
| DoD | DTRA Contract | 2,359,548 | 2,035,452 | 1,592,565 | 442,887 |
| | | 55,238,796 | 12,070,412 | 7,903,199 | 4,167,213 |
| Russian Federation Ministry of Industry & Trade | Xenomycins Pre-clinical (2) | 4,817,870 | 3,550,284 | 949,264 | 2,601,020 |
| Skolkovo Foundation | Curaxin research (2) | 4,892,382 | 4,892,382 | 1,577,464 | 3,314,918 |
| | | $ 64,949,048 | $ 20,513,078 | $ 10,429,927 | $ 10,083,151 |

(1) Includes a $30M conditional purchase option for 37,500 doses of Entolimod as a radiation countermeasure, exercisable upon approval.

(2) The contracts received from Russian government entities are denominated in Russian Rubles (RUR). The contract value above is calculated based on the cumulative revenue recognized to date plus our backlog valued at the December 31, 2012 exchange rate.

Research and Development Expenses

R&D expenses decreased by $0.3 million to $22.5 million for the year ended December 31, 2012 from $22.8 million for the year ended December 31, 2011, representing a decrease of 1%. For the year ended December 31, 2012, subcontractor costs decreased by $3.6 million. This cost decrease was partially offset by an increase of $3.3 million for Panacela being operational for a full year. The following table sets forth our R&D expenses for 2012 and 2011 by drug candidate.

| | 2012 | 2011 | Variance |
|---|---|---|---|
| Entolimod for Biodefense Applications | $11,986,020 | $17,294,937 | $(5,308,917) |
| CBLB612 | 1,039,832 | 481,371 | 558,461 |
| Entolimod for Oncology Applications | 605,365 | 260,777 | 344,588 |
| General | - | 872,455 | (872,455) |
| | 13,631,217 | 18,909,540 | (5,278,323) |
| Panacela product candidates | 5,593,722 | 748,497 | 4,845,225 |
| Curaxins | 3,276,866 | 3,130,850 | 146,016 |
| Total research & development expenses | $22,501,805 | $22,788,887 | $(287,082) |

General and Administrative Expenses

General and administrative expenses remained relatively unchanged for the years ended December 31, 2012 and 2011 at $11.1 million per year. Significant variances between periods included a $1.4 million increase in general and administrative costs associated with subsidiaries that were not active in the same periods in 2011, a $1.0 million

increase in business development expenses and a $0.4 million increase in miscellaneous general and administrative costs, offset by a decrease of $1.2 million due to a non-cash charge regarding a change in estimates for patents costs recorded in 2011.

Other Income and Expenses

Other income decreased by $12.2 million from $19.8 million for the year ended December 31, 2011 to $7.6 million for the year ended December 31, 2012, a change of 62%. The change in the fair market value of our stock yielded a change in the fair market value of our accrued warrant liability which was the primary reason for this decrease in other income.

YEAR ENDED DECEMBER 31, 2011 COMPARED TO YEAR ENDED DECEMBER 31, 2010

Revenue

Revenue decreased by $6.5 million to $8.8 million for the year ended December 31, 2011 from $15.3 million for the year ended December 31, 2010, representing a decrease of 42%. This decrease resulted primarily from a decrease in revenue from U.S. government contracts and grants, the most significant of which was the reduction in revenue recognized from BARDA as a result of our completion of work under such contract in February 2011.

See the table below for further details regarding the sources of our government grant and contract revenue:

| Funding Source | Program | 2011 | 2010 | Variance |
|---|---|---|---|---|
| DoD | CBMS-MITS Contract | $ 3,684,142 | $ 623,975 | $ 3,060,167 |
| NY State/RPCI | Sponsored Research Agreement | 2,317,218 | 12,398 | 2,304,820 |
| DoD | DTRA Contract | 1,462,417 | - | 1,462,417 |
| HHS | BARDA Contract | 237,748 | 9,968,445 | (9,730,697) |
| NIH | NIAID GO Grant | - | 4,091,879 | (4,091,879) |
| Various | Various | - | 634,870 | (634,870) |
| | | 7,701,525 | 15,331,567 | (7,630,042) |
| Skolkovo Foundation | Curaxin research (1) | 1,088,684 | - | 1,088,684 |
| | | | | |
| | | $ 8,790,209 | $ 15,331,567 | $ (6,541,358) |

(1)The grant received from Skolkovo Foundation is denominated in Russian Rubles (RUR). The revenue above was calculated using the average exchange rate for the period.

Research and Development Expenses

R&D expenses increased by $6.7 million to $22.8 million for the year ended December 31, 2011 from $16.1 million for the year ended December 31, 2010, representing an increase of 42%. Of our consolidated R&D expenses, subcontractor costs increased by $4.6 million, or 51%, to $13.7 million; and personnel related expenses grew by $1.0 million, or 20%, to $6.2 million. Combined these cost elements represent 84% of the total increase in R&D expense, with the remaining increase of $1.1 million primarily due to increased purchases of consumable supplies and travel costs. In general, R&D expenses increase as product candidates advance from one development stage to the next. The following table sets forth our R&D expenses for 2011 and 2010 by drug candidate. The increases in R&D expenses reflected below are due to either new compounds or indications entering research and development, or the general maturation of the research and development efforts for our active product candidates since 2010.

| | 2011 | 2010 | Variance |
|---|---|---|---|
| Entolimod for Biodefense Applications | $17,294,937 | $14,316,540 | $2,978,397 |
| General | 872,455 | 246,730 | 625,725 |
| CBLB612 | 481,371 | 5,140 | 476,231 |
| Entolimod for Oncology Applications | 260,777 | - | 260,777 |
| | 18,909,540 | 14,568,410 | 4,341,130 |
| Curaxins | 3,130,850 | 1,572,630 | 1,558,220 |
| Panacela product candidates | 748,497 | - | 748,497 |
| | | | |
| Total research & development expenses | $22,788,887 | $16,141,040 | $6,647,847 |

General and Administrative Expenses

General and administrative expenses increased by $1.2 million to $11.1 million for the year ended December 31, 2011 from $9.9 million for the year ended December 31, 2010, representing an increase of 12%. This increase resulted primarily from an increase of $1.2 million in amortization expense, related to our change in estimate of capitalized patent costs recorded during the three months ended September 30, 2011. Additionally, professional fees and other miscellaneous expenses increased by $0.8 million. This increase includes additional costs to form and maintain our majority-owned subsidiaries, support the intellectual property of our expanding drug candidate pipeline and enhance

our investor relations activities. These increases were partially offset by a decrease in personnel costs of $0.8 million that resulted from a decrease in non-cash stock based compensation expense resulting mainly from the change in the fair market value of our stock.

Other Income and Expenses

For the year ended December 31, 2011, other income was $19.9 million, a change of $35.8 million from the other expenses of $15.9 million for the year ended December 31, 2010. The change in the fair market value of our stock yielded a change in the fair market value of our accrued warrant liability which was the primary reason for this decrease in other income.

Liquidity and Capital Resources

We have incurred net losses of $118.3 million since inception through December 31, 2012. 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:

- Since its initial public offering in 2006, CBLI has raised $91.8 million through periodic access of the U.S. equity markets. Since its inception in 2003, CBLI has raised $107.7 million of net equity capital, including amounts received from the exercise of options and warrants.
- The U.S. Departments of Defense and Health and Human Services awarded grants and contracts totaling $85.9 million for the development of Entolimod as a radiation countermeasure, including a $30 million purchase option for 37,500 doses, which is exercisable upon FDA approval. Of the total amount awarded, we earned $42.3 million through December 31, 2012 and expect to earn $2.0 million in 2013. Additionally, we submitted a proposal to BARDA for the continued development of Entolimod as a radiation countermeasure. If awarded in full, this contract could fund all remaining work necessary to complete development of Entolimod as a radiation countermeasure and allow us to file a BLA with the FDA.
- Entities affiliated with the Russian Federation have awarded us contracts totaling $14.3 million, including awards for the development of Curaxins ($4.9 million), CBLB612 ($4.6 million) and Xenomycins ($4.8 million). All awards are valued based on revenue recognized to date, with the remaining backlog valued at the December 31, 2012 exchange rates. These contracts include a requirement for us to contribute matching funds, which are satisfied with both the value of developed intellectual property at the time of award and future expenses. At December 31, 2012, $11.5 million of the awards was funded; $6.7 million was received, of which $3.3 million remains as deferred revenue. We expect to recognize approximately $5.7 million and $2.4 million of the remaining funding in 2013 and 2014, respectively.
- Incuron was formed to develop and commercialize our Curaxin product line, namely two compounds CBL0102 and CBL0137. BCP committed to contribute up to $17.7 million (based on current exchange rates) of funding as development milestones were accomplished. To date, Incuron has received $11.7 million of funding from BCP, including $5.9 million received in June of 2012. BCP’s remaining capital contribution of $6.0 million is due upon completion of certain developmental milestones which the Company believes will occur in 2013.
- Panacela was formed to develop and commercialize five preclinical compounds. Rusnano contributed $9.0 million at formation and has commitments to contribute up to $17 million of additional funding as development milestones are accomplished. CBLI contributed $3.0 million plus intellectual property at formation and has options to contribute additional capital based on agreed-upon terms.
- We have been awarded $4.0 million in grant and contracts not described above, all of which has been recognized at December 31, 2012.
- We actively pursue all reasonable domestic and international sources of grant and contract funding for our drug pipeline.

At December 31, 2012, we had cash, cash equivalents and short-term investments of $28.3 million. Of that total, $10.3 million was restricted for the use of our majority-owned subsidiaries, leaving $18.0 million available for general use. In addition, Panacela restricted $1.6 million of cash as a performance bond in connection with the Xenomycin grant, which is classified as a long-term asset.

Operating Activities

Net cash used in operations increased by $3.7 million to $20.6 million for the year ended December 31, 2012 from $16.9 million for the year ended December 31, 2011. This increase is due to the maturing nature of our research activities as our compounds advance from pre-clinical research into clinical development. After adjusting for non-cash items, the net loss increased by $7.9 million, while changes in working capital provided cash and cash equivalents of $4.2 million.

Investing Activities

Net cash provided by (used in) investing activities increased by $7.4 million to $1.4 million for the year ended December 31, 2012 from ($6.1 million) for the year ended December 31, 2011. Most of the net cash provided by investing activities related to a decrease in short-term investments of $8.1 and a reduction in the amount of capitalized equipment and patent costs of $0.8 million. These variances were offset by the restriction of $1.6 million of Panacela's cash to guarantee performance on their grant with the Russian Federation Ministry of Industry and Trade.

Financing Activities

Cash provided by financing activities decreased by $13.3 million to $21.5 million for the year ended December 31, 2012, from $34.8 million for the year ended December 31, 2011. This net decreased was comprised of a decrease in the amount of cash raised through the issuance of common stock by $6.3 million, a decrease in the amount of cash raised by our majority-owned subsidiaries of $5.5 million and a decrease in the amount of cash proceeds from the exercise of stock options and stock warrants of $1.5 million.

Other

We have incurred cumulative net losses and expect to incur additional losses related to our research and development activities. We do not have commercial products and have limited capital resources. We will need additional funds to complete the development of our products. Our plans with regard to these matters may include seeking additional capital through a combination of government contracts, collaborative agreements, strategic alliances, research grants and future equity and debt financing. Although we continue to pursue these plans, there is no assurance that we will be successful in obtaining future financing on commercially reasonable terms or that we will be able to secure funding from anticipated government contracts and grants.

We believe that our existing funds combined with cash flows from existing government grants and contracts will be sufficient to fund our projected operating requirements for at least the next twelve months based upon current operating plans and spending assumptions. The success of our company is dependent upon commercializing our research and development programs and our ability to obtain adequate future financing. 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.

Contractual Obligations and Purchase Commitments

The following table summarizes our contractual obligations and purchase commitments as of December 31, 2012:

| | | Payments Due by Period | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 Year | 1-3 Years | 3-5 Years | More than 5 Years |
| Operating lease obligations | $2,615,318 | $571,640 | $755,615 | $720,483 | $ 567,580 |
| Capital lease obligations | 198,016 | 91,392 | 106,624 | - | - |
| Purchase obligations (1) | 3,022,503 | 2,907,057 | 83,202 | 20,338 | 11,906 |
| Total | $5,835,837 | $3,570,089 | $945,441 | $740,821 | $ 579,486 |

(1) At December 31, 2012, we had approximately $3.0 million in committed purchase obligations with fixed and determinable terms. In addition to the above, we are party to an agreement with RPCI related to our clinical trial for Entolimod for refractory cancer patients with liver metastases with an estimated cost of $1.2 million remaining for the trial. This agreement is contingent on future events, e.g. the rate of patient accrual and the duration of testing. This agreement can be cancelled by either party, in which case we would only be liable to RPCI for work performed 30 days after the date of cancellation, as such this amount is not included in the table above.

In addition to the above listed commitments, we intend to match approximately $8.6 million in development funding over the next two years to fully realize the funding of our Russian grants.

Off-Balance Sheet Arrangements

The Company does not have any off-balance sheet arrangements.

Item 7A: Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is primarily confined to our cash and cash equivalents, short-term investments and certain warrants we account for as derivative instruments. Because of the short-term maturities of our cash and cash equivalents and short-term investments, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments. At December 31, 2012, approximately 78.4% of our cash and cash equivalents were denominated in US dollars and the balance of 21.6% was denominated in Russian Rubles. A 10% increase or decrease in the value Russian Ruble exchange rate would have resulted in a corresponding increase or decrease to our year-end cash and cash equivalents balance of approximately $0.6 million. Changes in our stock price could have a significant impact on the fair market value of certain warrants we have issued, which could result in an adverse or positive impact on our results of operations. At December 31, 2012, a 10% increase or decrease in our stock price would have resulted in a corresponding increase or decrease of approximately $0.7 million in our accrued warrant liability.

Item 8: Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Cleveland BioLabs, Inc and Subsidiaries

We have audited the accompanying consolidated balance sheets of CLEVELAND BIOLABS, INC. AND SUBSIDIARIES as of December 31, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity (deficit), comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2012. We also have audited Cleveland BioLabs and Subsidiaries' internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Cleveland BioLabs and Subsidiaries' management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on these financial statements and an opinion on the Company's internal control over financial reporting 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance

with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

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, 2012 and 2011, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, Cleveland BioLabs, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

MEADEN & MOORE, LTD.
Certified Public Accountants

Cleveland, Ohio
March 18, 2013

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

| | December 31, 2012 | December 31, 2011 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $25,652,083 | $22,872,589 |
| Short-term investments | 2,633,944 | 5,520,000 |
| Accounts receivable | 41,896 | 1,740,629 |
| Other current assets | 1,078,040 | 876,889 |
| Total current assets | 29,405,963 | 31,010,107 |
| | | |
| Equipment, net | 986,553 | 1,084,204 |
| Resctricted cash | 1,577,920 | - |
| Other long-term assets | 39,597 | 32,490 |
| | | |
| Total assets | $32,010,033 | $32,126,801 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| | | |
| Current liabilities: | | |
| Accounts payable | $1,523,875 | $909,144 |
| Accrued expenses | 2,410,592 | 1,686,202 |
| Deferred revenue | 3,314,918 | - |
| Accrued warrant liability | 4,105,659 | 7,285,959 |
| Current portion of capital lease obligation | 71,679 | - |
| Total current liabilities | 11,426,723 | 9,881,305 |
| | | |
| Noncurrent portion of capital lease obligation | 97,602 | - |
| | | |
| Commitments and contingencies | - | - |
| | | |
| Total liabilities | 11,524,325 | 9,881,305 |
| | | |
| Stockholders' equity: | | |
| Preferred stock, $.005 par value; 10,000,000 shares authorized, 0 shares issued and outstanding as of December 31, 2012 and December 31, 2011, respectively | - | - |
| Common stock, $.005 par value; 80,000,000 shares authorized, 44,730,445 and 35,612,192 shares issued and outstanding as of December 31, 2012 and December 31, 2011, respectively | 223,653 | 178,061 |
| Additional paid-in capital | 123,864,830 | 108,865,645 |
| Accumulated other comprehensive income | 546,473 | 84,613 |
| Accumulated deficit | (118,301,789) | (100,067,647) |
| Total Cleveland BioLabs, Inc. stockholders' equity | 6,333,167 | 9,060,672 |
| Noncontrolling interest in stockholders' equity | 14,152,541 | 13,184,824 |
| Total stockholders' equity | 20,485,708 | 22,245,496 |
| | | |

| | | |
|---|---|---|
| Total liabilities and stockholders' equity | $32,010,033 | $32,126,801 |

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

| | For the Years Ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Revenues: | | | |
| Grants and contracts | $3,570,710 | $8,790,209 | $15,331,567 |
| | | | |
| Operating expenses: | | | |
| Research and development | 22,501,805 | 22,788,887 | 16,141,040 |
| General and administrative | 11,115,511 | 11,106,493 | 9,927,725 |
| Total operating expenses | 33,617,316 | 33,895,380 | 26,068,765 |
| | | | |
| Loss from operations | (30,046,606) | (25,105,171) | (10,737,198) |
| | | | |
| Other income (expense): | | | |
| Interest and other income (expense) | (70,015) | 53,659 | 77,110 |
| Change in value of warrant liability | 7,701,981 | 19,821,787 | (16,011,769) |
| Total other income (expense) | 7,631,966 | 19,875,446 | (15,934,659) |
| | | | |
| Net loss | (22,414,640) | (5,229,725) | (26,671,857) |
| | | | |
| | | | |
| Net loss attributable to noncontrolling interests | 4,180,498 | 1,216,055 | 305,812 |
| | | | |
| Net loss attributable to Cleveland BioLabs, Inc. | $(18,234,142) | $(4,013,670) | $(26,366,045) |
| | | | |
| Net loss available to common stockholders per share of common stock, basic and diluted | $(0.49) | $(0.12) | $(1.01) |
| | | | |
| Weighted average number of shares used in calculating net loss per share, basic and diluted | 37,388,847 | 32,561,743 | 26,184,773 |

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

| | For the Years Ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Net loss including noncontrolling interests | $(22,414,640) | $(5,229,725) | $(26,671,857) |
| Other comprehensive income (loss) | | | |
| Foreign currency translation adjustment | 797,558 | 153,815 | (36,423) |
| Comprehensive loss including noncontrolling interests | (21,617,082) | (5,075,910) | (26,708,280) |
| Comprehensive loss attributable to noncontrolling interests | 3,844,800 | 1,177,397 | 311,691 |
| Comprehensive loss attributable to Cleveland BioLabs, Inc. | $(17,772,282) | $(3,898,513) | $(26,396,589) |

See Notes to Consolidated Financial Statements

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Cash flows from operating activities: | | | |
| Net income (loss) | $(22,414,640) | $(5,229,725) | $(26,671,857) |
| Adjustments to reconcile net income (loss) to net cash used in operating activities: | | | |
| Depreciation | 479,595 | 512,366 | 389,439 |
| Amortization | - | 13,147 | 17,850 |
| Unrealized currency loss on short-term investments | 52,726 | - | - |
| Loss on equipment disposal | 18,997 | - | - |
| Noncash compensation | 2,535,217 | 4,044,858 | 6,662,130 |
| Warrant issuance costs | 244,857 | 150,827 | 231,980 |
| Change in value of warrant liability | (7,701,981) | (19,821,787) | 16,011,769 |
| Patent costs | - | 1,481,318 | - |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | 1,736,199 | 3,641,491 | (1,990,774) |
| Other current assets | (182,428) | 123,197 | (611,885) |
| Other long-term assets | (6,414) | (919) | (8,656) |
| Accounts payable | 609,522 | (348,282) | 53,370 |
| Deferred revenue | 3,238,124 | (2,317,218) | (12,398) |
| Accrued expenses | 740,723 | 845,337 | 29,701 |
| Net cash used in operating activities | (20,649,503) | (16,905,390) | (5,899,331) |
| | | | |
| Cash flows from investing activities: | | | |
| Purchase of short-term investments | (5,220,781) | (5,520,000) | (459,364) |
| Sale of short-term investments | 8,312,120 | 434,835 | - |
| Issuance of note to Panacela Labs, LLC | - | - | - |
| Purchase of equipment | (178,271) | (655,553) | (465,650) |
| Increase in restricted cash | (1,541,366) | - | - |
| Investment in patents | - | (326,171) | (250,735) |
| Net cash provided by (used in) investing activities | 1,371,702 | (6,066,889) | (1,175,749) |
| | | | |
| Cash flows from financing activities: | | | |
| Issuance of common stock, net of offering costs | 15,675,727 | 21,946,801 | 12,234,693 |
| Noncontrolling interest capital contribution to Incuron, LLC | 5,893,557 | 2,340,374 | 3,509,564 |
| Noncontrolling interest capital contribution to Panacela Labs, Inc. | - | 9,000,066 | - |
| Exercise of options | 2,375 | 532,408 | 901,911 |
| Repayment of capital lease obligation | (52,410) | - | - |
| Exercise of warrants | - | 949,793 | 418,926 |
| Net cash provided by financing activities | 21,519,249 | 34,769,442 | 17,065,094 |
| | | | |
| Effect of exchange rate change on cash and equivalents | 538,046 | 156,889 | (34,577) |
| | | | |
| Increase in cash and cash equivalents | 2,779,494 | 11,954,052 | 9,955,437 |
| | | | |
| Cash and cash equivalents at beginning of period | 22,872,589 | 10,918,537 | 963,100 |
| | | | |

| | | | |
|---|---|---|---|
| Cash and cash equivalents at end of period | $25,652,083 | $22,872,589 | $10,918,537 |
| | | | |
| Supplemental disclosure of cash flow information: | | | |
| Cash paid during the period for interest | $23,708 | $- | $- |
| | | | |
| Supplemental schedule of noncash financing activities: | | | |
| Equipment acquired through lease financing | $221,690 | $- | $- |
| Conversion of warrant liability to equity upon warrant exercise | $- | $995,428 | $2,020,031 |
| Noncash financing costs on common stock offering | $- | $207,905 | $227,486 |
| Noncash warrant issuance costs | $- | $19,361 | $91,283 |

See Notes to Consolidated Financial Statements

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

| | Common Stock | | Preferred Stock | | Additional Paid-in | Accu C Compr In (L |
|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | |
| Balance at January 1, 2010 | 20,203,508 | $101,018 | 467 | $2 | $62,786,418 | $- |
| Issuance of common stock net of offering costs of $1,238,098 | 2,938,462 | 14,692 | - | - | 12,133,212 | - |
| Allocation of financing proceeds to fair value of warrants | - | - | - | - | (2,629,847) | - |
| Conversion of preferred shares to common shares | 4,576,979 | 22,885 | (467) | (2) | (22,883) | - |
| Noncontrolling interest capital contribution to Incuron, LLC | - | - | - | - | - | - |
| Exercise of options | 336,674 | 1,683 | - | - | 900,228 | - |
| Exercise of warrants | 442,357 | 2,212 | - | - | 2,436,745 | - |
| Stock based compensation | 461,196 | 2,306 | - | - | 4,637,844 | - |
| Net loss | - | - | - | - | - | - |
| Foreign currency translation | - | - | - | - | - | (3 |
| Balance at December 31, 2010 | 28,959,176 | 144,796 | - | - | 80,241,717 | (3 |
| Issuance of common stock net of offering costs of $1,619,638 | 5,872,500 | 29,363 | - | - | 21,840,999 | - |
| Allocation of financing proceeds to fair value of warrants | - | - | - | - | (2,525,175) | - |
| Noncontrolling interest capital contribution to Incuron, LLC | - | - | - | - | 176,092 | - |
| Noncontrolling interest capital contribution to Panacela Labs, Inc. | - | - | - | - | - | - |
| Stock based compensation | 308,850 | 1,544 | - | - | 6,656,742 | - |
| Exercise of options | 190,255 | 951 | - | - | 531,457 | - |
| Exercise of warrants | 281,411 | 1,407 | - | - | 1,943,813 | - |
| Net loss | - | - | - | - | - | - |
| Foreign currency translation | - | - | - | - | - | 11 |
| Balance at December 31, 2011 | 35,612,192 | 178,061 | - | - | 108,865,645 | 84 |
| Issuance of common stock net of offering costs of $1,129,916 | 8,525,000 | 42,625 | - | - | 15,877,959 | - |
| Allocation of financing proceeds to fair value of warrants | - | - | - | - | (4,521,681) | - |
| Noncontrolling interest capital contribution to Incuron, LLC | - | - | - | - | 1,081,040 | - |
| Stock based compensation | 592,003 | 2,961 | - | - | 2,559,498 | - |
| Exercise of options | 1,250 | 6 | - | - | 2,369 | - |
| Net loss | - | - | - | - | - | - |
| Foreign currency translation | - | - | - | - | - | 46 |
| Balance at December 31, 2012 | 44,730,445 | $223,653 | - | $- | $123,864,830 | $54 |

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

Cleveland BioLabs, Inc. ("CBLI") is a clinical-stage biotechnology company with a focus on oncology drug development. Since inception, CBLI has pursued the research, development and commercialization of products that have the potential to treat cancer, reduce death from total body irradiation and counteract the toxic effects of radio- and chemotherapies for oncology patients.

CBLI was incorporated under the laws of the State of Delaware on June 5, 2003 and is headquartered in Buffalo, New York. CBLI has one wholly-owned operating subsidiary, BioLab 612, LLC ("BioLab 612"), which began operations in 2012. CBLI also has two majority-owned operating subsidiaries, Incuron, LLC ("Incuron") and Panacela Labs Inc. ("Panacela"), which were formed in 2010 and 2011, respectively. Additionally, Panacela has a wholly-owned operating subsidiary, Panacela Labs, LLC.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements include the accounts of CBLI and its subsidiaries, BioLab 612, Incuron and Panacela, collectively referred to herein as the "Company." All significant intercompany balances and transactions have been eliminated in consolidation. These financial statements have been prepared on the accrual basis in accordance with accounting principles generally accepted in the United States of America ("GAAP").

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

Cash equivalents are highly liquid investments with a maturity of 90 days or less at the date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions. As of December 31, 2012, $7,706,936 of cash was restricted to the use of its majority-owned subsidiaries.

Short-Term Investments

The Company's short-term investments are classified as held to maturity given the intent and ability to hold the investments to maturity. Accordingly, these investments are carried at amortized cost. Short-term investments classified as held-to-maturity consisted of certificates of deposit with maturity dates beyond three months and less than one year. As of December 31, 2012, the Company's short-term investments, in the amount of $2,633,944, were restricted to the use of its majority-owned subsidiaries.

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. 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, 2012, the Company held 30% of its cash and cash equivalents and 100% of its short-term investments in accounts located outside of the United States.

Significant Customers and Accounts Receivable

Grant and contract revenue from the United States government accounted for 34.8%, 87.6% and 100.0% of total revenue for the years ended December 31, 2012, 2011 and 2010, respectively. Although the Company anticipates ongoing federal government contract and grant revenue, there is no guarantee that this revenue stream will continue in the future.

Grant and contract revenue received by subsidiaries from Russian government agencies accounted for 65.2%, 12.4% and 0% of total revenues for the years ended December 31, 2012, 2011 and 2010, respectively.

Accounts receivable consist of amounts due under contracts with certain government and foreign entities. The Company extends unsecured credit to customers under normal trade agreements, which generally require payment within 30 days.

Management estimates an allowance for doubtful accounts that is based upon management's review of delinquent accounts and an assessment of the Company's historical evidence of collections. There were no allowances for doubtful accounts as of December 31, 2012 and 2011, as the collection history from the Company’s customers indicated that collection was probable.

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, including equipment, 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 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, 2012 includes a certificate of deposit, posted by Panacela, as a performance guarantee for its grant with the Ministry of Industry and Trade of the Russian Federation for the development of the drug candidate, Xenomycins. The guarantee requires Panacela to satisfactorily perform its statement of work under the grant. Panacela anticipates receiving the full proceeds of the deposit upon its expiration in January 2016.

Intellectual Property

Costs related to filing and pursuing patent applications are recognized as general and administrative expenses ("G&A 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.

During the year-ended December 31, 2011, the Company performed its periodic review of capitalized patent costs and incorporated a more restrictive standard of capitalization widely utilized in the biotechnology industry, which includes a prerequisite of the FDA marketability approval as one of several factors needed to justify the continued capitalization of costs associated with securing patents. Given that the Company is currently developing requisite data towards submission to the FDA of biological license and new drug applications in support of its existing product candidates, capitalized patent costs of approximately $1,500,000 were expensed during the year ended December 31, 2011. This item has been treated as a change in estimate in the accompanying financial statements.

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.

Line of Credit

As of December 31, 2012, CBLI had a working capital line of credit that was fully secured by cash equivalents and short-term investments. The working capital line of credit carried an interest rate equal to the prime rate, had a borrowing limit of $600,000 and has since been closed. At December 31, 2012 and 2011, there were no outstanding borrowings under this credit facility.

Accrued Warrant Liability

Certain warrants are accounted for as derivative instruments in accordance with the Financial Accounting Standards Board ("FASB") 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."

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. Furthermore, these warrants do not contain any contingent exercise provisions or anti-dilution provisions that impact the fair value of a fixed-for-fixed option, and accordingly, the warrants are considered indexed to CBLI's stock.

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 subsidiaries 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).

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 G&A 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, materials and related expenses for personnel and facility expenses. Other R&D expenses include fees paid to consultants and outside service providers, the costs of materials used in clinical trials and research and development and stock-based compensation.

Accounting for Stock-Based Compensation

The 2006 Equity Incentive Plan, as amended (the “Plan”), authorizes CBLI to grant (a) options to purchase common stock, (b) restricted or unrestricted stock units, and (c) 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 2012 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, 2012, an aggregate of 10.0 million shares of common stock were authorized for issuance under the Plan, of which a total of approximately 3.0 million shares of common stock remained available for future awards. A single participant cannot be awarded more than 400,000 shares annually. Awards granted under the Plan have a contractual life of no more than 10 years. The 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 the Company’s compensation committee.

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, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Risk-free interest rate | .65 - 1.49% | .96 - 2.61% | 1.42 - 2.75% |
| Expected dividend yield | 0% | 0% | 0% |
| Expected life - years | 5 - 6 | 5 - 6 | 5 - 6 |
| Expected volatility | 86.58 - 92.60% | 84.28 - 92.38% | 84.23 - 89.55% |

"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.

Income taxes

No income tax expense was recorded for the years ended December 31, 2012, 2011 and 2010, 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:

| | As of December 31, | | |
|---|---|---|---|
| Common Equivalent Securities | 2012 | 2011 | 2010 |
| Warrants | 10,377,995 | 12,564,193 | 9,450,633 |
| Options | 5,016,966 | 4,117,979 | 3,264,440 |

| | | | |
|---|---|---|---|
| Total | 15,394,961 | 16,682,172 | 12,715,073 |

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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.

Reclassifications

Certain amounts presented in the prior year financial statements have been reclassified to conform with the current year presentation.

Recently Issued Accounting Pronouncements

In October 2012, the FASB issued Accounting Standards Update ("ASU") 2012-04, "Technical Corrections and Improvements." The amendments in this update cover a wide range of Topics in the Accounting Standards Codification. These amendments include technical corrections and improvements to the Accounting Standards Codification and conforming amendments related to fair value measurements. The amendments in this update will be effective for fiscal periods beginning after December 15, 2012. The adoption of ASU 2012-04 is not expected to have a material impact on our financial position or results of operations.

In July 2012, the FASB issued ASU 2012-02, "Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment." This update amends ASU 2011-08, Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment and permits an entity first to assess qualitative factors to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired as a basis for determining whether it is necessary to perform the quantitative impairment test in accordance with Subtopic 350-30, Intangibles - Goodwill and Other - General Intangibles Other than Goodwill. The amendments are effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. The adoption of ASU 2012-02 is not expected to have a material impact on our financial position or results of operations.

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 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, 2012 and December 31, 2011:

| | As of December 31, 2012 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Investment in money market funds (1) | $13,009,688 | $- | $- | $13,009,688 |
| Total assets | $13,009,688 | $- | $- | $13,009,688 |
| Liabilities: | | | | |
| Accrued warrant liability | font>$- | $- | $4,105,659 | $4,105,659 |
| Total liabilities | $- | $- | $4,105,659 | $4,105,659 |

| | As of December 31, 2011 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Investment in money market funds (1) | $16,326,888 | $- | $- | $16,326,888 |
| Total assets | $16,326,888 | $- | $- | $16,326,888 |
| Liabilities: | | | | |
| Compensatory stock options not yet issued (2) | $- | $- | $378,750 | $378,750 |
| Accrued warrant liability | - | - | 7,285,959 | 7,285,959 |
| Total liabilities | $- | $- | $7,664,709 | $7,664,709 |

(1) Included in cash and cash equivalents in the accompanying consolidated balance sheets.

(2) 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, 2012 and 2011, which were determined in a manner consistent with that described for grants of options to purchase common stock as set forth in Note 2:

| | 2012 | 2011 |
|---|---|---|
| Stock Price | $ 1.33 | $ 2.86 |
| Exercise Price | $ 1.60 - 5.00 | $ 1.60 - 5.00 |
| Term in years | 1.09 - 2.41 | 1.58 - 2.23 |
| Volatility | 82.75 - 95.91% | 66.68 - 71.55% |
| Annual rate of quarterly dividends | 0 % | 0 % |
| Discount rate- bond equivalent yield | .17 - .29 % | .20 - .28 % |

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, 2012 and 2011:

| | Year Ended December 31, 2012 | |
|---|---|---|
| | Accrued Warrant Liability | Compensatory Stock Options Issued After Year End |
| Beginning Balance | $ 7,285,959 | $ 378,750 |
| Total (gains) or losses (realized/unrealized) included in earnings (1)(2) | (7,701,981) | 51,823 |
| Issuances | 4,521,681 | - |
| Settlements | - | (430,573) |
| Balance, December 31, 2012 | $ 4,105,659 | $ - |

| | Year Ended December 31, 2011 | |
|---|---|---|
| | Accrued Warrant Liability | Compensatory Stock Options Issued After Year End |
| Beginning Balance | $ 25,350,733 | $ 2,992,180 |
| Total (gains) or losses (realized/unrealized) included in earnings (1)(2) | (19,821,787) | (17,953) |
| Issuances | 2,752,441 | 378,750 |
| Settlements | (995,428) | (2,974,227) |
| Balance, December 31, 2011 | $ 7,285,959 | $ 378,750 |
| Amount of total (gains) or losses for the period included in earnings as change in value of warrant liability attributable to the change in unrealized (gains) or losses relating to liabilities recorded at the reporting date: | | |
| December 31, 2011 | $ (19,790,451) | $ - |
| December 31, 2012 | $ (7,701,981) | $ - |

(1) Realized & unrealized gains or losses related to the accrued warrant liability were included as change in value of accrued warrant liability.
(2) Realized gains or losses related to compensatory stock options were included in research & development expense and general & administrative expense.

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, 2012 and 2011, the Company had no assets or liabilities that were measured at fair value on a nonrecurring basis.

The Company considers the accrued warrant liability to be Level 3 because some of the inputs into the measurements are neither directly or indirectly observable. The accrued warrant liability uses 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:

| Description | Fair Value | Valuation Technique | Unobservable | Range |
|---|---|---|---|---|

| | | | | Input | | |
|---|---|---|---|---|---|---|
| Accrued warrant liability | $ | 4,105,659 | Black-Scholes pricing model | Expected term (in years) | 1.09 - | 2.41 |
| | $ | 4,105,659 | | | | |

Management believes the value of the accrued warrant liability is more sensitive to a change in the Company's stock price at the end of the respective reporting period as opposed to a change in the expected term. At December 31, 2012, 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 3%, while a 10% decrease in the expected term would decrease the warrant liability by approximately 5%. A 10% increase or decrease in the Company's stock price would result in an increase or decrease in the accrued warrant liability of approximately 18%.

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, 2012 and 2011:

| | As of December 31, | |
|---|---|---|
| | 2012 | 2011 |
| Lab equipment | $1,903,533 | $1,739,217 |
| Computer equipment | 335,264 | 357,316 |
| Furniture | 523,665 | 499,791 |
| | 2,762,462 | 2,596,324 |
| Less accumulated depreciation | (1,775,909) | (1,512,120) |
| Equipment, net | $986,553 | $1,084,204 |

5. Noncontrolling Interests

On May 31, 2012, Bioprocess Capital Partners, LLC ("BCP"), the noncontrolling interest holder in Incuron, contributed approximately 194.0 million Russian rubles (approximately $5.9 million) to Incuron, which increased its ownership percentage to 40.8% and decreased CBLI's ownership percentage to 59.2%, which is the current ownership percentage at December 31, 2012.

On January 20, 2011 and March 14, 2011, BCP contributed 68.0 million Russian Rubles (approximately $2.3 million) and 1.73 million Russian Rubles (approximately $0.1 million), respectively, to Incuron, increasing their ownership percentage from 16.1% to 24.2% and decreasing CBLI's ownership percentage from 83.9% to 75.8%.

The following quantifies the effects of changes in CBLI's ownership interest in Incuron, on CBLI's equity for the years ending December 31, 2012 and 2011:

| | For the Year Ending December 31, | |
|---|---|---|
| | 2012 | 2011 |
| Net loss attributable to CBLI | $ (18,234,142 ) | $ (4,013,670 ) |
| Increase in CBLI's additional paid-in capital due to the issuance of additional membership interests to the noncontrolling interest of Incuron | 1,081,040 | 176,092 |
| Change from net income attributable to CBLI and issuance of additional membership interests to the noncontrolling interest of Incuron | $ (17,153,102 ) | $ (3,837,578 ) |

On October 4, 2011, CBLI consummated the transactions contemplated by the Investment Agreement, dated as of September 19, 2011 (the "Investment Agreement"), with "Rusnano," an open joint stock company organized under the laws of the Russian Federation, to provide funding to Panacela to carry out a complete cycle of development, research, performance of clinical trials, production and sales of a line of pharmaceutical drugs for the treatment of oncological, infectious or other diseases.

Pursuant to the Investment Agreement, (a) CBLI invested $3.0 million in Panacela preferred shares and warrants, and, together with certain third-party owners, assigned and/or provided exclusive licenses, as applicable, to Panacela in respect of certain intellectual property in exchange for Panacela common shares, and (b) Rusnano invested $9.0 million in Panacela preferred shares and warrants, with additional amounts of up to $17.0 million to be provided by Rusnano upon the achievement of certain development milestones as set forth in the Investment Agreement. At December 31, 2012, CBLI had an ownership stake of 54.6% in Panacela.

The Panacela preferred shares are convertible into common shares at any time following issuance. The conversion price is equal to the preferred share issuance price of $1,057 per share, subject to proportional adjustment for any stock split, stock dividend, reclassification or similar event with respect to the Panacela common shares. The preferred shares are automatically convertible into common shares upon the occurrence of a qualifying public offering of Panacela, carry no redemption rights and have the ability to vote and participate in dividends on a basis consistent with common shareholders.

The Panacela warrants provide CBLI and Rusnano with an option to increase their respective investments at two and four years following the initial investment. The warrants are exercisable into Panacela preferred shares at an exercise price equal to 20% or 40% above the preferred stock issuance price of $1,057 per share, subject to proportional adjustment for any stock split, stock dividend, reclassification or similar event with respect to the Panacela common shares.

The preferred shares and warrant instruments have been classified as permanent equity instruments by Panacela. The value assigned to the preferred shares and warrants was based on their relative fair value at the date of issuance. The resultant embedded beneficial conversion feature relating to the preferred shares was considered a deemed dividend, and since Panacela had an accumulated deficit, had no impact on the Panacela statement of stockholders' equity.

6. Stockholders' Equity

In October 2012, the Company completed a public offering of 7,500,000 units at a price of $2.00 per unit, with each unit consisting of one share of the Company's common stock, par value $0.005 per share, and one warrant to purchase 0.5 of a share of Common Stock at an exercise price of $3.00 per whole share (the "2012 offering"). The shares of Common Stock and the Warrants issued in the Offering were issued separately. Under the terms of the Underwriting Agreement, the Company also granted the Underwriters an option, exercisable for 30 days, to purchase up to an additional 1,125,000 shares of Common Stock (with an over-allotment price of $1.995 per share) and/or additional Warrants to purchase up to 562,500 shares of Common Stock (with an over-allotment price of $0.0094 for each Warrant to purchase a whole share) to cover over-allotments, if any. The underwriter exercised their option in part by purchasing 1,025,000 shares and 562,500 warrants of the over-allotment option within 30 days of the closing.

Certain warrants issued during the 2012 offering contain provisions that could require the Company to settle the warrants in cash and, accordingly, were originally recorded as a liability in the amount of $4,521,681 determined by the Black-Scholes valuation model with the following assumptions:

| | | |
|---|---|---|
| Stock price | $4.45 | |
| Exercise price | $5.00 | |
| Term in years | 2.50 | |
| Volatility | 69.36 | % |
| Annual rate of quarterly dividends | - | |
| Discount rate- bond equivalent yield | 0.53 | % |

The 2012 offering triggered a reduction in the exercise price of the Company's warrants issued in March 2010 from $4.00 to $2.00 per share.

In June 2011, the Company issued 5,872,500 shares of its common stock and warrants to purchase a total of 2,936,250 shares of its common stock for gross proceeds of $23.5 million. The common stock and warrants were sold in units, at a price of $4.00 per unit, with each unit consisting of: (a) one share of common stock; (b) a warrant to purchase 0.25 of a share of common stock, with an exercise price of $4.50 per share; and (c) a warrant to purchase 0.25 of a share of common stock, with an exercise price of $5.00 per share. In addition, the placement agent and the financial advisor also collectively received warrants to purchase up to 176,175 shares of common stock. In the event of stock splits,

stock dividends, combinations of shares and similar recapitalization transactions, the number of shares issuable and the exercise price associated with all warrants issued in this transaction may be adjusted. At December 31, 2011, all outstanding warrants were exercisable.

Certain warrants issued in June 2011 contain provisions that could require the Company to settle the warrants in cash, and accordingly, were originally recorded as a liability in the amount of $2,525,175 determined by the Black-Scholes valuation model with the following assumptions:

| | | |
|---|---|---|
| Stock price | $2.48 | |
| Exercise price | $3.00 | |
| Term in years | 2.51 | |
| Volatility | 79.70 | % |
| Annual rate of quarterly dividends | - | |
| Discount rate- bond equivalent yield | 0.35 | % |

In December 2010, the Company issued 1,400,000 shares of common stock to a single institutional accredited investor for an aggregate purchase price of $8,386,000. After related fees and expenses, the Company received net proceeds of approximately $7,730,000.

In March 2010, the Company issued 1,538,462 shares of common stock and warrants to purchase an aggregate of 1,015,385 shares of common stock, for an aggregate purchase price of $5,000,002. The placement agent also received warrants to purchase 123,077 shares of common stock. All of these warrants expire on March 2, 2015 and had an initial exercise price of $5.00, subject to adjustment.

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

| | Number of Warrants | Weighted Average Exercise Price | Number of Common Shares Exerciseable Into |
|---|---|---|---|
| Outstanding at December 31, 2010 | 7,530,689 | $ 3.71 | 9,450,633 |
| Granted | 3,112,425 | 4.76 | 3,112,425 |
| Exercise Price Adjustment | - | (0.70) | 592,341 |
| Exercised | (301,895) | 3.96 | (371,206) |
| Forfeited, Canceled | (220,000) | 8.09 | (220,000) |
| Outstanding at December 31, 2011 | 10,121,219 | 3.76 | 12,564,193 |
| Granted | 4,312,500 | 3.00 | 4,312,500 |
| Exercise Price Adjustment | - | (0.18) | - |
| Forfeited, Canceled | (4,055,724) | 5.07 | (6,498,698) |
| Outstanding at December 31, 2012 | 10,377,995 | $ 2.94 | 10,377,995 |

The following table sets forth the details of the outstanding warrants as of December 31, 2012:

| Expiration Date | Current Exercise Price | Number of Warrants |
|---|---|---|
| 3/2/2015 | $ 2.00 | 935,385 |
| 6/17/2015 | 5.00 | 176,175 |
| 2/12/2016 | 1.60 | 929,826 |
| 3/19/2016 | 1.60 | 1,921,795 |
| 3/26/2016 | 1.60 | 634,189 |

| | | |
|---|---|---|
| 6/22/2016 | 5.00 | 1,468,125 |
| 10/24/2017 | 3.00 | 4,312,500 |
| | | |
| | | 10,377,995 |

Equity Incentive Plan

The following is a summary of option award activity under the Plan for the year ended December 31, 2012:

| | Year Ended December 31, 2012 | | | |
|---|---|---|---|---|
| | Total Stock Options Outstanding | Weighted Average Exercise Price per Share | Nonvested Stock Options | Weighted Average Grant Date Fair Value per Share |
| December 31, 2011 | 4,117,979 | $ 5.21 | 356,100 | $ 3.38 |
| Granted | 1,132,383 | 1.89 | 1,132,383 | 1.32 |
| Vested | - | - | (960,233) | 1.61 |
| Exercised | (1,250) | 1.90 | - | - |
| Forfeited, Canceled | (232,196) | 3.49 | (123,750) | 1.73 |
| December 31, 2012 | 5,016,916 | $ 4.54 | 404,500 | $ 2.30 |

The following is a summary of outstanding stock options under the Plan as of December 31, 2012:

| | Stock Options Outstanding | Vested Stock Options |
|---|---|---|
| Quantity | 5,016,916 | 4,612,416 |
| Weighted-average exercise price | $ 4.54 | $ 4.66 |
| Weighted Average Remaining Contractual Term (in Years) | 7.33 | 7.20 |
| Intrinsic value | $ 38,634 | $ 33,522 |

For the years ended December 31, 2012, 2011 and 2010, the Company granted 1,132,383, 1,459,393 and 1,175,930 stock options, respectively, with a weighted-average grant date fair value of $1.32, $4.04 and $2.66, respectively. For the years ended December 31, 2012, 2011 and 2010, the total fair value of options vested was $1,549,888, $5,381,855 and $3,222,417, respectively. The total intrinsic value of options exercised for the years ended December 31, 2012, 2011 and 2010 was $1,485, $818,723 and $921,258, respectively.

As of December 31, 2012, total compensation cost not yet recognized related to nonvested stock options was $396,672. The Company expects to recognize this cost over a weighted average period of 0.83 years.

7. Significant Alliances and Related Parties

Roswell Park Cancer Institute

The Company has entered into several agreements with Roswell Park Cancer Institute (“RPCI”) including: various sponsored research agreements, an exclusive license agreement and a Clinical Trial Agreement pursuant to which CBLI has transferred the Entolimod IND for oncology indications to RPCI and RPCI is a sponsor of the currently ongoing Entolimod Advanced Cancer Phase 1 clinical trial. Additionally, the Company’s Chief Scientific Officer (“CSO”) is the Senior Vice President of Basic Research at RPCI.

The Company recognized $0, $2,317,218 and $12,398 of revenue from RPCI during the years ended December 31, 2012, 2011 and 2010, respectively. The Company incurred $3,876,073, $2,689,503 and $2,014,379 in expense to

RPCI related to research grants and agreements for the years ended December 31, 2012, 2011 and 2010, respectively. The Company had $900,300 and $29,298 included in accounts payable owed to RPCI at December 31, 2012 and 2011, respectively. In addition, the Company had approximately $553,644 and $237,451 in accrued expenses payable to RPCI at December 31, 2012 and 2011, respectively.

The Cleveland Clinic Foundation

The Cleveland Clinic Foundation (“CCF”) has entered into a strategic alliance to allow CBLI exclusive use of CCF licensed patents and technology. CBLI has the primary responsibility to fund all newly developed patents; however, CCF retains ownership of those patents covered by the agreement. CBLI also has 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. CCF will receive milestone payments for each product developed with CCF technology as development of such product(s) passes through major developmental stages. In addition, CBLI will pay CCF royalties and sublicense royalties as a percentage of net sales of all commercial products developed with CCF technology. Milestone payments amounted to $100,000, $100,000 and $0 for the years ended December 31, 2012, 2011 and 2010, respectively.

The Company also recognized $4,804, $2,558 and $3,459 as research and development expense to CCF for the years ended December 31, 2012, 2011 and 2010, respectively. The Company did not have any liabilities to CCF at December 31, 2012 and 2011.

Children's Cancer Institute Australia

Panacela entered into an agreement with Children's Cancer Institute Australia ("CCIA") to exclusively license certain rights to our Antimycon technology. In consideration for this exclusive license, Panacela agreed to make certain milestone, royalty and sublicense royalty payments. Under this agreement, Panacela has the right to exclusively license any inventions developed by CCIA relating to the Panacela compounds. CCIA 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. The license does not have a specified term, however, the royalty term is 20 years.

The Company recognized $120,106, $0 and $0 as research and development expense to CCIA for the years ended December 31, 2012, 2011 and 2010, respectively. The Company did not have any liabilities to CCIA at December 31, 2012 and 2011.

Consultants

CBLI has entered into a consulting agreement with our CSO, Dr. Andrei Gudkov. The Company incurred $200,695, $186,224 and $140,000 for consulting services in the years ending December 31, 2012, 2011 and 2010, respectively. The Company incurred $0, $24,476 and $62,238 in bonuses for the years ending December 31, 2012, 2011 and 2010, respectively. The Company incurred $32,659, $109,137 and $757,495 in non-cash, stock based compensation expense for the years ending December 31, 2012, 2011 and 2010, respectively.

The Company had $28,245 and $15,519 for consulting services included in accrued expenses at December 31, 2012 and 2011, respectively. The Company had $24,476 and $138,101 included in accrued bonuses for cash bonuses and compensation stock options not yet issued at December 31, 2012 and 2011, respectively.

Dr. Gudkov has equity interests in other entities that are unaffiliated with the Company. During the years ended December 31, 2012 and 2011, the Company recognized other income from these entities of $407,395 and $55,528, respectively. In addition, the Company held $1,959 and $283 in accounts receivable from these entities at December 31, 2012 and 2011, respectively.

8. 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, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| US operations | $(14,317,608) | $(1,775,053) | $(24,819,169) |
| Foreign operations | (8,097,032) | (3,454,672) | (1,852,688) |
| | $(22,414,640) | $(5,229,725) | $(26,671,857) |

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, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Deferred tax assets: | | | |
| Operating loss carryforwards | $37,642,000 | $28,972,000 | $22,452,000 |
| Accrued expenses | 8,576,000 | 7,778,000 | 5,618,000 |
| Tax credit carryforwards | 2,921,000 | 2,537,000 | 2,217,000 |
| Intellectual property | 3,377,000 | 1,604,000 | 395,000 |
| Outside tax basis difference in affiliate | 1,616,000 | 1,378,000 | 472,000 |
| Equipment | 237,000 | 156,000 | 21,000 |
| Other | 4,000 | 4,000 | 4,000 |
| Total deferred tax assets | 54,373,000 | 42,429,000 | 31,179,000 |
| | | | |
| Deferred tax liabilities | - | - | - |
| | | | |
| Net deferred tax asset | 54,373,000 | 42,429,000 | 31,179,000 |
| Valuation allowance | (54,373,000) | (42,429,000) | (31,179,000) |
| | | | |
| | $- | $- | $- |

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:

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | 2012 | 2011 | 2010 |
| Tax at the U.S. statutory rate | $(7,621,000) | $(1,778,000) | $(9,110,000) |
| Change in value of warrant liability | (2,619,000) | (6,739,000) | 5,444,000 |
| Stock option expenses | - | (140,000) | (92,000) |
| Valuation allowance | 10,204,000 | 8,639,000 | 3,729,000 |
| Other | 36,000 | 18,000 | 29,000 |
| | $- | $- | $- |

At December 31, 2012, the Company has U.S. federal net operating loss carryforwards of approximately $94,078,000, which begin to expire if not utilized by 2023, and approximately $2,921,000 of tax credit carryforwards that begin to expire if not utilized by 2024. The Company also has U.S. state net operating loss carryforwards of approximately $83,558,000, which begin to expire if not utilized by 2027 and state tax credit carryforwards of approximately $650,000, which begin to expire if not utilized by 2013.

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, 2011, 2010 and 2009 are still open for examination.

The following presents a rollforward of the unrecognized tax benefits and the associated interest and penalties:

| | Unrecognized Tax Benefits | Interest and Penalties |
|---|---|---|
| Balance at January 1, 2011 | $ 357,000 | $ - |
| Prior year tax position | - | - |
| Current year tax position | - | - |
| Deferred tax position | 50,000 | - |
| Settlements with tax authorities | - | - |
| Expiration of the statute of limitations | - | - |
| Balance at December 31, 2011 | 407,000 | - |
| Prior year tax position | - | - |
| Current year tax position | - | - |
| Deferred tax position | 30,000 | - |
| Settlements with tax authorities | - | - |
| Expiration of the statute of limitations | - | - |
| Balance at December 31, 2012 | $ 437,000 | $ - |

CBLI received New York State incentive tax credit refunds of $537,000, $367,000 and $438,000 during 2012, 2011 and 2010, 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.

9. Employee Benefit Plan

CBLI maintains an active defined contribution retirement plan for its employees (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’ contributions. The Company’s expense relating to the Benefit Plan was $201,510, $182,669 and $132,944 for the years ended December 31, 2012, 2011 and 2010, respectively.

10. 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 and minimum royalty payments for licensed patents. These amounts do not include any additional amounts that the Company may be required to pay under its license agreements upon the achievement of scientific, regulatory and commercial milestones, including milestones such as the submission of an investigational new drug application to the FDA and the first commercial sale of the Company's products in various countries. As of December 31, 2012 the Company is uncertain as to whether any of these contingent events will become realized. The Company is also party to five agreements that require it to make milestone payments, royalties on net sales of the Company's products, and payments on sublicense income received by the Company. There were no milestone payments or royalties on net sales

accrued for any of these agreements as of December 31, 2012 and 2011 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 is not a party to any pending material litigation or other material legal proceedings.

The Company has entered into employment agreements with three key executives who, if terminated by the Company without cause as described in these agreements, would be entitled to severance pay.

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. The Company made payments of $76,118 in 2012 under this capitalized lease obligation of which $23,708 was classified as interest payments and $52,410 were classified as principal payments. As of December 31, 2012 and 2011, accumulated depreciation for the leased equipment was $50,779 and $0, respectively.

As of December 31, 2012, future minimum future lease payments under capital leases are as follows:

| | |
|---|---|
| 2013 | $91,392 |
| 2014 | 91,392 |
| 2015 | 15,232 |
| Total minimum lease payments | 198,016 |
| Interest expense related to future periods | 28,735 |
| Present value of minimum lease payments | 169,281 |
| Less: current portion | 71,679 |
| | |
| Non-current portion | $97,602 |

Operating Leases

The Company leases laboratory facilities and office facilities at various locations with expiration dates ranging from 2013 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, 2012, 2011 and 2010, total rent expense related to the Company's operating leases was $459,150, $396,667 and $345,722, respectively.

As of December 31, 2012, future minimum payments under operating leases are as follows:

| | |
|---|---|
| 2013 | $571,640 |
| 2014 | 374,452 |
| 2015 | 381,163 |
| 2016 | 354,918 |
| 2017 | 365,565 |
| 2018 & beyond | 567,580 |
| | |
| Total minimum lease payments | $2,615,318 |

11. Quarterly Financial Data (Unaudited)

The following is a summary of the quarterly consolidated results of operations for the years ended December 31, 2012 and December 31, 2011:

| | March 31, 2012 | June 30, 2012 | September 30, 2012 | December 31, 2012 |
|---|---|---|---|---|
| Revenues | $931,397 | $258,237 | $ 219,575 | $ 2,161,501 |
| Loss from Operations | (7,481,875 ) | (9,161,724 ) | (7,841,541 ) | (5,561,466 ) |
| Net Income (Loss) | (6,398,894 ) | (5,906,870 ) | (12,315,676 ) | 2,206,800 |
| Net Income (Loss) Attributable to Cleveland BioLabs, Inc. | (5,387,146 ) | (5,078,684 ) | (10,877,836 ) | 3,109,524 |
| Basic Earnings (Loss) Per Share Available for Common Shareholders | $(0.15 ) | $(0.14 ) | $ (0.30 ) | $ 0.07 |
| Fully Diluted Earnings (Loss) Per Share Available for Common Shareholders | $(0.15 ) | $(0.14 ) | $ (0.30 ) | $ 0.07 |
| Weighted Average Shares Outstanding, Basic | 35,657,563 | 35,745,675 | 35,879,245 | 42,236,226 |
| Weighted Average Shares Outstanding, Diluted | 35,657,563 | 35,745,675 | 35,879,245 | 42,565,945 |

| | March 31, 2011 | June 30, 2011 | September 30, 2011 | December 31, 2011 |
|---|---|---|---|---|
| Revenues | $2,473,982 | $569,049 | $ 3,801,267 | $ 1,945,911 |
| Loss from Operations | (5,112,153 ) | (6,627,596 ) | (6,961,324 ) | (6,404,098 ) |
| Net Income (Loss) | (5,745,366 ) | 11,130,148 | (2,878,554 ) | (7,735,953 ) |
| Net Income (Loss) Attributable to Cleveland BioLabs, Inc. | (5,499,059 ) | 11,368,224 | (2,691,341 ) | (7,191,494 ) |
| Basic Earnings (Loss) Per Share Available for Common Shareholders | $(0.19 ) | $0.38 | $ (0.08 ) | $ (0.20 ) |
| Fully Diluted Earnings (Loss) Per Share Available for Common Shareholders | $(0.19 ) | $0.30 | $ (0.08 ) | $ (0.20 ) |
| Weighted Average Shares Outstanding, Basic | 29,110,979 | 30,033,049 | 35,447,032 | 35,553,413 |
| Weighted Average Shares Outstanding, Diluted | 29,110,979 | 37,588,006 | 35,447,032 | 35,553,413 |

12. Subsequent Events

None.

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, or the Exchange Act, as of December 31, 2012. 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 evaluation of our disclosure controls and procedures as of December 31, 2012, 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 declared 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 principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. 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, 2012.

The effectiveness of our internal control over financial reporting as of December 31, 2012 has been audited by Meaden & Moore, Ltd., an independent registered public accounting firm, as stated in their report which appears herein.

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, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B: Other Information

None.

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 the Company's Proxy Statement for the 2013 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," "Compensation Discussion and Analysis," "Management and Corporate Governance Matters - Compensation Committee Interlocks and Insider Participation," and "Compensation Committee Report" in the Company's Proxy Statement for the 2013 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 the Company's Proxy Statement for the 2013 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 Matters" in our Proxy Statement for the 2013 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 the Company's Proxy Statement for the 2013 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits, Financial Statement Schedules

The following exhibits are incorporated herein by reference or attached hereto.

| 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 Form 10-K for the year ended December 31, 2009, filed on March 22, 2010). |
| 3.2 | Second Amended and Restated By-Laws (Incorporated by reference to Form 8-K filed on December 5, 2007). |
| 4.1 | Form of Warrants issued to underwriters (Incorporated by reference to Amendment No. 3 to Registration Statement on Form SB-2 filed on July 10, 2006 (File No. 333-131918)). |
| 4.2 | Form of Common Stock Purchase Warrant (Series D Transaction) (Incorporated by reference to Form 8-K filed on March 30, 2009). |
| 4.3 | Form of Common Stock Purchase Warrant (Private Placement closed on March 2, 2010) (Incorporated by reference to Form 8-K/A filed on February 26, 2010). |
| 4.4 | Form of Series E and F Warrants (Incorporated by reference to Form 8-K filed on June 21, 2011). |
| 4.5 | Form of Warrant Agreement by and between Cleveland BioLabs, Inc. and Continental Stock Transfer & Trust Company (Incorporated by reference to Form 8-K filed on October 22, 2012). |
| 10.1 | Library Access Agreement by and between ChemBridge Corporation and Cleveland BioLabs, Inc., effective as of April 27, 2004 (Incorporated by reference to Amendment No. 1 to Registration Statement on Form SB-2 filed on April 25, 2006 (File No. 333-131918)). |
| 10.2 | Restricted Stock and Investor Rights Agreement between Cleveland BioLabs, Inc. and ChemBridge Corporation, dated as of April 27, 2004 (Incorporated by reference to Amendment No. 1 to Registration Statement on Form SB-2 filed on April 25, 2006 (File No. 333-131918)). |
| 10.3.1 | Exclusive License Agreement by and between The Cleveland Clinic Foundation and Cleveland BioLabs, Inc., effective as of July 1, 2004 (Incorporated by reference to Amendment No. 1 to Registration Statement on Form SB-2 filed on April 25, 2006 (File No. 333-131918)). |
| 10.3.2 | Second Amendment to Exclusive License Agreement, dated September 22, 2011, by and between The Cleveland Clinic Foundation and the registrant (Incorporated by reference to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).† |
| 10.4.1 | Employment Agreement by and between Cleveland BioLabs, Inc. and Dr. Michael Fonstein, dated August 1, 2004 (Incorporated by reference to Amendment No. 1 to Registration Statement on Form SB-2 filed on April 25, 2006 (File No. 333-131918)). |
| 10.4.2 | Amendment to Employment Agreement by and between Cleveland BioLabs, Inc. and Dr. Michael Fonstein, dated as of December 31, 2008 (Incorporated by reference to Form 10-K for the year ended |

December 31, 2008, filed on March 30, 2009).

10.5.1 Employment Agreement by and between Cleveland BioLabs, Inc. and Dr. Yakov Kogan, dated August 1, 2004 (Incorporated by reference to Amendment No. 1 to Registration Statement on Form SB-2 filed on April 25, 2006 (File No. 333-131918)).

10.5.2 Amendment to Employment Agreement by and between Cleveland BioLabs, Inc. and Dr. Yakov Kogan, dated as of December 31, 2008 (Incorporated by reference to Form 10-K for the year ended December 31, 2008, filed on March 30, 2009).

10.6 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 Form 10-Q for the period ended September 30, 2010, filed on November 15, 2010).

| | |
|---|---|
| 10.7.1 | Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Proxy Statement on Schedule 14A filed on April 1, 2008). |
| 10.7.2 | First Amendment to Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Form 8-K filed on June 9, 2010). |
| 10.7.3 | Second Amendment to Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Form 8-K filed on June 15, 2012). |
| 10.7.4 | Form of Stock Award Grant Agreement (Incorporated by reference to Form 8-K filed on June 15, 2012). |
| 10.7.5 | Form of Non-Qualified Stock Option Agreement (Incorporated by reference to Form 8-K filed on June 15, 2012). |
| 10.8.1 | Contract (W9113M-10-C-0088), effective as of September 15, 2010, between Cleveland BioLabs, Inc. and the U.S. Army Space and Missile Defense Command/Army Forces Strategic Command (the "2010 DoD Contract") (Incorporated by reference to Form 10-Q for the period ended September 30, 2010, filed on November 15, 2010). |
| 10.8.2 | Amendment of Solicitation/Modification of Contract No. 1, effective as of September 17, 2010, to the 2010 DoD Contract (Incorporated by reference to Form 10-Q for the period ended September 30, 2010, filed on November 15, 2010). |
| 10.8.3 | Amendment of Solicitation/Modification of Contract No. 2, effective as of June 23, 2011, to the 2010 DoD Contract (Incorporated by reference to Form 8-K filed on June 29, 2011). |
| 10.9 | 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 Form 8-K filed on October 25, 2006). |
| 10.10 | Sponsored Research Agreement between Cleveland BioLabs, Inc. and Roswell Park Cancer Institute Corporation, effective as of January 12, 2007 (Incorporated by reference to Form 8-K filed on January 12, 2007). |
| 10.11 | Form of Securities Purchase Agreement (Incorporated by reference to Form 8-K filed on March 30, 2009). |
| 10.12 | Form of Registration Rights Agreement (Incorporated by reference to Form 8-K filed on March 30, 2009). |
| 10.13 | Amendment and Waiver Agreement, dated March 20, 2009 (Incorporated by reference to Form 8-K filed on March 30, 2009). |
| 10.14 | Form of Amendment and Reaffirmation Agreement (Incorporated by reference to Form 8-K filed on March 30, 2009). |
| 10.15 | License Agreement between Cleveland BioLabs, Inc. and Zhejiang Hisun Pharmaceutical Co., Ltd., dated September 3, 2009 (Incorporated by reference to Form 8-K filed on September 9, 2009). |

| | |
|---|---|
| 10.16.1 | Participation Agreement, dated December 30, 2009, by and between Cleveland BioLabs, Inc. and Bioprocess Capital Partners, LLC (Incorporated by reference to Form 8-K filed on January 5, 2010). |
| 10.16.2 | First Amendment to Participation Agreement, dated April 13, 2010, by and between Cleveland BioLabs, Inc. and Bioprocess Capital Partners, LLC (Incorporated by reference to Form 10-Q for the period ended June 30, 2010, filed on August 16, 2010). |
| 10.17.1 | Securities Purchase Agreement dated February 25, 2010 (Incorporated by reference to Form 8-K filed on February 26, 2010). |
| 10.17.2 | Form of Amendment to Securities Purchase Agreement, dated December 23, 2010, among the Company and the amending purchasers identified on the signature pages thereto (Incorporated by reference to Form 8-K filed on December 29, 2010). |
| 10.18.1 | Consulting Agreement, dated January 1, 2010, between Cleveland BioLabs, Inc. and Andrei Gudkov (Incorporated by reference to Form 8-K filed on June 13, 2011). |

| | |
|---|---|
| 10.18.2 | First Amendment to Consulting Agreement, dated June 10, 2011, between Cleveland BioLabs, Inc. and Andrei Gudkov (Incorporated by reference to Form 8-K filed on June 13, 2011). |
| 10.19 | Engagement letter, dated as of June 16, 2011, by and between Cleveland BioLabs, Inc. and Rodman & Renshaw, LLC (Incorporated by reference to Form 8-K filed on June 21, 2011). |
| 10.20 | Form of Securities Purchase Agreement, dated June 17, 2011, by and between Cleveland BioLabs, Inc. and the investors in the Offering (Incorporated by reference to Form 8-K filed on June 21, 2011). |
| 10.21 | Employment Agreement, dated August 4, 2011, between the Company and C. Neil Lyons (Incorporated by reference to Form 8-K filed on August 4, 2011). |
| 10.22 | Investment Agreement, dated September 19, 2011, by and among Panacela Labs, Inc., the Registrant and Open Joint Stock Company Rusnano (Incorporated by reference to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011). |
| 10.23 | 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 Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).† |
| 10.24 | 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 Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011).† |
| 10.25 | Amended and Restated Exclusive Sublicense Agreement, dated September 23, 2011, by and between the registrant and Panacela Labs, Inc. (Incorporated by reference to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011). |
| 10.26 | Assignment Agreement, dated September 23, 2011, by and between Panacela Labs, Inc. and the registrant (Incorporated by reference to Form 10-Q for the period ended September 30, 2011, filed on November 9, 2011). |
| 10.27 | 2012 Executive Compensation Plan (Incorporated by reference to Form 8-K/A filed on April 30, 2012). |
| 10.28 | 2012 Long-term Executive Compensation Plan (Incorporated by reference to Form 8-K filed on June 15, 2012). |
| 14.1 | Code of Ethics for Senior Executives and Financial Officers (Incorporated by reference to Form 8-K filed on June 15, 2012). |
| 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, 2012: (i) Consolidated Balance Sheets at December 31, 2012 and 2011; (ii) Consolidated Statements of Operations for years ended December 31, 2012, 2011, and 2010; (iii) Consolidated Statements of Stockholders' Equity for period from January 1, 2010 to December 31, 2012; (iv) Consolidated Statements of Cash Flows for years ended December 31, 2012, 2011, and 2010; and (v) Notes to Consolidated Financial Statements as blocks of text.*

* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

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

SIGNATURES

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

CLEVELAND BIOLABS, INC.

Dated: March 18, 2013 By: /s/ YAKOV KOGAN
Yakov Kogan
Chief Executive Officer

CLEVELAND BIOLABS, INC.

Dated: March 18, 2013 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<br>Yakov Kogan | Chief Executive Officer and Director<br>(Principal Executive Officer) | March 18, 2013 |
| / S / C. Neil Lyons<br>C. Neil Lyons | Chief Financial Officer (Principal Financial and Accounting Officer) | March 18, 2013 |
| / S / James Antal<br>James Antal | Director | March 18, 2013 |
| / S / Paul DiCorleto<br>Paul DiCorleto | Director | March 18, 2013 |
| / S / Andrei Gudkov<br>Andrei Gudkov | Director | March 18, 2013 |
| / S / Bernard L. Kasten<br>Bernard L. Kasten | Director | March 18, 2013 |
| / S / Michael Fonstein<br>Michael Fonstein | Director | March 18, 2013 |
| / S / David Hohn<br>David Hohn | Director | March 18, 2013 |

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