CLEVELAND BIOLABS INC
Form 10-K
March 13, 2012

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, 2011

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). Yes x No ¨

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

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

Large accelerated filer ¨	Accelerated filer 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 $120,622,257. There were 35,612,912 shares of common stock outstanding as of March 6, 2012.

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant's 2012 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, 2011

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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, whose lead drug candidate CBLB502 is being developed for dual indications under (i) 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 (ii) under the FDA's traditional drug approval pathway as an anti-cancer agent and an oncology supportive care therapy. We anticipate that CBLB502, (i) once approved as a radiation countermeasure, will be sold to the U.S. government for the national stockpile and other defense-related purposes, allied foreign governments and the nuclear energy industry, and (ii) once approved as a cancer drug, will be sold to the public through traditional distribution channels.

Since our inception, we have pursued the research, development and commercialization of products that have the potential to evidence direct anti-cancer activity, prevent and treat acute radiation syndrome ("ARS"), and counteract the genotoxic effects of radio and chemotherapies for oncology patients. Presently we have nine product candidates in our pipeline that are being developed directly by us and our majority-owned subsidiaries. An illustration of our pipeline follows:

Indication	Product Candidate	Description	Development Stage
Radiation Countermeasure	CBLB502*	Radioprotectant and mitigating agent targeting increased survival from lethal exposure	Entering pivotal studies
Targeted Anti-Cancer	CBLB502	TLR5 agonist inducing innate immune response to targeted tumor types and liver metastases	Phase I
Supportive Care in Oncology	CBLB502	TLR5 agonist inducing downstream pro-survival cytokines yielding protection and regeneration of hypersensitive tissues	Pre-clinical
Neutropenia/HSCT**	CBLB612	Hematopoietic stem cell inducer and mobilizer to peripheral blood	Pre-clinical
Liver Cancer	CBLC102	Quinacrine	Phase Ib
Broad Anti-Cancer	CBLC137	Small molecule targeting FACT***	Pre-clinical/Phase I
Broad Anti-Cancer	Revercom	Chemotherapy adjuvant	Pre-clinical
Broad Anti-Cancer	Mobilan	Immunotherapy	Pre-clinical
Targeted Anti-Cancer	Arkil	Inhibitor of Androgen receptor	Pre-clinical
Targeted Anti-Cancer	Antimycon	Inhibitor of Myc oncogene	Pre-clinical
Anti-Infective	Xenomycins	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

To date, we have successfully negotiated contracts and grants with the U.S. government totaling $85.2 million for the development and procurement of our lead compound, CBLB502, for biodefense application as a radiation countermeasure. Of this $85.2 million, we have received development funding of approximately $43.8 million, of which we have recognized approximately $41.0 million in revenue through December 31, 2011. As of December 31, 2011, the federal government has the potential to fund an additional $41.4 million under our existing contracts and grants, including a $30 million procurement option for CBLB502. We have performed extensive safety and efficacy studies in non-human primates (“NHPs”) and rodents and have evaluated CBLB502’s safety profile in 150 healthy human volunteers. We are currently negotiating remaining studies with the FDA including animal efficacy trials, human safety trials and requisite data needed to confirm proper dose conversion between NHPs and humans, all of which are necessary to complete a dossier of information needed to submit a Biologic License Application, or BLA, to the FDA for marketing approval.

Our research in animal models has shown that CBLB502 may also exhibit anti-cancer effects, which provided the scientific rationale that supported an Investigational New Drug ("IND") application that was opened in the fourth quarter of 2011. A Phase I/II trial evaluating the safety and pharmacokinetic profile of CBLB502 in refractory patients with advanced cancers who evidence liver metastases is open for enrollment at Roswell Park Cancer Institute ("RPCI"). Evaluation of the effect that CBLB502 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 December 2010, we entered into a Participation Agreement with BioProcess Capital Ventures, a Russian Federation venture capital fund, to create a joint venture, Incuron, LLC ("Incuron"), to develop our Curaxin line of anti-cancer product candidates: specifically CBLC102, a nonproprietary molecule originally used to combat the effects of malaria, which we have identified as having direct anti-cancer properties; and CBLC137, a new, proprietary molecule that leverages similar mechanisms of action in combating cancer. Incuron is our majority owned subsidiary, with approximately 75.8% of its equity interests held by us at December 31, 2011.

In September 2011, we entered into an Investment Agreement with Open Joint Stock Company "Rusnano", or Rusnano, a $10 billion Russian Federation fund, governing the investment by both CBLI and Rusnano into Panacela Labs, Inc. ("Panacela"), a joint venture company formed to develop five separate product candidates (Revercom, Mobilan, Arkil, Antimycon and Xenomycins), all of which were in pre-clinical development at the end of 2011. Panacela is our majority owned subsidiary, with 54.6% of its shares held by us at December 31, 2011.

Additionally, we leverage close development relationships with RPCI, Cleveland Clinic Foundation ("CCF") and Children's Cancer Institute of 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.

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, and the threat of terrorist activities continues to exist globally.

The U.S. government provides funding to conduct biodefense research and support the development of drugs and vaccines as medical countermeasures against potential terrorist attacks. 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 Health and Human Services ("HHS"):

o National Institutes of Health ("NIH")/National Institutes of Allergy and Infectious Disease Health ("NIAID")

o Biomedical Advanced Research and Development Agency ("BARDA")

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- Department of Defense ("DoD"):

  - Joint Program Executive Office ("JPEO")/ Chemical Biological Medical Systems ("CBMS")

  - The Defense Threat Reduction Agency ("DTRA")

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 and countermeasures against emerging infectious diseases. NIH/NIAID is responsible for basic research and early stage development of biomedical products, which includes drugs such as CBLB502. Annual congressional appropriations provide funding to BARDA and NIH/NIAID to continue carrying out these roles. 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 was enacted in 2004 to procure HHS' medical countermeasures against biological, chemical, radiological and nuclear attacks and Congress subsequently appropriated $5.6 billion under the Project BioShield Act to be expended over ten years. HHS procures countermeasures under The Project Bioshield Act 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. To date, HHS has procured more than $2 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.

In June 2011, the U.S. House Energy and Commerce Committee approved a bill to reauthorize PAHPA, and the House of Representatives subsequently passed the legislation. In March 2012, the Senate passed its own version of the legislation. Members of the House of Representatives and the Senate will be meeting to resolve the differences, and bicameral legislation is expected to be approved and sent to the President for signature. In addition, the President's 2013 proposed budget supports an increase to $547 million to BARDA to enhance the advanced development of next generation medical countermeasures against chemical, biological, radiological and nuclear threats.

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

- Most biodefense countermeasures cannot ethically be studied for efficacy in humans. As a result, the Animal Rule, whereby efficacy is determined in animal models under conditions in which the results are predictive of the human response and safety is determined, was adopted by the FDA to allow for the approval of drugs and biologics in humans (see "Government Regulation –Animal Rule"); and

- Under a declared state of emergency, countermeasures may be procured for the Strategic National Stockpile under an Emergency Use Authorization prior to their full FDA licensure 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

Cancer is among the leading causes of death worldwide and is the second leading cause of death in the U.S., accounting for nearly 1 of every 4 deaths, and exceeded only by heart disease. The American Cancer Society estimates that about 1.6 million new cancer cases are expected to be diagnosed in 2012. In 2011, estimated annual sales of all anti-cancer drugs worldwide totaled approximately $110 billion. In recent years targeted therapies have become the preferred and most desired anti-cancer 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 made up approximately 60% of the total worldwide anti-cancer market of approximately $60 billion. 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.

Supportive care in cancer is another important area of the oncology market. Supportive care drugs can treat side-effects of a cancer therapy, reduce pain caused by cancer and/or improve immune-health during treatment. In 2009, the market size for supportive care products for cancer patients reached $11 billion; however, it has been on the decline due to the approval of more targeted and less toxic anti-cancer treatments. Because cancer is dependent on complex combination regimens, there will continue to be a need to develop newer and more effective supportive care products for cancer patients. One segment of this market, 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), which commanded a worldwide market of approximately $5.1 billion in 2008.

Also, in the supportive care space are medical radiation-protectors, which include only a single approved therapeutic with limited use due to side effects and limited drug efficacy.

STRATEGIES AND OBJECTIVES

Our strategy is to leverage our resources to achieve commercialization of our most advanced product candidate, CBLB502, while we establish our position as a leading developer of a broad range of oncology therapeutics. Key elements of our strategy include:

· Aggressively working towards the commercialization of CBLB502 as a radiation countermeasure. Our most advanced drug candidate, CBLB502, offers the potential to protect normal tissues against lethal exposure to radiation and is being developed under the Animal Rule for this indication. Moreover, because CBLB502 demonstrates the potential to address an unmet medical need and is intended to treat a serious or life-threatening condition, CBLB502 has been granted Fast Track and Orphan Drug status by the FDA. Due to the Fast Track designation of CBLB502, we are eligible to engage in early 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 a period of product exclusivity following approval of our BLA filing by the FDA (see “Government Regulation – Orphan Drug Designation”).

· Utilizing government initiatives to fund development and target initial markets. We anticipate that by partnering with government agencies to develop CBLB502 for applications that have been deemed useful for military and defense purposes, we have

created a market for our drug candidate for procurement by such agencies. To date, we have successfully negotiated contracts that have provided $43.8 million in development funding from government agencies and have the potential to provide an additional $41.4 million in development funding from government agencies, including a $30 million procurement option, for CBLB502 as a radiation countermeasure, and we continue to solicit additional development funding support. For more information see “Products in Development – Protectans – CBLB502 – Government Funding.” In addition, we have received a $5 million funding commitment for development of Curaxins from the Russian government through a Skolkovo Foundation grant.

- Creating a corporate structure that enables us to fund and develop multiple product candidates simultaneously. We believe that our corporate structure enables us to develop our pipeline of product candidates without distraction of our core management team. Our subsidiaries have independent management and substantially independent funding sources, which allows each of our companies to focus on the development of their respective product candidates. For more information on "Our Joint Venture Partnerships."

- 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."

- Developing clinical applications of our product candidates. Our R&D capabilities allow us to develop multiple products at various stages of development, the most advanced of which are CBLB502 and CBLC102, both of which are at the clinical stage of development, and CBLC137 for which an IND application has been filed in the Russian Federation. We expect these and other product candidates to progress through the various steps of pre-clinical and clinical development.

- Pursuing collaborations with pharmaceutical and biopharmaceutical companies to advance development of our pipeline of oncology therapeutics. We have initiated discussions with several established pharmaceutical companies with a focus on oncology therapeutics. These potential collaborators or others could provide the infrastructure, expertise and funding to advance our oncology compounds through later stage clinical development to commercialization. Of note, executed oncology licenses outpaced executed licenses in other therapeutic areas by 15% in 2011, coming in at over 35% of all therapeutic licenses. Early stage deals (i.e. licenses of product candidates in pre-clinical to Phase I development) represented approximately 73% of all deals consummated in 2011.

- Capitalizing on our knowledge and connections in the Russian Federation to expedite clinical data and, in some cases, to expedite the licensing of our pipeline compounds. Our Incuron and Panacela subsidiaries are examples of our ability to capitalize on our unique knowledge of the expedited Russian drug development process, alternative financing sources and researchers who can deliver high quality data. Incuron is using Russian clinical data and research infrastructure to expedite parallel development tracks in both the Russian and U.S. markets, while Panacela is exploring a development paradigm aimed at accelerating global clinical development through initial development and commercialization in the Russian Federation.

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 anti-cancer radiation 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 NF-κB (a pro-survival regulator).

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

(i) Temporary and reversible suppression of apoptosis in normal cells to protect healthy tissues from stress-induced damage using compounds categorized as Protectans; and

(ii) Reactivation of apoptosis in tumor cells to eliminate cancer using compounds categorized as Curaxins.

Protectans, including our lead compounds CBLB502 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 CBLB502 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 our lead compounds CBLC102 and CBLC137, 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 anti-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. Curaxins: anti-cancer compounds that simultaneously suppress NF-kB and activate p53 by targeting FACT. Science Translational Medicine 2011 Aug 10; Volume 3, pp. 1-12). 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 2010, we entered into our Incuron joint venture with Bioprocess Capital Ventures , a Russian Federation venture capital fund, to develop our Curaxin compounds for cancer, liver, viral and age related disease applications. According to the terms of the agreement, we transferred the aforementioned rights of Curaxin molecules to the new joint venture, and Bioprocess Capital Ventures will contribute an aggregate of 549,497,000 Russian rubles (approximately $17.1 million based on the current exchange rate) to support development of the compounds. As of December 31, 2011, we have received from Bioprocess Capital Ventures payments of 175,570,000 Russian rubles (approximately $5.5 million based on the current exchange rate). Bioprocess Capital Ventures will make the balance of its contribution of 373,927,000 Russian rubles (approximately $11.6 million based on the current exchange rate) upon the achievement of predetermined development milestones.

As of December 31, 2011, we had an approximately 75.8% ownership interest in Incuron. Although it is anticipated that we will ultimately own 50.1% of the membership interest in Incuron, depending on the U.S. dollar/Russian ruble exchange rate and the U.S. dollar-equivalent value of the aggregate contributions made by BCV, we may be required to either transfer a portion of our ownership interest to Bioprocess Capital Ventures or make a cash contribution to Incuron. In such a case, if we choose to transfer a portion of its ownership interest to Bioprocess Capital Ventures, 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 the board of directors of Incuron. We also serve as a subcontractor to Incuron to support certain mechanistic studies and oversee clinical development in the U.S.

Panacela

In October 2011, we consummated the transactions contemplated by the Investment Agreement, dated as of September 19, 2011 (the “Investment Agreement”), with Panacela and Rusnano to provide funding to Panacela. Panacela was formed 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, (i) 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 our Mobilan, Revercom, Antimycon, Arkil and Xenomycin product candidates in exchange for Panacela common shares, and (ii) 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. Some of the milestones must be satisfied within designated time frames in order for Rusnano to make the related milestone payments.

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 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.

As of December 31, 2011, we have an ownership stake of approximately 54.6% in Panacela. It is anticipated that we will retain an ownership stake of approximately 51% in Panacela after giving effect to all subsequent investments by Rusnano, the exercise of all the warrants held by us and the completion of the third party investment.

PRODUCTS IN DEVELOPMENT

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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 CBLB502, would be expected to selectively protect only normal cells and, therefore, be useful to prevent side effects of anti-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 the Nuclear Factor kappa-B (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 classes of these compounds (which we refer to as Protectans): CBLB500 and CBLB600. CBLB500 and CBLB600 series 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, CBLB500 series compounds are pharmacologically optimized derivatives of the Salmonella flagellin protein and CBLB600s are synthetic lipopeptides that mimic 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 have demonstrated that both classes of Protectans (CBLB500s and CBLB600s) are capable, within safe dose ranges, of protecting mammalian organisms from lethal doses of radiation (Burdelya, et al., 2008. An agonist of Toll-like receptor 5 has radioprotective activity in mouse and primate models. Science 320:226; Singh, et al., 2011. CBLB613: A TLR2/6 agonist, natural lipopeptide of Mycoplasma arginini, as a novel radiation countermeasure. Radiation Research [Dec. 16 Epub ahead of print]; Shakhov, et al., 2012. Prevention and mitigation of acute radiation syndrome in mice by synthetic lipopeptide agonists of Toll-like receptor 2 (TLR2). PLoS, in press). 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. These findings validate our original concept aimed at development of apoptosis-suppressing microbial products as tissue

protectants.

Our tests 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 is not associated with prevention of apoptosis, but rather 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 outside of their original intended uses as tissue protective supportive care drugs in oncology. Thus, we believe that Protectans are strong prospective candidates for use in cancer immunotherapy, hematopoietic stem cell amplification and mobilization and protection from ischemia-reperfusion injuries. We have filed a number of patent applications in respect of Protectans.

CBLB502

CBLB502 is our lead compound in the CBLB500 series of Protectans. CBLB502 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 CBLB502 has in vivo tissue protective effects in animal models of a number of tested scenarios, including (i) protection against death following acute high-dose radiation exposure, (ii) protection of healthy tissues (but not tumors) from radiation and chemotherapy in cancer treatment models, and (iii) alleviation of ischemia-reperfusion-induced acute kidney injury.

We also believe that CBLB502 has direct anti-cancer effects, which appear 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 recently demonstrated that liver hepatocytes show a rapid, primary NF-kB activation response following in vivo administration of CBLB502 in mice and NHPs. The response of these cells was shown to be essential for CBLB502's efficacy in protecting the HP system against radiation damage. In addition, studies showed that CBLB502 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 CBLB502.

In summary, we believe that CBLB502 is a promising drug candidate in that it 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 safe for the organism as a whole. Our recent success in solving the crystal structure of flagellin bound to TLR5 revealed the structural basis of CBLB502-induced TLR5 signaling (Yoon, et al. (2012) Structural Basis of TLR5-Flagellin Recognition and Signaling. Science 335:859-864), which may allow future precise manipulation of the activity of CBLB502.

CBLB502 Biodefense Application: Prevention and Mitigation of Acute Radiation Syndrome

Acute high-dose whole body or significant partial body radiation exposure induces massive apoptosis of cells of the HP system and GI tract, which leads to ARS, a frequently 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 real possibilities 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 CBLB502, 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 CBLB502 as a radiation countermeasure in humans, development of the compound for this indication is guided by the Animal Rule (see "Government Regulation – Animal Rule").

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The efficacy of CBLB502 as a radiation countermeasure has been primarily assessed in mice and NHPs (Rhesus macaques). These studies demonstrated that a single intramuscular injection of CBLB502 given either before or after lethal total body irradiation led to significant improvement in animal survival. On average, these studies show that treatment resulted in a four-fold increase in survival. For example, survival of NHPs was increased from 20% in the control group to 70% to 80% in CBLB502-treated groups when injections were administered 48 hours after irradiation.

We believe that an important advantage of CBLB502, over any other radiation countermeasure known to us, is its ability to effectively protect against both 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 CBLB502 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 also shown that CBLB502 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;
- Protects against/mitigates both HP and GI sub-syndromes of ARS;
- Stability, storage and administration characteristics consistent with requirements for stockpiling and emergency civilian or military field use; and
- High-yield manufacturing processes.

Regulatory Status of CBLB502 for Biodefense Applications

For use as a medical radiation countermeasure, CBLB502's development 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 CBLB502 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 ARS. The mechanism of action of CBLB502 is well understood and dose-dependent biomarkers of CBLB502 efficacy that are relevant to its mechanism of action and easily measured in quantitative assays have been identified. 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. We anticipate moving forward with remaining pivotal animal studies after determining expected requirements to satisfy a BLA filing through discussions with the FDA.

In addition, we have made progress towards establishing the safety of CBLB502 by completing two clinical studies that involved administration of a range of doses of CBLB502 into 150 healthy human volunteers. Both studies indicated that administration of CBLB502 resulted in rapid and potent cytokine responses, indicative of tissue specific NF-kB activation, similar to those seen in previously conducted NHP studies. The most frequent adverse event associated with CBLB502 administration was a transient flu-like syndrome, which was predictable based upon the mechanism of action of the compound. We anticipate moving forward with a third definitive safety study in an appropriate number of healthy human subjects as determined through discussions with the FDA.

In July 2010, the FDA granted our application for Fast Track status in respect of CBLB502 (see "Government Regulation – Fast Track Designation"). Fast Track status will allow 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 CBLB502 development plan and preparation and approval of the BLA. The FDA is engaging in a highly interactive review of the IND application at this time.

CBLB502 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 CBLB502 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 CBLB502, we have established a high-yield cGMP compliant manufacturing process. The process that we developed gives us the ability to manufacture up to five million estimated doses within a year without any additional scale-up. We currently have drug substance corresponding to several hundred thousand projected human doses.

Prior to our submission for FDA licensure for CBLB502 for biodefense applications, we will need to complete several remaining steps, including:

- Conducting pivotal animal efficacy studies in accordance with Good Laboratory Practices, or GLP. Studies will utilize our cGMP manufactured drug. We expect to complete dosing in these studies in 2013;

- Performing a third human safety study in a larger number of volunteers. We estimate completion of dosing in this study in 2013; and

- Filing a BLA, which we expect to submit in 2014.

Government Funding of CBLB502 for Biodefense Applications

CBLB502 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 CBLB502 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 CBLB502 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 setting.

CBLI has received multiple grants and contracts for development funding for CBLB502'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 - 03/2013
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	1,589,106	01/2011 - 05/2012
Various	Various	5,790,905	Various
	Total federal government funding	$ 85,178,468	

* 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 CBLB502 through the receipt of approval from the FDA. Selected tasks related to the advanced development of CBLB502 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 Harmonisation-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 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.

Medical Applications of CBLB502

Targeted Anti-Cancer Treatment

CBLB502 may be used as a targeted anti-cancer agent. We have demonstrated this effect in a number of models of transplanted tumors grown in mice and rats, including colon and lung cancer, lymphoma and melanoma. In one of the animal models of transplanted colon cancer, CBLB502 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 anti-cancer effect of CBLB502 involves tissue-specific activation of innate immune responses via interaction of CBLB502 with its receptor, TLR5. The strength of the anti-tumor effect largely depends upon the level of TLR5 expression in the tumor. However, in our animal experiments of tumors residing in the liver, which has been identified as a natural primary target organ of CBLB502, tumors are effectively suppressed by the CBLB502-induced immune response regardless of their TLR5 status, indicating that CBLB502 may be particularly effective in treating liver

metastases and primary tumors located in the liver.

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

CBLB502 may also be used as an adjuvant to standard anti-cancer 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 CBLB502 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 CBLB502-mediated protection is limited to normal, non-cancerous cells. CBLB502 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., 2011. Toll-like receptor 5 agonist protects mice from dermatitis and oral mucositis caused by local radiation: implications for head-and-neck cancer radiotherapy. International Journal of Radiation Oncology, Biology, Physics [Oct 14 Epub ahead of print]). CBLB502 was also shown to reduce the toxicity of chemotherapeutic drugs in preliminary animal studies. At the current time, we plan to pursue development of CBLB502 as a broadly applicable adjuvant capable of improving the therapeutic index of existing anti-cancer agents.

These findings indicate that CBLB502 combines properties of both supportive care and direct anti-cancer drugs. We, therefore, plan to initiate multiple Phase I/II studies with CBLB502 in cancer patients to explore both supportive care and targeted anti-cancer effects.

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 CBLB502 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. Journal of Immunology 187:3831).

Based on this scientific foundation, the DoD awarded a $1 million grant to CCF in 2008 to conduct pre-clinical studies on CBLB502 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 CBLB502 treatment accelerated limb recovery in an animal model of tourniquet-mediated injury. Administration of CBLB502 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.

Regulatory Status of CBLB502 for Oncology Applications

An IND application for clinical testing of CBLB502 in oncology patients was opened with the FDA in October 2011. Enrollment was recently opened in a study to evaluate the safety and pharmacokinetic profile of CBLB502 in patients with advanced cancers. Up to forty-eight patients are expected to be enrolled in multiple trial cohorts to determine the safety, tolerability and maximum tolerated dose of repeated administrations of CBLB502. Evaluations for any preliminary evidence of anti-cancer activity of CBLB502 in advanced cancer patients will also be performed.

In contrast to the biodefense application of CBLB502 as a radiation countermeasure, other applications of CBLB502 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 CBLB502 as an anti-cancer treatment, we expect to complete various tasks, including:

- Performing one or two initial Phase I/II human efficacy studies on a small number of cancer patients. We expect to complete these studies two years from the receipt of allowance from the FDA of the IND amendment;

- 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 CBLB502, 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 (Singh, et al., 2011. CBLB613: A TLR2/6 agonist, natural lipopeptide of Mycoplasma arginini, as a novel radiation countermeasure. Radiation Research [Dec. 16 Epub ahead of print]; Shakhov, et al., 2012. Prevention and mitigation of acute radiation syndrome in mice by synthetic lipopeptide agonists of Toll-like receptor 2 (TLR2). PLoS, in press).

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 (i) 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 (ii) 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.

Our 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 I clinical trial is expected to be performed, following the release of a cGMP batch and allowance of an IND application by the FDA in healthy subjects 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 with cGMP-manufactured CBLB612;
- Submitting an IND application and receiving allowance from the FDA to conduct clinical trials;
- Performing a Phase I 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.

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 recently 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. Science Translational Medicine Volume 3, pp. 1-12). 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 new mechanistic knowledge provided additional rationale for the use of Curaxins as anti-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.

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Our Curaxin program has already brought two molecules to advanced stages of development. These include an old anti-malaria drug quinacrine (CBLC102), which was found to act as a Curaxin, and CBLC137, a representative of a new generation of Curaxins with proprietary structure and significantly improved anti-cancer activity. Moreover, we recently 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. Journal of Virology 84:9390). 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-fungal applications (see below).

CBLC102

CBLC102 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. CBLC102 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 an anti-cancer agent.

Development/Regulatory Status of CBLC102

Based upon Quinacrine's historical safety record and our extensive basic research and pre-clinical studies with CBLC102 and other Curaxins (including demonstration of CBLC102's efficacy in suppressing growth of human tumor cells transplanted into primates), we filed an IND application for the application of the CBLC102 as a cancer treatment. The first human anti-cancer trial with this drug was a Phase II 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. CBLC102 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 CBLC102 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 CBLC102 in cancer patients in the Russian Federation. The study is an open-label, dose escalation, Phase 1b 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 CBLC102. Secondary objectives include describing the pharmacokinetics and response to CBLC102.

The study includes a dose escalation arm of up to 30 patients divided into five cohorts, with an additional six patients enrolled at the selected therapeutic dose. Patients are treated with CBLC102 for eight weeks, with a loading dose administered in week 1 and maintenance doses administered in weeks 2 through 8. Dose escalation is done gradually, starting with a loading dose of 300mg and a maintenance dose of 100mg. Dosing in this study is currently ongoing.

We anticipate that additional clinical efficacy studies will be required before we are able to apply for licensure of CBLC102. Because of the uncertainties of the scope of the remaining clinical studies, we cannot currently estimate when any development efforts may be completed or the cost of completion. Nor can we estimate when we may realize any cash flow from the development of CBLC102.

CBLC137

Based on our research relating to CBLC102 and other first generation Curaxins, we set out to identify related compounds with similar activities and mechanisms of action, but potentially improved efficacy and other characteristics. Therefore, a focused chemical library of more than 800 proprietary compounds was built around one of the original Curaxin “hits” and used for structure-activity optimization.

CBLC137 has emerged as our lead second generation Curaxin, demonstrating reproducible anti-tumor effects in animal models of colon, breast, renal and prostate cancers. Our tests indicate that CBLC137 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 CBLC137

An IND for the oral formulation of CBLC137 was filed with the regulatory authority in the Russian Federation. An intravenous formulation for CBLC137 is being optimized and prepared for formal pre-clinical studies in the United States.

CBLC137 is at an early stage of its development and, as a result, it is premature to estimate when any development may be completed, the cost of development or when any cash flow could be realized from development.

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 anti-cancer and anti-infective compounds with diverse mechanisms of action in various early stages of development. Currently, these product candidates are being developed by Panacela. These include:

Revercom

Revercom is an anti-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.

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, 2011, 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, 2011.

Patents Relating to Protectans

CBLB502

As of December 31, 2011, we co-owned one U.S. provisional patent application and held exclusive licenses to two U.S. patents, six U.S. patent applications, 26 foreign patents and 20 foreign patent applications relating to our product candidate CBLB502. The U.S. provisional patent application was converted to a PCT application in January 2012. 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, 2011, 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, three foreign patents, and 15 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

CBLC102

As of December 31, 2011, we co-owned and exclusively licensed one U.S. patent application and 6 foreign patent applications and we exclusively licensed three U.S. patent applications and 3 foreign patent applications relating to our product candidate CBLC102. The patents that may be issued based on these patent applications are scheduled to expire between 2026 and 2029.

CBLC137

As of December 31, 2011, we owned one U.S. patent application and 22 foreign patent applications relating to our product candidate CBLC137. The patents that may be issued based on these patent applications are scheduled to expire in 2029.

Other Compounds

Mobilan

As of December 31, 2011, we co-owned and exclusively licensed one PCT patent application relating to our product candidate Mobilan. The patents that may be issued based on the PCT patent application are scheduled to expire in 2030.

In addition, Mobilan incorporates the composition of matter of CBLB502, for which we exclusively license one U.S. patent, two U.S. patent applications and six foreign patent applications. The patent covering the CBLB502 composition of matter, and the patents that may be issued based on the patent applications, are scheduled to expire in 2026.

Revercom

As of December 31, 2011, we exclusively licensed seven foreign patents and one U.S. non-provisional patent application. The issued patents, and the patents that may be issued based on these patent applications, are scheduled to expire in 2026.

Arkil

As of December 31, 2011, we co-owned and exclusively licensed one U.S. patent application and one PCT patent application. The patents that may be issued based on the patent applications are scheduled to expire between 2026 and 2030.

Antimycon

As of December 31, 2011, we exclusively licensed two U.S. provisional patent applications relating to our product candidate Antimycon. Each of these applications is scheduled to expire in 2012 if a non-provisional application claiming priority thereto is not filed. We currently intend to file such non-provisional patent applications prior to the expiration of the provisional patent applications.

Xenomycin

As of December 31, 2011, we owned one U.S. patent application and 22 foreign patent applications relating to our product candidate Xenomycin. The patents that may be issued based on these patent applications are scheduled to expire in 2029.

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 (i) the Uniformed Services University of the Health Sciences, which includes the Armed Forces Radiobiology Research Institute, (ii) the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., and (iii) 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 CBLB502 and perform analysis of HP stem cell mobilization in NHPs. This agreement expires in August 2012, but may be unilaterally terminated by any party upon 30 days prior written notice with or without cause.

Under the CRADA, ownership of any inventions made in the performance of the CRADA is determined in a manner substantially similar to U.S. patent law. In addition, under the CRADA, CBLI and CCF granted to the U.S. government (i) a non-exclusive, non-transferable, irrevocable, paid-up license to practice any subject inventions and throughout the world by or on behalf of the government for research or other government purposes; and (ii) a non-exclusive, non-transferable, irrevocable, paid-up copyright license in respect of all works of authorship and mask works prepared pursuant to the CRADA. The CRADA provides that data and other research materials produced in the performance of the CRADA will be owned by the party(ies) who produced it.

Roswell Park Cancer Institute

We have entered into 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 CBLC102. 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 (i) any technological improvements to the Mobilan, Antimycon, Arkil, Revercom and Xenomycin technologies developed by RPCI before September 2016, and (ii) 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. This sponsored research agreement has a term of six years from its effective date of January 12, 2007 and may be terminated at any time upon mutual agreement by the parties. 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 between February 29, 2012 and July 31, 2012.

We entered into an asset transfer and clinical trial agreement with RPCI for the conduct, by RPCI, of our Phase I clinical trial to evaluate the safety and pharmacokinetic profile of CBLB502 in patients with advanced cancers. Either party may terminate this agreement upon thirty days' notice to the other party.

Children's Cancer Institute of 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 Antimycon, Mobilan, Revercom, Arkil or Xenomycin. 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 twenty years.

Zhejiang Hisun Pharmaceutical Co. Ltd.

In September 2010, we executed a license agreement granting Zhejiang Hisun Pharmaceutical Co. Ltd., or Hisun, a leading pharmaceutical manufacturer in the People's Republic of China, exclusive rights to develop and commercialize CBLB612 in China, Taiwan, Hong Kong and Macau (the "Territory"). Under the terms of the license agreement, we received product development payments of $1.65 million for protectan research (including CBLB502). Hisun will be responsible for all development and regulatory approval efforts for CBLB612 in the Territory. In addition, Hisun will pay us a royalties on net sales over the 20-year term of the agreement.

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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 CBLB502 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 CBLC102, we have contracted with Regis Technologies, Inc., based in Illinois, to manufacture sufficient amounts for clinical trials. For CBLC137, we have contracted with Aptuit, Inc., based in Missouri, to manufacture sufficient amounts for clinical trials. For Mobilan, we have contracted with Lonza Houston, Inc., based in Texas, to manufacture sufficient amounts for pre-clinical testing leading to clinical trials. We do not have contracts for the manufacture of any of our other potential products.

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 important advantages 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

Our biodefense product candidate, CBLB502, 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, particularly 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.

In the area of radiation countermeasures, various companies, such as Cellerant Therapeutics, Aeolus Pharmaceuticals, Neumedicines, Inc., Onconova Therapeutics, Inc., Araim Pharmaceuticals, Inc., RxBio, Inc., Exponential Biotherapies Inc., ImmuneRegen BioSciences, Inc. and Humanetics Corporation are developing biopharmaceutical products that potentially directly compete with CBLB502, 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 CBLB502 is intended to address.

Medical Applications

The number of anti-cancer therapies is extremely large, numbering in the thousands. In recent years targeted therapies have become the preferred and most desired anti-cancer 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.

Chemotherapy is the second largest anti-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. Given the genotoxic effects that typically accompany chemotherapy regimens, supportive care medical countermeasures is another category important to the oncology market.

Supportive care treatments, such as Procrit® (Janssen Products, LP) to increase red blood cells, Zometa® (Novartis) for bone metastases and Emend® (Merck & Co.) an anti-emetic, are just a few of the types of drugs in the supportive cancer care category. These drugs can treat side-effects of a cancer therapy, reduce pain of the cancer or improve immune-health during treatment. Because cancer treatments are dependent on complex combination (and still toxic) regimens, there will continue to be a need to develop newer and more effective supportive care products for cancer patients.

Also in the supportive care space are medical radiation-protectors, which are currently limited to Ethyol® (MedImmune). This radiation-protector is limited because of the side effects and limited efficacy of the drug.

Stem cell mobilization is yet 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.:

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- 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 Good Clinical Practices in the case of clinical trials and according to Good Laboratory Practices 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 I: 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 II: 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 III: 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 points typically occur prior to submission of an IND, at the end of Phase II, 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 II meeting to discuss their Phase II clinical results and present their plans for the pivotal Phase III 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 I, Phase II and Phase III 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 CBLB502 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 CBLB502 to foreign countries.

All data obtained from the pre-clinical studies and clinical trials of CBLB502, 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 CBLB502.

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. CBLB502 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 CBLB502 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 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

CBLB502 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

CBLB502 has 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. 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.

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 7, 2012, we had 60 employees, 58 of whom were full-time employees.

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.

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 $5.3 million, $26.6 million and $12.8 million for the years ended December 31, 2011, 2010 and 2009, 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, CBLB502;
- 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. 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. 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 late-stage 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, 2011, we had federal net operating loss carryforwards, or NOLs, of $72.5 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 imposes 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, 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 CBLB502 for biodefense applications and clinical trials of CBLB502, CBLB612, CBLC102 and CBLC 137 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 CBLB502 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 CBLB502 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;

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

As of December 31, 2011, we owned 75.8% of the equity interests in Incuron and 54.6% of the equity interests in Panacela. Although our subsidiaries are majority owned by us and are consolidated in our results, they have significant non-controlling interest holders, each of which are funds controlled 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 subsidiaries, both we and our co-owners have certain rights in respect of such subsidiaries. Our subsidiaries provide the right to each party to designate certain of the board members and certain decisions in respect of our 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 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 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 subsidiaries. In the case of Panacela, we are required to meet the milestones within set time periods. As of December 31, 2011, Incuron and Panacela were potentially entitled to $11.6 and $17 million of future milestone-based payments, respectively (in the case of Incuron, based on an exchange rate of 32.1961 Rubles/USD as of December 31, 2011). 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 CBLB502, one collaborator to produce CBLC102, one collaborator to produce CBLC137, and one collaborator to produce Mobilan, and we do not have any collaborative manufacturing agreements for our other product candidates. For a variety of reasons, dependence on any single manufacturer may adversely affect our ability to develop and commercialize our product candidates on a timely and competitive basis. In addition, our current contractual arrangements alone may not be sufficient to guarantee that we will be able to procure the needed supplies as we complete clinical development and/or enter commercialization.

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

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

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

- Contract manufacturers are businesses and, hence, are subject to various business risks inherent to their company.

- 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 CBLB502 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, the timing thereof, or the scope. 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 CBLB502 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 2010, the IND application for CBLB502 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 three (3) additional background information meetings with DMIP during 2011 to review the product mechanisms of action, safety profile and preliminary estimation of an

effective human dose and are now in the process of working towards reaching an agreement with FDA on the scope and design of our remaining developmental program for CBLB502. However, there can be no guarantee that we will reach a satisfactory agreement in a timely manner, or at all.

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. 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 CBLB502 for biodefense applications outside the U.S. based on our animal efficacy and human safety data.

The Fast Track designation for CBLB502 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 CBLB502 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.

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 2011, we received 87.6% of our revenues from government contract and grant development work in connection with grants from the DoD, NIH and BARDA. In 2010 and 2009, we received 100% and 88.5% 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, on May 31, 2011, we announced that we had concluded advanced stages of contract negotiation with BARDA for the funding of certain development activities relating to CBLB502 for biodefense applications in our 2010 proposal to BARDA. BARDA indicated that further contract-related negotiations will require clarification of the development path for CBLB502 for biodefense applications with the FDA, which is in the process of actively reviewing our IND application for CBLB502. 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 have initiated the process of responding to BARDA's currently open Broad Agency Announcement by submitting a white paper. However, as with any federal contract proposal, there is no assurance that BARDA will invite us to submit a proposal or that if we are invited that our new proposal will result in an award from BARDA. Additionally, there is no assurance that BARDA will review our white paper or our proposal (if requested) 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 radioprotectors 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.

We do not believe that any of the products we are currently developing infringe upon the rights of any third parties or are infringed upon by third parties; however, 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. 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.

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 safely 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.

CBLB502 for biodefense applications is being developed to treat a disease radiation sickness, which is a disease that may be caused 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 CBLB502. Changes in government budgets and agendas, however, may result in future funding being decreased and de-prioritized, and 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.

The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. On July 21, 2010, the Dodd-Frank Wall Street Reform and Protection Act (the "Dodd-Frank Act") was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access, and such rulemaking is ongoing. 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 2011 through December 2011, the market price of our common stock, which is listed on the NASDAQ Capital Market, fluctuated from a high of $9.60 per share in the first quarter of 2011 to a low of $2.10 in the third quarter of 2011. 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, 2011, we had 35,612,192 shares of our common stock and 0 shares of our preferred stock issued and outstanding and 10,121,219 warrants exercisable into 12,564,193 shares and 4,117,979 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.

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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 you may not receive funds without selling your 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, you may have to sell some or all of your common stock in order to generate cash from your investment. You may not receive a gain on your investment when you sell our common stock and may lose the entire amount of your 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.

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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 14.1% in 2008, 11.7% in 2009, 7.0% in 2010 and 6.1% 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.