CLEVELAND BIOLABS INC
Form 10-K
March 15, 2011
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, 2010

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 ¨ 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 $79,516,413. There were 29,123,144 shares of common stock outstanding as of March 7, 2011.

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant's Annual Meeting of Stockholders, to be held on June 7, 2010, is incorporated by reference in Part III to the extent described therein.

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Cleveland BioLabs, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2010

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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 subsidiary and ‘the Company,” “we,” “us” and “our” refer to Cleveland BioLabs, Inc. together with its consolidated subsidiary.

PART I

Item 1. Business

GENERAL OVERVIEW

Cleveland BioLabs, Inc. is a biotechnology company focused on developing biodefense, tissue protection and cancer treatment drugs based on the concept of modulation of cell death for therapeutic benefit. CBLI was incorporated in Delaware and commenced business operations in June 2003. We have devoted substantially all of our resources to the identification, development and commercialization of new types of drugs for protection of normal tissues from exposure to radiation and other stresses, such as toxic chemicals and cancer treatments. Our pipeline includes products from two primary families of compounds: protectans and curaxins. We are developing protectans as drug candidates that protect healthy tissues from acute stresses such as radiation, chemotherapy and ischemia (pathologies that develop as a result of blocking blood flow to a part of the body). Curaxins are being developed by Incuron, LLC, our majority-owned Russian subsidiary (“Incuron”), as anticancer agents that could act as mono-therapy drugs or in combination with other existing anticancer therapies.

On July 20, 2006, we sold 1,700,000 shares of common stock, par value $0.005 per share, in our initial public offering at a per share price of $6.00. Our common stock is listed on the NASDAQ Capital Market under the symbol “CBLI.”

Technology

Our development efforts are based on discoveries made in connection with the investigation of the cell-level process known as apoptosis. Apoptosis is a highly specific and tightly regulated form of cell death that can occur in response

to external events such as exposure to radiation, toxic chemicals or internal stresses. Apoptosis is a major determinant of tissue damage caused by a variety of medical conditions including cerebral stroke, heart attack and acute renal failure. Conversely, apoptosis is also an important protective mechanism that allows the body to shed itself of defective cells, which otherwise can cause cancerous growth.

Research has demonstrated that apoptosis is sometimes suppressed naturally. For example, most cancer cells develop resistance to apoptotic death caused by drugs or natural defenses of the human body. Our research is geared towards identifying the means by which apoptosis can be affected and manipulated depending on the need.

If the need is to protect healthy tissues against an external event such as exposure to radiation, we focus our research efforts on attempting to temporarily and reversibly suppress apoptosis in those healthy tissues, thereby imitating the apoptotic-resistant tendencies displayed by cancer cells. A drug with this effect would also be useful in ameliorating the toxicities of anticancer drugs and radiation that cause collateral damage to healthy tissues during cancer treatment. Because the severe toxicities of anticancer drugs and radiation often limit their dosage in cancer patients, an apoptosis suppressant drug may enable a more aggressive treatment regimen using anticancer drugs and radiation and thereby increase their effectiveness.

On the other hand, if the need is to destroy cancerous cells, we focus our research efforts on restoring apoptotic mechanisms that are suppressed in tumors, so that those cancerous cells will once again become vulnerable to apoptotic death. In this regard, we believe that our drug candidates could have significant potential for improving, and becoming vital to, the treatment of cancer patients.

Through our research and development ("R&D"), and our strategic partnerships, we have established a technological foundation for the development of new pharmaceuticals and their rapid preclinical evaluation.

We have acquired rights to develop and commercialize the following prospective drugs:

- Protectans - modified factors of microbes that protect cells from apoptosis, and which therefore have a broad spectrum of potential applications. The potential applications include both non-medical applications such as protection from exposure to radiation, whether as a result of military or terrorist action or as a result of a nuclear accident, as well as medical applications such as reducing cancer treatment toxicities.

- Curaxins - small molecules designed to kill tumor cells by simultaneously targeting two regulators of apoptosis. Initial test results indicate that curaxins can be effective against a number of malignancies, including hormone-refractory prostate cancer, renal cell carcinoma ("RCC") (a highly fatal form of kidney cancer), and soft-tissue sarcoma.

In the area of radiation protection, we have achieved high levels of protection in animal models. With respect to cancer treatment, the biology of cancer is such that there is no single drug that can be successfully used to treat a significant proportion of the large number of different cancers and there is wide variability in individual responses to most therapeutic agents. This means there is a continuing need for additional anticancer drugs for most cancers.

Our drug candidates demonstrate the value of our scientific foundation. Based on the accelerated review and approval status currently available for drugs qualifying for Fast Track status, we believe that our most advanced drug candidate, Protectan CBLB502 may be approved for treatment of acute radiation syndrome within 18 - 24 months. Another drug candidate, Curaxin CBLC102, demonstrated activity and safety in a Phase IIa clinical trial concluded in late 2008. In November 2010, the first patient was dosed in an ongoing multi-center clinical trial of Curaxin CBLC102 on patients with liver tumors in the Russian Federation.

INDUSTRY

CBLI is a biotechnology, or biotech, company focused on developing biodefense, tissue protection and cancer treatment drugs. Historically, biotech was defined by newly discovered “genetic engineering” technology, which was first developed in universities and new startup biotech companies in the mid-1970s. Later, other technologies (based on a constant flow of discoveries in the field of biology) started playing a leading role in biotech development. Medicine, and specifically drug development, is a lucrative field for use of these technologies. Large pharmaceutical (“Pharma”) companies joined the biotech arena through licensing, sponsored research, and corporate agreement relationships. Biotechnology is a $360 billion industry (based on total market capitalization of U.S. public companies tracked by Burrill and Company) and includes large companies such as Amgen, Inc. and Genzyme. The U.S. biotechnology industry includes about 1,500 companies with combined annual revenue of more than $90 billion.

The traditional biotech business model is a derivative of the long drug development process. Typical biotech companies go through the following stages:

- During the first stage, biotech companies fund their development through equity or debt financings while conducting R&D, which culminates in phased drug trials.

- During the second stage, when their lead drug candidates enter the drug trials, biotech companies may start licensing their drug candidates to Pharma companies in order to (1) generate revenue, (2) gain access to additional expertise, and (3) establish relations with Pharma companies who can eventually take a leading role in distributing successful drugs.

- At the most advanced stage, biotech companies generate revenues by selling drugs or other biotech products to consumers or through alliances of equals.

The Project BioShield Act, which was signed into law in July 2004, allocated $5.6 billion over ten years to fund the research, development and procurement of drugs, biological products or devices to treat or prevent injury from exposure to biological, chemical, radiological or nuclear agents as a result of a military, terrorist or nuclear attack. The legislation provides for a more expedited approval process by allowing for approval based on Phase I safety studies in humans and efficacy studies in two animal species (rodents and non-human primates) instead of Phase II and III human clinical trials (see Government Regulation). With the Project BioShield Act, biotech companies now have greater access to grants and contracts with the U.S. government. Several biotech companies, including CBLI, have secured grants and contracts from the U.S. government to develop drugs and vaccines as medical countermeasures against potential terrorist attacks. For biotech companies focused on these types of drugs and vaccines, this type of funding, together with the modified U,S. Food and Drug Administration (“FDA”), approval process, are major departures from the traditional biotech business model. The principal provisions of this law are to:

- Facilitate R&D efforts of biomedical countermeasures by the National Institutes of Health;
- Provide for the procurement of needed countermeasures through a special reserve fund of $5.6 billion over ten years; and
- Authorize, under limited circumstances, the emergency use of medical products that have not been approved by the FDA.

STRATEGIES AND OBJECTIVES

Our primary objective is to become a leading developer of drugs for the protection of human tissues against radiation and other stresses and for cancer treatment. Key elements of our strategy include:

- Aggressively working towards the commercialization of Protectan CBLB502. Our most advanced drug candidate, Protectan CBLB502, offers the potential to protect normal tissues against exposure to radiation. Because Protectan CBLB502 demonstrates the potential to address an unmet medical need and is intended to treat a serious or life-threatening condition, Protectan CBLB502 has been granted Fast Track status by the FDA. The Fast Track designation will allow us to file a Biologic License Application ("BLA") on a rolling basis and will allow the FDA to review the filing as it is received rather than waiting for the complete submission prior to commencing the review process. In addition, our BLA filing will be eligible for priority review, which could result in an abbreviated review time of six months. We expect to complete development of Protectan CBLB502 to treat radiation injury following exposure to radiation from nuclear or radiological weapons, or from nuclear accidents and submit a BLA to the FDA in 2012.
- Leveraging our relationship with leading research and clinical development institutions. The Cleveland Clinic ("CCF"), one of the top research medical facilities in the world, is one of our co-founders. In January 2007, we entered into a strategic research partnership with Roswell Park Cancer Institute ("RPCI") in Buffalo, New York. We have continued our research and development program that we initiated at CCF at RPCI and RPCI shares valuable expertise with us as developmental efforts are performed on our drug candidates. These partnerships will enhance the speed and efficiency of our clinical research and provide us with access to the state-of-the-art clinical development facilities of a globally recognized cancer research center.
- Utilizing governmental initiatives to target our markets. Our focus on drug candidates such as Protectan CBLB502, which has applications that have been deemed useful for military and defense purposes, provides us with a built-in market for our drug candidates. This enables us to invest less in costly retail and marketing resources. In an effort to improve our responsiveness to military and defense needs, we have established a collaborative relationship with the Department of Defense ("DoD"), and the Biomedical Advanced Research and Development Authority ("BARDA")

of the Department of Health and Human Services (" HHS").

- Utilizing and developing other strategic relationships. We have collaborative relationships with other leading organizations that enhance our drug development and marketing efforts. For example, one of our founders, with whom we maintain a strategic partnership, is ChemBridge Corporation (“ChemBridge”). Known for its medicinal chemistry expertise and synthetic capabilities, ChemBridge provides valuable resources to our drug development research including access to a chemical library of almost 2,000,000 compounds.

RESEARCH AND DEVELOPMENT

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.

There are significant risks and uncertainties inherent in the preclinical and clinical studies associated with our R&D projects. As a result, the costs to complete such projects, as well as the period in which net cash outflows from such programs are expected to be incurred, may not be reasonably estimated. From our inception to December 31, 2010, we spent $73,729,435 on R&D. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Year Ended December 31, 2010 Compared to Year Ended December 31, 2009—Operating Expenses” for a more detailed discussion of our R&D spending.

Our ability to complete our R&D on schedule is, however, subject to a number of risks and uncertainties. In addition, we have sustained losses from operations in each fiscal year since our inception in June 2003, and we may exhaust our financial resources and be unable to complete the development of our products due to the substantial investment in R&D that will be required for the next several years. We expect to spend substantial additional sums on the continued R&D of proprietary products and technologies with no certainty that losses will not increase or that we will ever become profitable as a result of these expenditures.

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 such FDA approval and whether any such approval will ultimately be granted. Preclinical 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 or terminated. Moreover, obtaining approval for certain products may require testing on human subjects of substances whose effects on humans are not fully understood or documented. 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 the product's potential commercial success and on our business, prospects, financial condition and results of operations. In addition, 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.

PRODUCTS IN DEVELOPMENT

Protectans

We are exploring a new natural source of factors that temporarily suppress the programmed cell death (apoptosis) response in human cells, which can be rapidly developed into therapeutic products. These inhibitors, known as protectans, are anti-apoptotic factors developed by microorganisms of human microflora throughout millions of years of co-evolution with mammalian hosts. We have established a technological process for screening of these factors and their rapid preclinical evaluation. These inhibitors may be used as protection from cancer treatment toxicities and antidotes against injuries induced by radiation and other stresses associated with severe pathologies (i.e., heart attack or stroke).

We currently have issued patents and pending patent applications relating to eight families of patent applications that were filed over the past seven years around various aspects and qualities of the protectan family of compounds. The first patent covering the method of protecting a mammal from radiation using flagellin or its derivatives was granted by the U.S. Patent and Trademark Office (US Patent No. 7,638,485 titled "Modulating Apoptosis") and the European Patent Office (European Publication Number FP 1706133, titled "Methods of Protecting Against Radiation Using Flagellin.") . This patent was also granted by the nine member countries of the Eurasian Patent Organization (which includes the Russian federation), Ukraine and China. A second patent titled "Method of Protecting Against Apoptosis using Lipopeptides" was granted by South Africa (Patent Number 2008/00126) and we have received notices of intent to grant patent from New Zealand and the Eurasian Patent Organization. A third patent titled "Method of Increasing Hematopoietic Stem Cells" (Patent Number 2009/05378) has been granted by South Africa. We believe that with the patent applications filed to date in the U.S. and internationally around various properties of protectan compounds, we have protected the potentially broad uses of our protectan technology. The patents/patent applications belonging to the first patent family referenced above have a legal expiration date of December 1, 2024, the patents/patent applications belonging to the second patent family referenced above have a legal expiration date of June 12, 2026 and the patents/patent applications belonging to the third patent family referenced above have a legal expiration date of May 13, 2025.

We spent approximately $14,321,680 and $13,738,983 on R&D for protectans for all applications in the fiscal years ended December 31, 2010 and 2009, respectively. From our inception to December 31, 2010, we spent $54,569,163 on R&D for protectans.

Protectan CBLB502

Protectan CBLB502 is our leading radioprotectant molecule in the protectans family. Protectan CBLB502 represents a rationally designed derivative of the microbial protein, flagellin. Flagellin is secreted by Salmonella typhimurium and many other Gram-negative bacteria, and in nature, arranges itself in a hollow cylinder to form the filament in bacterial flagellum and acts as a natural activator of NF-kB (nuclear factor-kappa B), a protein complex widely used by cells as a regulator of genes that control cell proliferation and cell survival. Thus, Protectan CBLB502 reduces injury from acute stresses by mobilizing several natural cell protective mechanisms, including inhibition of apoptosis, reduction of oxidative damage and induction of factors (cytokines) that induce protection and regeneration of stem cells in bone marrow and the intestines.

Protectan CBLB502 is a single agent, anti-radiation therapy with demonstrated significant survival benefits at a single dose in animal models. Animal studies indicate that Protectan CBLB502 protects mice without increasing the risk of radiation-induced cancer development. The remarkably strong radioprotective abilities of Protectan CBLB502 are the result of a combination of several mechanisms of action. Potential applications for Protectan CBLB502 include reduction of radiation therapy or chemotherapy toxicities in cancer patients, protection from Acute Radiation Syndrome ("ARS") in defense scenarios and protection from acute organ failure. Protectan CBLB502 is administered through intramuscular injection.

Six families of patent applications have been filed for Protectan CBLB502, which include two U.S. patent applications related to various aspects and properties for Protectan CBLB502 and related protectan compounds, including new methods of the use of flagellin derivatives and screening for new compounds with similar properties.

We spent approximately $14,316,540 and $13,732,416 on R&D for Protectan CBLB502 in the fiscal years ended December 31, 2010 and 2009, respectively. From our inception to December 31, 2010, we spent $51,427,082 on R&D for Protectan CBLB502.

Non-medical Applications

Our scientists have demonstrated that injecting Protectan CBLB502 into mice, rats and non-human primates protects them from lethal doses of total body gamma radiation. An important advantage of Protectan CBLB502, above any other radioprotectant known to us, is the ability to effectively protect not only the hematopoietic system, but also the gastrointestinal ("GI"), tract which is among the most sensitive areas of the human body to radiation. High levels of radiation, among other effects, induce moderate to severe bone marrow damage. The immune and blood stem cells are also depleted and death is caused by anemia, infection, bleeding or poor wound healing. GI damage often occurs at higher doses of radiation and may result in death through sepsis as a result of perforation of the GI tract. Protectan CBLB502's ability to effectively protect the hematopoietic system and GI tract may make Protectan CBLB502 uniquely useful as a radioprotective antidote. Protectan CBLB502 was shown to be safe at its therapeutic doses in rodents and non-human primates. In addition, Protectan CBLB502 has proved to be a stable compound for storage purposes. It can be stored at temperatures close to freezing, room temperature or extreme heat. Manufacturing of Protectan CBLB502 is cost efficient due to its high yield bacterial producing strain and simple purification process.

Protectan CBLB502 is being developed under the FDA's animal efficacy rule (21 C.F.R. § 314.610, drugs; § 601.91, biologics) to treat radiation injury following exposure to radiation from nuclear or radiological weapons, or from nuclear accident. The animal efficacy rule creates a new regulatory paradigm for measuring efficacy by permitting the FDA to approve drugs and biologics for counterterrorism uses based on animal data when it is unethical or unfeasible to conduct human efficacy studies. Thus, this approval pathway requires demonstration of efficacy in at least one well-characterized animal model and safety and pharmacodynamics studies in animals and representative samples of healthy human volunteers to allow selection of an effective dose in humans. Protectan CBLB502 has demonstrated activity as a radioprotectant in several animal species, including non-human primates. Human safety, pharmacokinetic, pharmacodynamic and biomarker studies are the only stage of human testing required for approval in this indication.

We have successfully established current Good Manufacturing Practices ("cGMP"), quality manufacturing for Protectan CBLB502 and have completed two Phase I human safety studies for Protectan CBLB502 in ARS. The initial human Phase I safety and tolerability study involved single injections of Protectan CBLB502 in ascending-dose cohorts. The 50 participants in the study were assessed for adverse side effects over a 28-day time period and blood samples were obtained to assess the effects of Protectan CBLB502 on various biomarkers. Data from these subjects indicates that Protectan CBLB502 was well tolerated and that normalized biomarker results corresponded to previously demonstrated activity in animal models of ARS. A pattern of biomarker production was observed consistent with those patterns seen in animals during mitigation of radiation-induced injury by dosing with Protectan CBLB502.

In January 2010, we began dosing in the second human safety study, a Phase Ib study, for Protectan CBLB502 and completed dosing in May 2010. This safety study included a total of 100 healthy volunteers randomized among four dosing regimens of Protectan CBLB502. Participants in the 100-subject study were assessed for adverse side effects and blood samples were obtained to assess the effects of Protectan CBLB502 on various biomarkers. The primary objectives of this study were to gather additional data on safety, pharmacokinetics, and cytokine biomarkers in a larger

and broader subject population. Administration of Protectan CBLB502 resulted in a rapid and potent cytokine response, similar to that seen in the prior clinical trial and in previously conducted non-human primate studies. Single and double doses of Protectan CBLB502 were well tolerated. The primary adverse event associated with Protectan CBLB502 administration was a transient flu-like syndrome consistent with what was observed in the previous trial and which generally resolved within 24 hours. There was no difference in the adverse event profile between the doses tested. We anticipate moving forward with a definitive safety study in a larger group of healthy human volunteers after determining an appropriate dose to take forward and determining the size of a definitive human safety study in conjunction with the FDA.

The Defense Threat Reduction Agency (“DTRA”) of the DoD awarded us a $1.3 million grant in March 2007, to fund “development leading to the acquisition” of Protectan CBLB502 as a radiation countermeasure, in collaboration with Armed Forces Radiobiology Research Institute (“AFRRI”), which has also received significant independent funding for work on Protectan CBLB502.

In March 2008, the DoD awarded us a contract valued at up to $8.9 million over eighteen months through the Chemical Biological Medical Systems Joint Project Management Office Broad Agency Announcement ("BAA"), for selected tasks in the advanced development of Protectan CBLB502 as a Medical Radiation Countermeasure ("MRC"), to treat radiation injury following exposure to radiation from nuclear or radiological weapons (the “2008 DoD Contract”). The specific tasks include the completion by us of non-Good Laboratory Practices ("non-GLP") efficacy animal studies, Chemistry, Manufacturing and Controls ("CMC") tasks, in vitro and in vivo studies supporting Protectan CBLB502’s Investigational New Drug ("IND") application, definitive GLP efficacy studies, and drug formulation from single-dose vials within the timeframe of the contract. In September 2009, the DoD increased the funding under this contract by $0.6 million to $9.5 million to support bridging studies between lyophilized and liquid drug formulations. We successfully completed all tasks related to the 2008 DoD Contract by the contract end date of August 31, 2010.

As a government contract subject to the Federal Acquisition Regulations (“FAR”), pursuant to FAR 52.227-11 (Patent Rights – Ownership by the Contractor) we were permitted to retain title to any patentable invention or discovery made while performing the contract. However, no inventions were made by us during the performance of the 2008 DoD Contract. Had any inventions been made while performing under the 2008 DoD Contract, the U.S. government would have received a non-exclusive, non-transferable, irrevocable, paid-up license to the subject inventions throughout the world. In addition, pursuant to FAR 52.227-14 (Rights in Data – General), which was incorporated into the base 2008 DoD Contract and removed by the first amendment to the contract in June 2008, the U.S. government retains unlimited rights in the technical data produced between March and June 2008 in the performance of the 2008 DoD Contract.

In September 2008, we were awarded a $774,183 grant from the National Institute of Allergy and Infectious Diseases ("NIAID") of the National Institutes of Health ("NIH") to further study certain mitigating properties of Protectan CBLB502 in the context of hematopoietic damage from radiation exposure. In September 2009, NIAID awarded us an additional $458,512 for the continuation of the same grant.

In September 2008, BARDA awarded us a contract under the BAA titled, "Therapies for Hematopoietic Syndrome, Bone Marrow Stromal Cell Loss, and Vascular Injury Resulting from Acute Exposure to Ionizing Radiation," for selected tasks in the advanced development of Protectan CBLB502. BARDA seeks to acquire developed medical countermeasures that will be clinically useful in a civilian medical emergency situation that results from or involves exposure of a large population to the effects of a nuclear detonation, a radiologic dispersive device (such as a dirty bomb) or exposure to radioactive material with or without combined injury or trauma.

The selected tasks in the Statement of Work include the following:

- Performing certain non-clinical experiments, including non-human primate experiments.
- Facilitating bone marrow transplantation in the rescue of irradiated mice by Protectan CBLB502 treatment.
- Performing stability studies of Good Manufacturing Practices-grade Protectan CBLB502 and conducting Phase Ib clinical trials.
- Submitting necessary regulatory documents to the BARDA and the FDA for approval.
- Planning, initiating and overseeing Phase Ib trials on healthy volunteers and drafting and finalizing the Phase Ib clinical reports and submitting such reports to the BARDA and the FDA.

The total contract value including all milestone-based options started at $13.3 million over a three-year period, with the first year's award of $3.4 million. In September 2009, BARDA increased the total contract value $2.3 million to $15.6 million and awarded the first milestone option of $6.3 million. BARDA has since awarded the second, third and fourth milestone options under the contract for $1.47 million, $0.46 million and $4.14 million, respectively. We successfully completed all tasks related to this contract by February 15, 2011.

As a government contract subject to the FAR, 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 invention throughout the world. The U.S. government will also have unlimited rights in the data produced in the performance of the HHS Contract.

In September 2010, we were awarded a contract (the “2010 DoD Contract”) by the Chemical Biological and Medical Systems ("CBMS") Medical Identification and Treatment Systems ("MITS") of the DoD for the advanced development and procurement of Protectan CBLB502 as a medical radiation countermeasure. The 2010 DoD Contract is valued at up to $45 million, including all options provided thereunder. Under the terms of the contract, CBMS-MITS will initiate funding of $14.8 million, including all options, for the advanced development of Protectan CBLB502 through the receipt of approval from the FDA. Selected tasks related to the advanced development of

Protectan CBLB502 under the 2010 DoD Contract include, among others, conducting pilot animal model studies to support approval under the FDA 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.

As a government contract subject to the FAR, we will be permitted to retain title to any patentable invention or discovery made while performing the contract. The U.S. government, in return, will receive a non-exclusive, non-transferable, irrevocable, paid-up license to the subject inventions throughout the world. In addition, the U.S. government will also have unlimited rights in the technical data produced in the performance of the 2010 DoD Contract. Furthermore, the DoD has the right to terminate the 2010 DoD Contract at any time. In certain instances, the 2010 DoD Contract also limits our ability to engage in certain activities, such as subcontracting a portion of the work, without prior approval from the DoD.

In January 2011, we received a $1,589,106 development contract from the DTRA of the DoD to fund additional research into the pharmacodynamic profile of Protectan CBLB502, and to further define mediators of Protectan CBLB502's radiomitigating effects.

The Project BioShield Act of 2004, which further expedites the approval of drug candidates for certain uses, is intended to bolster our nation's ability to provide protections and countermeasures against biological, chemical, radiological or nuclear agents that may be used in a military, terrorist or nuclear attack. This law also allows for the use of expedited peer review when assessing the merit of grants and contracts of up to $1,500,000 for countermeasure research. We have been awarded and successfully completed a $1,500,000 research grant pursuant to this law.

Three families of patent applications have been filed for the non-medical applications for Protectan CBLB502.

We spent approximately $14,316,540 and $13,676,289 on R&D for the non-medical applications of Protectan CBLB502 in the fiscal years ended December 31, 2010 and 2009, respectively. From our inception to December 31, 2010, we spent $49,594,026 on R&D for the biodefense applications of Protectan CBLB502.

Protectan CBLB502 is a candidate for procurement by the DoD, HHS/BARDA and other countries / territories facing imminent nuclear and radiation threats. The HHS opportunity is particularly positive 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. Our contract awards from the DoD and BARDA evidence the government's focus on acquiring adequate protection against nuclear and radiation threats for military and civilian populations. Upon FDA approval, Protectan CBLB502 should be well positioned to fulfill both of these needs, with its demonstrated unprecedented efficacy and survival benefits, unique ability to address both hematopoietic and GI damage, broad window of efficacy relative to radiation exposure and suitability for both military and civilian delivery scenarios. We believe that Protectan CBLB502 is the only radiation countermeasure with these capabilities in advanced development that can be self or buddy-administered, without the need of additional supportive care in a battlefield or civilian community setting.

We intend to enter into contracts to sell Protectan CBLB502 to various U.S. government agencies. Future sales to U.S. government agencies will depend, in part, on our ability to meet federal contract requirements and the existence and development of competitive compounds.

Regulatory Status

Extraordinary radioprotective properties, an excellent toxicity profile, outstanding stability and cost efficient production of Protectan CBLB502 to date make it a primary candidate for clinical studies. Initially, Protectan CBLB502 is being developed for non-medical purposes — as a radioprotectant antidote for the protection of people with possible exposure to high doses of ionizing radiation. Our drug development strategy complies with the recently adopted FDA rules for investigational drugs that address situations such as radiation injury, where it would be unethical to conduct efficacy studies in humans. While Phase II and Phase III human clinical trials are normally required for the approval of marketing an investigational drug, under the FDA rules, Protectan CBLB502 would be considered for approval for this indication based on Phase I safety studies in humans and efficacy studies in two animal species. Based upon this expedited approval process, as a result of its Fast Track status, we believe that Protectan CBLB502 could be approved for non-medical applications within 18 - 24 months. Because Phase II and Phase III testing involves applying a drug candidate to a large numbers of participants who suffer from the targeted disease and condition and can last for a total of anywhere from three to six or additional years, bypassing these phases represents a significant time and cost savings in receiving FDA approval.

As part of this expedited approval process, the FDA has indicated that it intends to engage in a highly interactive review of IND applications, New Drug Applications ("NDA") and BLAs and to provide for accelerated review and licensure of certain medical products for counterterrorism applications, including granting eligible applications “Fast Track” status. The Fast Track program is designed to expedite the review of investigational drugs for the treatment of patients with serious or life-threatening diseases where there is an unmet medical need. Fast Track designations allow a company to file a NDA or BLA on a rolling basis and permits the FDA to review the filing as it is received, rather than waiting for the complete submission prior to commencing the review process. Additionally, NDAs and BLAs for fast track development programs are eligible for priority review, which may result in an abbreviated review time of six months. In July 2010, the FDA granted our application for Fast Track status in respect of Protectan CBLB502. 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 will expedite implementation of the Protectan CBLB502 development plan and preparation and approval of the BLA.

Protectan CBLB502 was granted Fast Track status by the FDA in July 2010 for reducing the risk of death following total body irradiation during or after radiation disaster.

The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis, or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 people but are not expected to recover the costs of developing and marketing the treatment.

Orphan Drug status qualifies Protectan CBLB502 for an accelerated review process, tax credits, financial assistance for development costs, and seven years of marketing exclusivity upon approval by the FDA for this indication. The designation also allows for a possible exemption from the FDA-user fee and assistance in clinical trial protocol design.

Protectan 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.

As part of the process to receive final FDA licensure for Protectan CBLB502 for non-medical applications, we have established cGMP compliant manufacturing of Protectan CBLB502. We were able to develop a complicated, high-yield manufacturing process for Protectan CBLB502 and prototype the process and resolve multiple challenges during the industrial development. We currently have drug substance corresponding to several hundred thousand projected human doses. The process we developed gives us the ability to manufacture up to five million estimated doses within a year without any additional scale-up; and if necessary, scale-up could be implemented relatively easily.

Prior to our submission for FDA licensure for Protectan CBLB502 for biodefense or non-medical applications, we will need to complete several interim steps, including:

- Conducting pivotal animal efficacy studies with the cGMP manufactured drug candidate under GLP - Good Laboratory Practices conditions. We expect to complete dosing in these studies in 2011. We anticipate that these studies will have an approximate cost of $2,500,000 and are covered by a government development contract pending approval.

- Performing a Phase II human safety study in a larger number of volunteers using the dose of Protectan CBLB502 previously shown to be safe in humans and efficacious in animals. We estimate completion of dosing in this study in 2011 and will have an approximate cost of $7,000,000 based on 500 subjects tested in four locations. This study is covered by a government development contract pending approval.

- Filing a BLA which we expect to submit in 2012. We anticipate that this filing will have an approximate cost of $4,000,000 and is covered by a government development contract pending approval.

Medical Applications

While our current focus remains on its non-medical applications, Protectan CBLB502 has been observed to dramatically increase the efficacy of radiotherapy of experimental tumors in mice. Protectan CBLB502 appears to increase the tolerance of mice to radiation while having no effect on the radiosensitivity of tumors, thus opening the possibility of combining radiotherapy with Protectan CBLB502 treatment to improve the overall anticancer efficacy of radiotherapy. Our animal efficacy studies have demonstrated that up to 100% of mice treated with Protectan CBLB502 prior to being exposed to radiation survived without any associated signs of toxicity. This compares to a 100% mortality rate in the animal group that received a placebo drug.

Protectan CBLB502 has demonstrated the ability to reduce the toxicities of a chemotherapeutic drug, cisplatin (Platinol), broadly used for the treatment of ovarian, endometrial, head and neck, lung, stomach and other types of cancer in animal models. Cisplatin treatment was used in the study as an example of chemotherapy-associated toxicity. Cisplatin injected at toxic doses is known to induce myelosuppression (suppression of bone marrow) and nephrotoxicity (kidney damage). The prospect of increasing patients' tolerance to chemotherapeutic drugs and optimizing treatment regimens would be a significant improvement in cancer treatment. It is estimated that approximately $10 billion of the roughly $50 billion annually spent on cancer treatment represents supportive care addressing toxicities of various treatments, including chemotherapy.

More recent discoveries have also pointed to potential direct anticancer effects of Protectan CBLB502 in several transplanted cancer models 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 animals. Experimental results suggest that CBLB502's anticancer effect stems from the same mechanism which underlies its ability to treat radiation exposure and which involves tissue-specific activation of innate immune response mediated by CBLB502's interaction with its receptor, TLR5. The strength of the antitumor effects largely depends on the expression of the receptor of Protectan CBLB502 by the tumor. However, in the case of tumors residing in the liver, the organ which has been identified as the natural primary target site for CBLB502 activity, tumors become effectively suppressed as a result of host immune system attack regardless of their TLR5 status. This characteristic makes liver metastasis a favorable target for potential anticancer applications of CBLB502.

In light of these new findings, we plan to initiate Phase I/II studies with Protectan CBLB502 in cancer patients to look at both supportive care and direct anticancer effects. Potential study protocols are under review and revision, including one for head and neck cancer patients. Our goal is to initiate one or possibly more medical trials for Protectan CBLB502 in cancer patients in mid-2011.

In other studies, we have demonstrated the potential of Protectan CBLB502 to be applicable to ischemic conditions. Our researchers, in collaboration with investigators from CCF, have demonstrated that a single injection of Protectan CBLB502 effectively prevents acute renal failure and subsequent death in a mouse model of ischemia-reperfusion renal injury.

The DoD awarded a $1 million grant to CCF in 2008 to conduct pre-clinical studies on Protectan 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. These studies have demonstrated Protectan CBLB502's ability to accelerate limb recovery in an animal model of tourniquet-mediated injury simulating the situation occurring in human. It has been demonstrated that injection of Protectan CBLB502 within 30 minutes of tourniquet removal leads to a marked reduction in the severity of injury, including reductions in tissue edema, pro-inflammatory cytokine production and leukocyte infiltration leading to accelerated recovery of limb function.

In September 2009, we were awarded a $5.3 million Grand Opportunities research grant under the American Recovery and Reinvestment Act of 2009 from the Office of the Director of NIH and NIAID. The grant will fund studies of molecular mechanisms by which Protectan CBLB502 mitigates GI damage from radiation exposure.

In contrast to the non-medical applications of Protectan CBLB502, the use of Protectan CBLB502 to ameliorate the side effects of radiation treatment and anticancer drugs will be subject to the full FDA approval process.

In order for us to receive final FDA licensure for Protectan CBLB502 for medical applications, we will need 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 at an approximate cost of $1,500,000 each.

- Performing an additional Phase II efficacy study on a larger number of cancer patients. At the present time, the costs and the scope of this study cannot be approximated with any level of certainty.

- Performing a Phase III human clinical study on a large number of cancer patients and filing a BLA with the FDA. At the present time, the costs and scope of these steps cannot be approximated with any level of certainty.

Five families of patent applications have been filed for the medical applications for Protectan CBLB502.

We spent approximately $0 and $56,127 on R&D for the medical applications of Protectan CBLB502 in the fiscal years ended December 31, 2010 and 2009, respectively. From our inception to December 31, 2010, we spent $1,833,056 on R&D for the medical applications of Protectan CBLB502.

Protectan CBLB612

While the bulk of our R&D has focused on Protectan CBLB502, we have conducted some preliminary research into a compound derived from the same family and which we refer to as Protectan CBLB612. Protectan CBLB612 is a modified lipopeptide mycoplasma that acts as a powerful stimulator and mobilizer of hematopoietic (bone marrow/blood production) stem cells ("HSC") to peripheral blood. Potential applications for Protectan CBLB612 include accelerated hematopoietic recovery during chemotherapy and during donor preparation for bone marrow transplantation.

Our research indicates that Protectan CBLB612 is not only a potent stimulator of bone marrow stem cells, but also causes their mobilization and proliferation throughout the blood. A single administration of Protectan CBLB612 resulted in a three-fold increase in the number of progenitor stem cells in mouse bone marrow within 24 hours after administration. Furthermore, the number of these stem cells in peripheral blood was increased ten-fold within four days of administration.

Protectan CBLB612 was also found to be highly efficacious in stimulating proliferation and mobilization of hematopoietic stem cells into peripheral blood in a primate model (Rhesus macaques). A single injection of Protectan CBLB612 in Rhesus macaques resulted in a 20-fold increase of hematopoietic progenitor cells in blood. At the peak of the effect (48-72 hours post-injection), the proportion of free-floating CD34+ cells in the total white blood cell count reached 30% (compared with 1.5% in normal blood). CD34 is a molecule present on certain cells within the human body. Cells expressing CD34, otherwise known as CD34+ cells, are normally found in the umbilical cord and bone marrow as hematopoietic cells.

This discovery opens a new and innovative way for us to address a broad spectrum of human diseases, some of which currently lack effective treatment. Direct comparisons of Protectan CBLB612 and the market leading drug used for stimulation of blood regeneration, G-CSF (Neupogen® or Neulasta®, Amgen, Inc.), demonstrated a stronger efficacy of Protectan CBLB612 as a propagator and mobilizer of HSC in peripheral blood.

Protectan CBLB612's strength as a stem cell stimulator was further demonstrated by the outcome of its combined use with G-CSF and Mozibil (AMD3100) (an FDA approved stem cell mobilizer from Genzyme Corporation) where the addition of Protectan CBLB612 resulted in eight to ten times higher yields of HSC in peripheral blood in comparison with the standard protocol.

In addition to efficacy in stimulation and mobilization of stem cells in animal models, Protectan CBLB612 was found to be highly effective in an animal bone marrow stem cell transplantation model. Blood from healthy mice treated by Protectan CBLB612 was transplanted into mice that received a lethal dose of radiation that killed hematopoietic (bone marrow/blood production) stem cells. A small amount of blood from the Protectan CBLB612 treated mice successfully rescued the mice with radiation-induced bone marrow stem cell deficiency. All of the deficient mice transplanted with blood from Protectan CBLB612 treated mice survived past the 60-day mark, while 85% of the untreated deficient mice died within the first three weeks of the experiment. The 60-day mark is considered to be the critical point in defining the presence of long-term, adult bone marrow stem cells, which are capable of completely restoring lost or injured bone marrow function. The rescuing effect of the peripheral blood of the treated mice was equivalent to that of conventional bone marrow transplantation.

Adult hematological bone marrow stem cell transplantation is currently used for hematological disorders (malignant and non-malignant), as well as some non-hematological diseases, such as breast cancer, testicular cancer, neuroblastoma, ovarian cancer, Severe Combined Immune Deficiency, Wiskott-Aldrich syndrome and Chediak-Higashi syndrome.

With efficacy and non-GLP safety already studied in mice and monkeys, Protectan CBLB612 entered formal pre-clinical safety and manufacturing development in February 2008. Further development of Protectan CBLB612 will continue upon achieving sufficient funding for completing pre-clinical development and a Phase I study. Development of Protectan CBLB612 has been supported by a grant from the Defense Advanced Research Projects Agency of the DoD.

Two families of patent applications have been filed for Protectan CBLB612. Both patent applications, entitled “Methods of Protecting Against Apoptosis Using Lipopeptides” (Patent Number 2008/00126) and “Method of Increasing Hematopoietic Stem Cells” (Patent Number 2009/05378) have been granted by South Africa and we have received notices of intent to grant the first patent application from New Zealand and the Eurasian Patent Organization.

In September 2009, we executed a license agreement granting Zhejiang Hisun Pharmaceutical Co. Ltd. ("Hisun"), a leading pharmaceutical manufacturer in the People's Republic of China, exclusive rights to develop and commercialize Protectan CBLB612 in China, Taiwan, Hong Kong and Macau. Under the terms of the license agreement, we received product development payments of $1.65 million for protectan research (including Protectan CBLB502). Hisun will be responsible for all development and regulatory approval efforts for Protectan CBLB612 in China. In addition, Hisun will pay us a 10% royalty on net sales over the 20-year term of the agreement. This royalty may decrease to 5% of net sales only in the event that patents for Protectan CBLB612 are not granted. We retain all rights to Protectan CBLB612 in the rest of the world.

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

- Conducting pivotal animal safety studies with cGMP-manufactured Protectan CBLB612;
- Submitting an IND application and receiving approval from the FDA to conduct clinical trials;
- Performing a Phase I dose-escalation human study;
- Performing Phase II and Phase III human efficacy studies using the dose of Protectan CBLB612 selected from the previous studies previously shown to be safe in humans and efficacious in animals; and
- Filing an NDA.

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 Protectan CBLB612.

We spent approximately $5,140 and $6,567 on R&D for Protectan CBLB612 in the fiscal years ended December 31, 2010and 2009, respectively. From our inception to December 31, 2010, we spent $3,142,081 on R&D for Protectan CBLB612. Further development and extensive testing will be required to determine its technical feasibility and commercial viability.

Curaxins

Curaxins are small molecules that are intended to destroy tumor cells by simultaneously targeting two regulators of apoptosis. Our initial test results indicate that curaxins may be effective against a number of malignancies, including RCC, soft-tissue sarcoma, and hormone-refractory prostate cancer.

The original focus of our drug development program was to develop drugs to treat one of the most treatment-resistant types of cancer, RCC. Unlike many cancer types that frequently mutate or delete p53, one of the major tumor suppressor genes, RCC belongs to a rare category of cancers that typically maintain a wild type form of this protein. Nevertheless, RCC cells are resistant to apoptosis, suggesting that in spite of its normal structure, p53 is functionally disabled. The work of our founders has shown that p53 function is indeed inhibited in RCC by an unknown dominant factor. We have established a drug discovery program to identify small molecules that selectively destroy tumor cells by restoring the normal function to functionally impaired p53 in RCC. This program yielded a series of chemicals with the desirable properties named curaxins (CBLC100 series). We have isolated three chemical classes of curaxins. One of them includes relatives of 9-aminoacridine, the compound that is the core structure of many existing drugs. Pre-existing information about this compound has allowed us to bypass the preclinical development and Phase I studies and bring one of our drug candidates into Phase IIa clinical trials, saving years of R&D efforts and improving the probability of success.

One of the most important outcomes of this drug discovery program was the identification of the mechanism by which curaxins deactivate NF-kB. This mechanism of action makes curaxins potent inhibitors of the production and the activity of NF-kB not only in its stimulated form, but also in its basal form. The level of active NF-kB is usually also increased in cancer cells. Moreover, due to curaxin-dependent functional conversion of NF-kB-DNA complexes, the cells with the highest basal or induced NF-kB activity are supposed to be the most significantly affected by curaxins. Clearly, this paradoxical activity makes deactivation of NF-kB by curaxins more advantageous compared to conventional strategies targeting NF-kB activators.

The discovery of the mechanism of action of curaxins allowed us to predict and later experimentally verify that curaxins could be used for treatment of multiple forms of cancers, including hormone-refractory prostate cancer, hepatocellular carcinoma, multiple myeloma, acute lymphocytic leukemia, acute myeloid leukemia, soft-tissue sarcomas and several others.

A significant milestone in the curaxin program was achieved with a breakthrough in deciphering the finer details of the mechanism of action of these compounds. Successful identification of the exact cellular moiety that binds to curaxins has provided a mechanistic explanation for the unprecedented ability of these compounds to simultaneously target several signal transduction pathways.

This additional mechanistic knowledge enabled us to discover additional advantages of curaxins and to rationally design treatment regimens and drug combinations, which have since been validated in experimental models. In addition, this understanding further strengthens our intellectual property position for this exciting class of principally new anticancer drugs.

In July 2010, a discovery regarding potential antiviral applications for our curaxin family of molecules was pre-published online in the Journal of Virology, the world's leading peer-reviewed journal in the field of virology (Gasparian, Neznanov, et al., Journal of Virology, doi:10.1128/JVI.02569-09; July 14, 2010).

The published study, conducted by our scientists in cooperation with investigators from RPCI and Cleveland State University, examined the ability of our prototype Curaxin CBLC102, or quinacrine, and other similar compounds to inhibit a mechanism used by picornaviruses to synthesize their proteins that is essential for their viability. This group

of viruses includes important human pathogens such as poliovirus. In particular, the specific interaction of curaxins with double-stranded RNA effectively blocks synthesis of viral, but not cellular proteins. This study provides proof of principle for the prospective extension of curaxins from anticancer to antiviral applications.

Twelve families of patent applications have been filed around the curaxin family of compounds. An application titled "Small Molecule Inhibitors of MRP1 and Other Multidrug Responders" was approved by several nations, not including the U.S., and the Eurasian Patent Organization.

We spent approximately $1,572,630 and $592,690 on R&D for curaxins overall in the fiscal years ended December 31, 2010 and 2009, respectively. From our inception to December 31, 2010, we spent $13,806,913 on R&D for curaxins.

In December 2009, we entered into our Incuron joint venture with Bioprocess Capital Ventures ("BCV"), 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 BCV will contribute an aggregate of 549,497,000 Russian rubles (approximately $18.0 million based on the current exchange rate) to support development of the compounds. BCV made the first payments of 105,840,000 Russian rubles (approximately $3.5 million based on the current exchange rate) during April and June of 2010. In January 2011, BCV made an additional payment of 68,000,000 Russian rubles (approximately $2.3 million based on the current exchange rate) as part of its initial contribution. Pursuant to the participation agreement, BCV will make an additional payment of 1,730,000 Russian Rubles (approximately $58,000 based on the current exchange rate) as part of its initial contribution. BCV will make the balance of its contribution upon the achievement of predetermined development milestones. The first milestone payment of 192,737,000 Russian rubles (approximately $6.3 million based on the current exchange rate) will be made upon the completion of the preclinical studies and receipt of approval to begin clinical trials on oncology patients using Curaxin CBLC137, or any other lead Curaxin compound or the completion of the “proof-of- principle” characterization of the clinical efficacy of Curaxin CBLC102 in at least ten oncology patients. The second milestone payment of 181,190,000 Russian rubles (approximately $5.9 million based on the current exchange rate) will be made when the Phase II protocol is submitted to the FDA and when a letter of approval is received from the Institutional Review Board of the clinical center (including those in the Russian Federation) where the Phase II trial is to be conducted, indicating approval of the Phase II protocol and permission to commence the Phase II trial, or the achievement of the clinical end-point in the Phase II trial for Curaxin CBLC102.

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 BCV or make a cash contribution to Incuron. In such a case, if we choose to transfer a portion of its ownership interest to BCV, 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 serve as a subcontractor to Incuron to support certain mechanistic studies and oversee clinical development in the U.S.

Curaxin CBLC102

One of the curaxins from the 9-aminoacridine group is a long-known, anti-infective compound known as quinacrine, which we refer to as Curaxin CBLC102. It has been used for over 40 years to treat malaria, osteoarthritis and autoimmune disorders. However, we have discovered new mechanisms of action for quinacrine in the area of apoptosis. Through assay testing performed at Dr. Andrei Gudkov’s laboratories at CCF beginning in 2002, which included testing in a variety of human tumor-derived cell lines representing cancers of different tissue origin (including RCC, sarcomas, prostate, breast and colon carcinomas), we have observed that Curaxin CBLC102 behaves as a potent NF-kB suppressor and activator of p53 in these types of cancer cells. As published in Oncogene (Guo et al., Oncogene, 2009, 28:1151-1161), it has now been shown that treatment of cancer cells with Curaxin CBLC102 results in the inhibition of the molecular pathway (PI3K/Akt/mTOR) that is important for cancer cell survival and is considered to be a highly relevant anticancer treatment target. Finally, Curaxin CBLC102 has favorable pharmacological and toxicological profiles and demonstrates the anticancer effect in transplants of human cancer cells into primates.

We launched a Phase II study with Curaxin CBLC102 in January 2007 to provide proof of safety and of anti-neoplastic activity in cancer patients and establish a foundation for clinical trials of our new proprietary curaxin molecules, which have been designed and optimized for maximum anticancer effects, as well as for additional treatment regimens based on ongoing research into the precise molecular mechanisms of action of curaxins. Thirty-one patients were enrolled in the Phase II study of Curaxin CBLC102 as a monotherapy in late stage,

hormone-refractory taxane-resistant prostate cancer. All patients had previously received hormonal treatment for advanced prostate cancer and 28 of the 31 had also previously received chemotherapy. One patient had a partial response, while 50% of the patients exhibited a decrease or stabilization in PSA velocity, a measure of the speed of prostate cancer progression. Curaxin CBLC102 was well tolerated and there were no serious adverse events attributed to the drug. The trial demonstrated indications of activity and a remarkable safety profile in one of the most difficult groups of cancer patients.

The indications of activity and remarkable safety demonstrated in the Curaxin CBLC102 Phase II trial, in conjunction with new mechanistic discoveries, point to additional potential treatment paradigms including combination therapies with existing drugs or prospective use as a cancer prevention agent. Additional potential uses for Curaxin CBLC102 will be explored in conjunction with our strategic partners at RPCI and through the Incuron joint venture.

In November 2010, the first patient was dosed in a multi-center clinical trial of Curaxin CBLC102 on patients with liver tumors 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 Curaxin CBLC102. Secondary objectives of the study include describing the safety profile, pharmacokinetics, and response to Curaxin CBLC102.

The study includes a dose escalation arm of up to 30 patients divided into five cohorts, with an additional six patients to be enrolled at the selected therapeutic dose. Patients will be treated with Curaxin CBLC102 for eight weeks, with a loading dose administered in week 1 and maintenance doses administered in weeks 2 through 8. Dose escalation will be done gradually, starting with a loading dose of 300mg and a maintenance dose of 100mg. Recruitment is anticipated to take approximately six months, with overall duration of the study to last approximately 12 months.

The lead center for the study is the Russian Oncological Scientific Center ("ROSC") in Moscow, a leading oncology center in Russia. The national coordinator for the study is Professor S.A. Tyulyandin, MD, D.Sc. Deputy Director of Clinical Oncology and Director of Clinical Pharmacology and Chemotherapy at ROSC. Dr. Tyulyandin is one of the leading experts in drug therapy of malignant tumors in Russia and is considered a recognized expert on chemotherapy. Complex methods for the treatment of malignant neoplasms of the testes, breast, ovarian and other tumors have been developed under his leadership.

Insights into the mechanism of action of Curaxin CBLC102 were published in one of the world's leading cancer journals, Oncogene (Guo et al., Oncogene, 2009, 28:1151-1161). The published study uncovered additional molecular mechanisms underlying the anticancer activity of Curaxin CBLC102, which was previously known to involve simultaneous targeting of two key regulators of the controlled cell death process (p53 and NF-kB). It has now been shown that treatment of cancer cells with Curaxin CBLC102 results in the inhibition of the molecular pathway (PI3K/Akt/mTOR) that is important for cancer cell survival and is considered to be a highly relevant anticancer treatment target.

Another breakthrough discovery related to the mechanism of action of Curaxin CBLC102 was published in an international health science journal, Cell Cycle (Neznanov et al., Cell Cycle 8:23, 1-11; December 1, 2009). This study examined the ability of Curaxin CBLC102 to inhibit heat shock response, a major adaptive pro-survival pathway that rescues cells from stressful conditions involving accumulation of misfolded proteins (known as proteotoxic stress). Tumor cells typically become dependent on constitutive activity of this salvaging mechanism making them selectively susceptible to its inhibitors, especially if applied in combination with certain cancer therapies provoking proteotoxic stress.

The potential use of curaxins as adjuvants to cancer therapies inducing proteotoxic stress, such as bortezomib (Velcade(R)) or thermotherapy, opens a whole new avenue of potential treatment options that may broaden the spectrum of responding tumors by cutting off an escape mechanism.

Three families of patent applications have been filed for Curaxin CBLC102.

We anticipate that additional clinical efficacy studies will be required before we are able to apply for FDA licensure. 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 Curaxin CBLC102.

We spent approximately $399,068 and $262,637 on R&D for Curaxin CBLC102 in the fiscal years ended December 31, 2010 and 2009, respectively. From our inception to December 31, 2010, we spent $7,128,188 on R&D for Curaxin CBLC102.

Other Curaxins

As mentioned above, screening of the chemical library for compounds capable of restoring normal function to wild type p53 in the context of RCC yielded three chemical classes of compounds. Generation of focused chemical libraries around the hits from one of these classes and their structure-activity optimization brought about a new generation of curaxins. As the part of this program performed in the partnership with ChemBridge Corporation, more than 800 proprietary compounds were screened for p53 activation, efficacy in animal tumor models, selective toxicity and metabolic stability in the presence of rat and human microsomes. The most active compounds were efficacious in preventing tumor growth in models for colon carcinoma, melanoma, ovarian cancer, RCC, and breast cancer.

As a result of this comprehensive hit-to-lead optimization program, we have developed Curaxin CBLC137, which is a drug candidate with proprietary composition of matter belonging to our next generation of highly improved curaxins. Curaxin CBLC137 has demonstrated reliable anti-tumor effects in animal models of colon, breast, renal and prostate cancers. Curaxin CBLC137 has favorable pharmacological characteristics, is suitable for oral administration and demonstrates a complete lack of genotoxicity. It shares all of the positive aspects of Curaxin CBLC102, but significantly exceeds the former compound's activity and efficacy in preclinical tumor models. Further development of Curaxin CBLC137 will continue through the Incuron joint venture.

Nine families of patent applications have been filed for other curaxins including one that also relates to Curaxin CBLC102.

We spent approximately $1,173,562 and $330,053 on R&D for other curaxins in the fiscal years ended December 31, 2010 and 2009, respectively. From our inception to December 31, 2010, we spent $6,678,725 on R&D for other curaxins.

Curaxin CBLC137 is at a very 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.

COLLABORATIVE RESEARCH AGREEMENTS

Cleveland Clinic Foundation

We have a unique opportunity to accelerate our development by utilizing intellectual property, drug leads, new research technologies, technical know-how and original scientific concepts derived from 25 years of research achievements relevant to cancer by Dr. Andrei Gudkov and his research team while at CCF. Pursuant to an agreement we entered into with CCF effective as of July 1, 2004, 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 to CCF 1,341,000 shares of common stock;

- Make certain milestone payments (ranging from $50,000 to $4,000,000, depending on the type of drug and the stage of such drug's development);

- Make royalty payments (calculated as a percentage of the net sales of the drugs ranging from 1-2%); and

- Make sublicense royalty payments (calculated as a percentage of the royalties received from the sublicenses ranging from 5-35%).

The schedule of milestone payments is as follows:

File IND application for Protectan CBLB502 (completed February 2008)	$50,000
Commence Phase II clinical trials for Protectan CBLB502	$100,000
File BLA application for Protectan CBLB502	$350,000
Receive regulatory approval to sell Protectan CBLB502	$1,000,000
File IND application for Curaxin CBLC102 (completed May 2006)	$50,000
Commence Phase II clinical trials for Curaxin CBLC102 (completed January 2007)	$250,000
Commence Phase III clinical trials for Curaxin CBLC102	$700,000
File NDA application for Curaxin CBLC102	$1,500,000
Receive regulatory approval to sell Curaxin CBLC102	$4,000,000

Under this license agreement, we may exclusively license additional technologies discovered by Dr. Gudkov in this field by providing CCF with notice within 60 days after receiving an invention disclosure report from CCF relating to any such additional technologies. We believe that this relationship will prove valuable, not only for the purposes of developing the discoveries of Dr. Gudkov and his colleagues, but also as a source of additional new technologies. We also expect that CCF will play a critical role in validating therapeutic concepts and in conducting trials. 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 that 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 AFRRI, (ii) the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., and (iii) CCF, to evaluate one of our radioprotective drug candidates and its effects on intracellular and extracellular signaling pathways. As a collaborator under this agreement, we are able to use the laboratories of the AFRRI to evaluate Protectan CBLB502 and its effects on intracellular and extracellular signaling pathways in order to improve countermeasures to lethal doses of radiation. Under the terms of the agreement, all parties are financially responsible for their own expenses related to the agreement. The agreement has a five-year term, but may be unilaterally terminated by any party upon 30 days prior written notice with or without cause.

Under the CRADA, if an invention from the performance of the CRADA is conceived or first actually reduced to practice by one party, then such party is entitled to the ownership of such invention. Two or more parties will jointly own such subject inventions if each such party employed at least one inventor thereof at the time of its conception or first actual reduction to practice. In addition, under the CRADA, CBLI and CCF granted to the U.S. government a non-exclusive, non-transferable, irrevocable, paid-up license to practice any subject inventions throughout the world by or on behalf of the government for research or other government purposes. We granted to the U.S. government an irrevocable, worldwide, royalty free 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 who produced it. If such data or research material is jointly produced, the CRADA provides for joint ownership in such data or research material.

In August 2010, the terms of the agreement were extended by an additional two years expiring August 15, 2012, and an additional scope of the research to be performed under the CRADA has been added. As the part of the extended research plan, AFRRI will perform additional experiments in non-human primates to evaluate radioprotection efficacy of Protectan CBLB502 and perform analysis of hematopoietic stem cell mobilization by Protectan CBLB612.

Roswell Park Cancer Institute

In January 2007, we entered into a strategic research partnership with RPCI to develop our anticancer and radioprotectant drug candidates.

RPCI, founded in 1898, is a world-renowned cancer research hospital and the nation's first cancer research, treatment and education center. RPCI is a member of the prestigious National Comprehensive Cancer Network, an alliance of the nation's leading cancer centers, and is one of only ten free-standing cancer centers in the nation.

RPCI and various agencies of the state of New York provided us with approximately $5 million of grant and other funding. We established a major research/clinical facility at the RPCI campus in Buffalo, New York, which has become the foundation for several of our advanced research and clinical trials and entered into a Sponsored Research Agreement ("SRA") to develop our cancer and radioprotectant drug candidates.

Under the SRA, title to any inventions under the agreement will reside with RPCI if RPCI's personnel are the sole inventors and will reside with us if our personnel are the sole inventors of such invention. If the invention was made jointly, the patent rights will be jointly owned. 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 SRA for commercial purposes. Pursuant to the SRA, we retain ownership of data generated through its research activities and retain the right to determine whether to publish the results of such activities. Investigators employed by RPCI or us are permitted to present and publish the methods and results of the research. The party proposing disclosure is required to send a copy of such information to the other party prior to the publication and the other party will have sixty days to review such information and determine whether patent protection should be sought prior to the publication.

The SRA has a term of six years from its effective date of January 12, 2007. The SRA may be terminated at any time upon mutual agreement by the parties. In addition, the SRA 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.

Our partnership with RPCI will enhance the speed and efficiency of our clinical research, and will provide us with access to state-of-the-art clinical development facilities in partnership with a globally recognized cancer research center. We believe that our proprietary technology, combined with the assistance of RPCI, and our continuing strong relationship with CCF, will position us to become a leading oncology company. A key element of our long-term business strategy is to partner with world-class institutions to aid us in accelerating our drug development timeline. We believe that our firm alliances with both RPCI and CCF provide us with a significant competitive advantage.

ChemBridge Corporation

Another vital component of our drug development capabilities is our strategic partnership with ChemBridge Corporation, an established leader in combinatorial chemistry and in the manufacture of diverse chemical libraries.

On April 27, 2004, we entered into a library access agreement with ChemBridge that, in exchange for shares of our common stock and warrants, delivered to us a chemical library of 214,000 compounds. Under the library access agreement, we have also agreed to collaborate with ChemBridge in the future on two optimization projects, wherein ChemBridge will have the responsibility of providing the chemistry compounds for the project and we will have the responsibility of providing the pharmacological/biological compounds. Upon providing ChemBridge with our data after at least two positive repeat screening assays, which have been confirmed in at least one additional functional assay, ChemBridge will have the option to select such compound as one of the two optimization projects. ChemBridge will retain a 50% ownership interest in two lead compounds selected by ChemBridge and all derivative compounds thereof. The parties will jointly manage the development and commercialization of any compounds arising from an optimization project. The library access agreement does not have a specified term or any termination provisions.

We believe that we have a strong working relationship with ChemBridge. We have fully completed one joint hit-to-lead optimization program with ChemBridge. As a result of this program, we have developed Curaxin

CBLC137, which is a drug candidate belonging to our next generation of highly improved curaxins with proprietary composition of matter and intellectual property protection. Curaxin CBLC137 has demonstrated reliable anti-tumor effects in animal models of colon, breast, renal and prostate cancers. Curaxin CBLC137 has favorable pharmacological characteristics, is suitable for oral administration and demonstrates a complete lack of genotoxicity. It shares all of the positive aspects of Curaxin CBLC102, but significantly exceeds that compound's activity and efficacy in preclinical tumor models.

PATENTS

The following is a summary of our current patents/patent applications:

Title	Product (Application)	Collaborator	Assignee	Priority Date	Expiration Date
Methods of Protecting Against Radiation Using Flagellin / Modulating Apoptosis	CBLB502 (medical and non-medical)	CCF	CCF	12/02/03	12/01/24
Flagellin Related Polypeptides and Uses Thereof	CBLB502 (medical and non-medical)	CCF	CCF	12/22/04	12/21/25
Method for Reducing the Effects of Chemotherapy Using Flagellin Related Polypeptides	CBLC502 (medical)	CCF	CCF/CBLI	02/11/08	02/10/29
Method of Reducing the Effects of Reperfusion	CBLB502 (medical)	CCF	CCF/CBLI	08/01/08	07/31/29
Vaccination of Autocrine Stimulation of Toll-like Receptors	CBLB502 (medical and non-medical)	RPCI	RPCI/CBLI	10/06/09	10/05/30
Method of Screening Modulators of Apoptosis (Divisional)	CBLB502 (non-medical)	CCF	CCF	12/02/03	12/01/24
Use of Flagellin to Protect Against Radiation (Continuation)	CBLB502 (non-medical)	CCF	CCF	12/02/03	12/01/24
Methods of Protecting Against Apoptosis Using Lipopeptides	CBLB612	CCF	CCF/CBLI	06/13/05	06/12/26
Method of Increasing Hematopoietic Stem Cells	CBLB612	none	CBLI	01/09/07	01/08/28
Inhibition of NF-kB	CBLC102	CCF	CCF	08/20/04	08/19/25
Modulation of Immune Responses	CBLC102	CCF	CCF	11/14/05	11/13/26
Activation of p53 and Inhibition of NF-kB for Cancer Treatment	CBLC102	CCF	CCF	02/02/06	02/01/27
Inducing Cell Death by Inhibiting Adaptive Heat Shock Reponse	Other Curaxins	RPCI	RPCI/CBLI	05/20/08	05/19/29
Modulation of Androgen Receptor for Treatment of Prostate Cancer	Other Curaxins	CCF	CCF/CBLI	09/30/05	09/29/26
Carbazole Compounds and Therapeutic Uses of the Compounds	Other Curaxins	none	CBLI	06/10/08	06/09/29
Method for Treating Androgen Receptor Positive Cancers	Other Curaxins	RPCI	RPCI/CBLI	09/23/09	09/22/30
Methods for Identifying Modulators of Apoptosis	Other Curaxins	none	CBLI	06/26/06	06/25/27
Small Molecule Inhibitors of MRP1 and Other Multidrug Transporters	Other Curaxins	CCF/CCIA	CCF/CCIA	05/14/04	05/13/25
Dual Cargo Nanoparticles for Treatment Drug Resistant Tumors (Provisional)	Other Curaxins	RPCI	RPCI/CBLI	12/16/10	12/15/31
Small Molecules Inhibiting Oncoprotein MYC (Provisional)	Other Curaxins	RPCI/CCIA	RPCI/ CCIA/ CBLI	10/12/10	10/11/31
Small Molecules Inhibiting Oncoprotein MYC (Provisional)	Other Curaxins	RPCI/CCIA	RPCI/ CCIA/ CBLI	12/16/10	12/15/31

Use of Toll-like Receptor Agonist for Treating Toll-like Receptor - Negative Cancer (Provisional)	CBLB502 (medical and non-medical)	RPCI	RPCI/CBLI	01/10/11	01/09/32

Our intellectual property platform is based primarily on ten patent families exclusively licensed to us by CCF, three patent applications we have filed and own exclusively, five patent applications filed in collaboration with RPCI and two patent applications filed in collaboration with RPCI and the Children's Cancer Institute Australia ("CCIA").

As a result of the license agreement with CCF, we currently have filed, on CCF's behalf (including one in which CCIA also collaborated), ten families of patents/patent applications, one of which includes divisional and continuation applications of the patent originally issued in the U.S., covering new classes of anticancer and radiation-protecting compounds, their utility and mode of action. One of the patent applications was approved by the U.S. Patent and Trademark Office and counterpart agencies in several other nations. The patent issued in the U.S. is US Patent No. 7,638,485 titled "Modulating Apoptosis" covering the method of protecting a mammal from radiation using flagellin including Protectan CBLB502. This patent was also granted by European Patent Office, the Eurasian Patent Organization, Ukraine and China. A second patent titled "Method of Protecting Against Apoptosis using Lipopeptides" was granted by South Africa (Patent Number 2008/00126) and we have received notices of intent to grant patent from New Zealand and the Eurasian Patent Organization. A third application entitled "Method of Increasing Hematopoietic Stem Cells" was granted in South Africa (Patent Number 2009/05378). A fourth application entitled "Small Molecule Inhibitors of MRP1 and Other Multidrug Responders" has been granted in seven European countries and the Eurasian Patent Organization and is pending in the U.S.

In 2010, two provisional patent applications were introduced and filed with the U.S. Patent Office. Both provisional patent applications were filed in collaboration with RPCI. In addition, in 2010, one provisional patent application filed in 2009 was abandoned with a new provisional patent application on the same subject matter filed, and the remaining four provisional patent applications filed in 2009 were converted to PCT applications.

In 2009, three provisional patent applications were introduced and filed with the U.S. Patent Office and two non-provisional patent applications were introduced and filed with the U.S. Patent Office. The two non-provisional patent applications are licensed from CCF and the three provisional patent applications were filed in collaboration with RPCI.

MANUFACTURING

We do not intend to establish or operate facilities to manufacture our drug 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. ("SynCo"), a leading biopharmaceutical manufacturer, to produce Protectan CBLB502 under cGMP specifications, and have completed an agreement to produce sufficient amounts for clinical trials and a commercial launch. As discussed above, the yields from the established manufacturing process at SynCo 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. For Curaxin CBLC102, we have contracted with Regis Technologies, Inc. to manufacture sufficient amounts for clinical trials.

GOVERNMENT REGULATION

Government authorities in the U.S., at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. 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 ("FDCA") and in the case of biologics, also under the Public Health Service Act, implementing regulations. Our product candidates must be approved by the FDA through the NDA process or BLA process before they may be legally marketed in the U.S., which generally involves the following:

- Completion of preclinical laboratory studies, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;
- Submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- Performance of adequate and well-controlled human clinical trials according to Good Clinical Practices 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; and
- FDA review and approval of the NDA or BLA.

As part of the IND, an IND sponsor must submit to the FDA the results of preclinical studies, which may include laboratory evaluations and animal studies, together with manufacturing information and analytical data, and the proposed clinical protocol for the first phase of the 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 detail, 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) 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 are 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.

If a Phase II clinical trial is the subject of discussion at an end-of-Phase II meeting with the FDA, a sponsor may be able to request a Special Protocol Assessment ("SPA"), the purpose of which is to reach agreement with the FDA on the design of the Phase III clinical trial protocol design and analysis that will form the primary basis of an efficacy claim. If such an agreement is reached, it will be documented and made part of the administrative record, and it will be binding on the FDA and may not be changed unless the sponsor fails to follow the agreed-upon protocol, data supporting the request are found to be false or incomplete, or the FDA determines that a substantial scientific issue essential to determining the safety or effectiveness of the drug was identified after the testing began. Even if a SPA is agreed to, approval of the NDA is not guaranteed since a final determination that an agreed-upon protocol satisfies a specific objective, such as the demonstration of efficacy, or supports an approval decision, will be based on a complete review of all the data in the NDA.

On occasion, the FDA may suggest or the sponsor of a clinical trial may decide to use an independent data monitoring committee ("DMC") 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 in which the use of a DMC is appropriate and suggests how a DMC should be established and operate. DMCs 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 detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. 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 can 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 usually complete additional animal studies and must also 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, among other things, the manufacturer 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.

If a drug is intended to treat a serious or life threatening condition for which there is an unmet medical need, a company may request that the FDA consider the drug for a fast track development program at the time of submitting its IND or at any time prior to receiving marketing approval. The fast track program is designed to facilitate the development and expedite the review of a new drug for the treatment of specific conditions. If the FDA agrees that the drug meets the criteria for fast track development for treatment of one or more conditions, it will grant fast track status.

Orphan Drug Designation

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 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. If a competitor obtains approval of the same drug, as defined by the FDA, or if our product candidate is determined to be contained within the competitor’s product for the same indication or disease, the competitor’s exclusivity could block the approval of our product candidate in the designated orphan indication for seven years.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product.

The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. Once the submission is accepted for filing, the FDA begins an in-depth and substantive review. The FDA may seek advice and a recommendation from an external advisory committee as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee. The FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require submission of additional clinical or other data and information which, upon agency review and interpretation, may or may not be deemed by the FDA to satisfy the criteria for approval. The FDA may also issue a "complete response" letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA or BLA.

NDAs and BLAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

If approved by the FDA, the product's use may be limited to specific diseases, dosages or indications. In addition, the FDA may require us to conduct post-approval, or Phase IV, testing which involves further nonclinical studies or clinical trials designed to further assess the drug's safety and effectiveness and may require additional testing and surveillance programs to monitor the safety of the drug in the marketplace.

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.

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain applications. The FDCA 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 FDCA 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 preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Biologics Price Competition and Innovation Act of 2009

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act which included the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"). The BPCIA amended the PHSA to create an abbreviated approval pathway for two types of "generic" biologics - biosimilars and interchangeable biologic products, and provides for a twelve-year exclusivity period for the first approved biological product, or reference product, against which a biosimilar or interchangeable application is evaluated. A biosimilar product is defined as one that is highly similar to a reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. An interchangeable product is a biosimilar product that may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

The biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

An application for a biosimilar product may not be submitted until four years after the date on which the reference product was first approved; however if pediatric studies are performed and accepted by the FDA, the twelve-year exclusivity period will be extended for an additional six months. The first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed, but the exclusivity period may be shortened under certain circumstances.

The FDA held a 2-day meeting in November 2010 regarding implementation of the BPCIA, but has not yet issued additional guidance. Nevertheless, the absence of such guidance does not preclude the FDA from reviewing and taking action on a biosimilar application.

Post-Approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Manufacturers and other entities involved in the manufacture and distribution of approved FDA-regulated products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

Any drug products manufactured or distributed by us or our partners pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the

market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. For example, the Food and Drug Administration Amendments Act of 2007 ("FDAAA") gave the FDA enhanced post-market authority, including the authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with a risk evaluation and mitigation strategy approved by the FDA. Additionally, the law expands the clinical trial registry so that sponsors of all clinical trials, except for Phase I trials, are required to submit certain clinical trial information for inclusion in the clinical trial registry data bank. Failure to comply with any requirements under FDAAA may result in significant penalties. In addition to new legislation, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters;
- fines, injunctions, civil penalties or criminal prosecution;
- seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusal to approval new products; and
- withdrawal of approvals.

Foreign Regulation

In addition to regulations in the U.S., we will be subject to a variety of foreign regulations governing clinical trials and 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.

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.

EMPLOYEES

As of March 7, 2011, we had 55 employees, 52 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.

Furthermore, we currently have no known exposures to any current or proposed climate change legislation which could negatively impact our operations or require capital expenditures to become compliant. Nonetheless, it is too soon to predict with any certainty the ultimate impact, either directionally or quantitatively, of climate change and related regulatory responses.

COMPETITION

Non-Medical Applications

In the area of radiation-protective antidotes, various companies, such as RxBio, Inc., Exponential Biotherapies Inc., Osiris Therapeutics, Inc., ImmuneRegen BioSciences, Inc., Neumedicines, Inc., Cellerant Therapeutics, Onconova Therapeutics, Inc., Araim Pharmaceuticals, Inc., EVA Pharmaceuticals, Terapio, Aeolus Pharmaceuticals, Cangene Corporation and Humanetics Corporation are developing biopharmaceutical products that potentially directly compete with our non-medical application drug candidates, even though their approaches to such treatment are different.

We believe that due to the global political environment, the progress of development is the critical factor in the marketing of an effective MRC for federal agencies, such as DoD and HHS. New developments in this area are expected to continue at a rapid pace in both industry and academia.

Medical Applications

The arsenal of medical radiation-protectors is limited to ETHYOL™ (amifostine), sold by MedImmune, and acquired by AstraZeneca International. This radiation-protector is limited because of the serious side effects of the drug. Other radiation-protectors may enter the market.

Biomedical research for anticancer therapies is a large industry, with many companies, universities, research institutions and foreign government-sponsored companies competing for market share. The top ten public U.S.-based companies involved in cancer therapy have a combined market capitalization exceeding $1 trillion. In addition, there are several hundred biotech companies who have as their mission anticancer drug development. These companies account for the approximately 150 anticancer compounds currently in drug trials. However, despite the numerous companies in this field, there is still a clear, unmet need in the anticancer drug development market.

Each of the approximately 200 types of cancer recognized by the National Cancer Institute has dozens of subtypes, both etiological and on a treatment basis. Due to this market segmentation, the paradigm of a one-size-fits-all, super-blockbuster approach to drug treatments does not work well in cancer therapy. Currently, even the most advanced therapeutics on the market do not provide substantial health benefits.

This suggests that innovative anticancer therapies are driven by the modest success of current therapeutics, the need for an improved understanding of the underlying science, and a shift in the treatment paradigm towards more personalized medicine. Our technology addresses this need for an improved understanding of the underlying science and implements a fundamental shift in the approach to developing anticancer therapies.

Stem Cell Mobilization

G-CSF is the current standard against which all other mobilization agents for stem cells are measured. This is because it has been shown to both mobilize more CD34+ stem cells and have less toxicity than any other single agent against which it has been tested to date. In a few cases, the use of G-SCF has caused deaths attributed to thrombosis (acute myocardial infarction and stroke) in sibling donors. Other side effects include pain, nausea, vomiting, diarrhea, insomnia, chills, fevers, and night sweats.

Mozobil (Genzyme Corporation) is a more recently 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.

Sargramostim (Bayer HealthCare Pharmaceuticals Inc.) as a single agent is used less often today for mobilization than G-CSF, because it mobilizes somewhat less well than G-CSF and because of a relatively higher incidence of both mild and severe side effects. Erythropoietin (Amgen, Inc.), now commonly used among cancer patients undergoing chemotherapy to maintain hemoglobin in the near normal range, also has some ability to mobilize CD34+ cells.

Other Sources of Competition

In addition to the direct competition outlined above, there is potential for adverse market effects from other outside developments. For example, producing a new drug with fewer side effects reduces the need for anti-side effects therapies. Because of this, we must monitor a broad area of anticancer R&D and be ready to fine-tune our development as needed.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and intense competition. This competition comes both from biotech firms and from major pharmaceutical and chemical 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 drug candidates' competitive position among other biotech and biopharmaceutical companies may 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 also experience competition in the development of our drug candidates from universities and other research institutions and compete with others in acquiring technology from such universities and institutions. In addition, certain of our drug candidates may be subject to competition from products developed using other technologies, some of which have completed numerous clinical trials. As a result, our actual or proposed drug candidates could become obsolete before we recoup any portion of our related R&D and commercialization expenses. However, we believe our competitive position is enhanced by our commitment to research leading to the discovery and development of new products and manufacturing methods.

Some of our competitors are actively engaged in R&D in areas where we also are developing drug candidates. The competitive marketplace for our drug candidates is significantly dependent upon the timing of entry into the market. 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.

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 major reallocation of government funds from radiation protection. 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 Protectan CBLB502 is intended to address.

Our Internet address is www.cbiolabs.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports, are available to you free of charge through the Investor Relations section of our website as soon as reasonably practicable after such materials have been electronically filed with, or furnished to, the Securities and Exchange Commission. The information available on, or accessible through, our website is not a part of this Annual Report on Form 10-K.

Item 1A. Risk Factors

Risks Relating to our Operations

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

We have a history of losses and can provide no assurance as to future operating results. 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 drug candidates.

We expect losses to continue for the next few years as we spend substantial additional sums on the continued R&D of proprietary drugs and technologies, and there is no certainty that we will ever become profitable as a result of these expenditures.

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

- our ability to obtain approval for, and if approved, to successfully commercialize, Protectan 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 drug candidates, we may not generate sufficient or sustainable revenue to achieve or sustain profitability.

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

Upon expiration of current capital reserves or sooner if we experience unanticipated cash requirements, we may be required to issue additional equity or debt securities or enter into other financial arrangements, including relationships with corporate and other partners, in order to raise substantial additional capital during the period 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. If we fail to raise sufficient additional financing, we will not be able to develop 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 planned clinical trials, development, and marketing of all, or of any, of our product candidates. In such event, our business, prospects, financial condition and results of operations could be materially adversely affected.

If we lose our funding from R&D contracts and grants, 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 2010, we received 100% of our revenues from government contract and grant development work in connection with grants from the DoD, NIH, and BARDA. In 2009 and 2008, we received 88.5% and 97.4% of our revenues from government contract and grant development work.

These revenues have funded some of our personnel and other R&D costs and expenses. However, if these awards are not funded in their entirety or if new grants and contracts are not awarded in the future, our ability to fund future R&D and implement technological improvements 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.

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

Our products are in their developmental stage. Further development and extensive testing will be required to determine their technical feasibility 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. Products that we may develop are not likely to be commercially available for a few years. The proposed development schedules for our products may be affected by a variety of factors, including technological difficulties, proprietary technology of others, 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 successfully develop and commercialize our products because they:

- are found to be unsafe or ineffective in clinical trials;
- do not receive necessary approval from the FDA or foreign regulatory agencies;
- fail to conform to a changing standard of care for the diseases they seek to treat; or
- are less effective or more expensive than current or alternative treatment methods.

Product development failure can occur at any stage of clinical trials and as a result of many factors and we and/or our collaborators may not be able to reach our anticipated clinical targets. Even if we or our collaborators complete our clinical trials, we do not know what the long-term effects of exposure to our product candidates will be. Furthermore, our products may be used in combination with other treatments and it is possible that such use could lead to unique safety issues. Failure to complete clinical trials or to prove that our product candidates are safe and effective would have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations.

Many of our projects are in the early stages of drug development and the successful development of biopharmaceuticals is highly uncertain, especially in the early stages.

Successful development of biopharmaceuticals is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Products that appear promising in the early phases of development may fail to reach the market for several reasons including:

- pre-clinical study or clinical trial results that 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;
- failure to receive the necessary regulatory approvals or 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;
- manufacturing costs, pricing or reimbursement issues, or other factors that make the product not economically feasible; and
- the proprietary rights of others and their competing products and technologies that may prevent our product from being commercialized.

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 clinical trials we are planning to conduct; for example, our R&D expenses may increase based on the number of 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 candidate will be available on terms acceptable to us, and some promising 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.

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.

As a U.S. government contractor, we may become subject to periodic audits and reviews. Based on the results of these audits, the U.S. government may adjust our contract-related costs and fees, including allocated indirect costs. As part of any such audit or review, the U.S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, compensation and/or management information systems. 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.

We are subject to numerous risks inherent in conducting clinical trials any of which could delay or prevent us from developing or commercializing our products.

Before obtaining required regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through pre-clinical testing and clinical trials that our product candidates are safe and effective for use in humans. We must outsource our clinical trials and negotiate with third parties to conduct such trials. We are not certain that we will successfully or promptly finalize agreements for the conduct of all our clinical trials. Delay in finalizing such agreements would delay the commencement of the Phase I/II trials of Protectan CBLB502 for medical applications and Phase II/III clinical trials of Curaxin CBLC102 in multiple cancers.

Agreements with clinical investigators and medical institutions for clinical 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 FDA-approved good clinical practices, we may be unable to use the data generated at those sites. If these clinical investigators, medical institutions 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 clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for or successfully commercialize Protectan CBLB502, Curaxin CBLC102 or other product candidates.

We or regulators may suspend or terminate our clinical trials for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the patients enrolled in our clinical trials. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in our clinical trials.

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.

We may not be able to obtain regulatory approval or 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 such FDA approval and whether any such approval will ultimately be granted. Preclinical 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. Delays in obtaining FDA or any other necessary regulatory approvals of any proposed product and failure to receive such approvals would have an adverse effect on the product’s potential commercial success and on our business, prospects, financial condition and results of operations. In addition, 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 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 the commercialization of our drug candidates and we may rely even more on strategic collaborations for R&D of our other drug candidates. Our business depends on our ability to sell drugs to both government agencies and to the general pharmaceutical market. Offering our drug 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 anticancer drugs, however, does require such development. We plan to sell anticancer 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 drug candidates or entered into successful collaborations for these services in order to ultimately commercialize our drug candidates.

We also rely on third-party collaborations with our manufacturers. Manufacturers producing our drug candidates must follow cGMP regulations enforced by the FDA and foreign equivalents. If a manufacturer of our drug candidates does not conform to the cGMP regulations and cannot be brought up to such a standard, we will be

required to find alternative manufacturers that do conform. This may be a long and difficult process, and may delay our ability to receive FDA or foreign regulatory approval of our drug candidates and cause us to fall behind on our business objectives.

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 drug 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 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 exclusively licensed ten families of patent applications from CCF and have filed ten families of patent applications on our own or in collaboration with others. We do not know whether, any of these patent applications 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 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. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

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 the Cleveland Clinic and other parties, we could lose our ability to develop our drug 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 licenses with regard to the use of the CCF's 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. 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 license with the CCF imposes 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 90 day period provided, 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 obligations we will be required to pay on sales of future products, if any, the amounts may be significant. The dollar amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any.

We may incur substantial liabilities from any product liability 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.

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.

Risks Relating to our Industry and Other External Factors

Adverse conditions in the capital and credit markets may significantly affect our ability to obtain financing. If we are unable to obtain financing in the amounts and on terms and dates acceptable to us, we may not be able to expand or continue our operations and development, and thus may be forced to curtail or cease operations or discontinue our business.

We cannot be certain that we will be able to obtain financing when it is needed. 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 are unable to obtain financing in the amounts and on terms and dates acceptable to us, we may not be able to continue our operations and development, and thus may be forced to curtail or cease operations or discontinue our business.

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

Products developed to treat diseases caused by or to combat the threat of bio-terrorism will be subject to changing political and social environments. The political and social responses to bio-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, BARDA and other government agencies for the development of our bio-defense product candidates. 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 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. 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 is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the biotech or pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees may be considered foreign officials.

Risks Relating to our Securities

The price of our common stock may be volatile, which may in turn expose us to securities litigation.

Our common stock is listed on the NASDAQ Capital Market. 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. Factors that could cause fluctuations include, but are not limited to, the following:

- 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 clinical trials;
- events affecting CCF, RPCI or any 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.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has occasionally been brought against that company. Due to the potential volatility of our stock price, we may therefore be the target of securities litigation in the future. Regardless of its outcome, securities litigation could result in substantial costs and divert management's attention and Company resources from our business.

Sales of additional equity securities may adversely affect the market price of our common stock.

We expect to continue to incur product development and selling, general and administrative costs, and in order to satisfy our funding requirements, we may need to sell additional equity securities. The sale or the proposed sale of substantial amounts of our common stock or other equity securities, such as warrants, or the perception that we may make such a sale, may adversely affect the market price of our common stock and our stock price may decline substantially. Any new securities issued may have greater rights, preferences or privileges than our existing common stock.

Additional authorized shares of common stock available for issuance may adversely affect the market price of our common stock.

We are currently authorized to issue 80,000,000 shares of our common stock and 10,000,000 of our preferred stock As of December 31, 2010, we had 28,959,176 shares of our common stock and 0 shares of our preferred stock issued and outstanding and 9,450,627 warrants and 3,259,865 options outstanding, of which 2,949,715 options are currently fully vested or vest within the next 60 days. To the extent the shares of common stock are issued or options and warrants are exercised, holders of our common stock will experience dilution.

In the event of any future issuances of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution. Furthermore, our outstanding warrants contain provisions that, in certain circumstances, could result in the number of shares of common stock issuable upon the exercise of such warrants to increase and/or the exercise price of such warrants to decrease.

Moreover, our board of directors is authorized to issue preferred stock without any action on the part of our stockholders. Our board of directors also has the power, without stockholder approval, to set the terms of any such preferred stock that may be issued, including voting rights, conversion rights, dividend rights, preferences over our common stock with respect to dividends or if we liquidate, dissolve or wind up our business and other terms. If we issue preferred stock in the future that has preference over our common stock with respect to the payment of dividends or upon our liquidation, dissolution or winding up, or if we issue preferred stock with voting rights that dilute the voting power of our common stock, the market price of our common stock could decrease. Any provision permitting the conversion of any such preferred stock into our common stock could result in significant dilution to the holders of our common stock.

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

We have no plans to pay dividends on our common stock, and 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 for future stock repurchases 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.

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. 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.

Item 1B. Unresolved Staff Comments

None

Item 2.Description of Properties

Our corporate headquarters is located at 73 High Street, Buffalo, New York 14203. We have approximately 28,000 square feet of laboratory and office space under a five year lease through June of 2012 with two, two-year renewals. This space serves as the corporate headquarters and primary research facilities. In addition, we have leased approximately 2,500 square feet of office space located at 9450 W. Bryn Mawr Rd., Rosemont, Illinois, 60018 through July 2011. We do not own any real property.

Item 3. Legal Proceedings

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

employment matters, product liability claims, environmental liabilities and intellectual property disputes.

Item 4. Removed and Reserved

PART II

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

Stock Exchange Listing

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

Stock Prices

The following table sets forth the range of high and low sale prices on The NASDAQ Capital Market, for each quarter during 2010 and 2009. On March 7, 2011, the last reported sale price of our common stock was $7.05 per share.

2010	High	Low
First Quarter	$ 4.76	$ 3.40
Second Quarter	$ 3.97	$ 2.91
Third Quarter	$ 5.21	$ 3.19
Fourth Quarter	$ 7.25	$ 5.07

2009	High	Low
First Quarter	$ 3.87	$ 1.15
Second Quarter	$ 4.50	$ 1.75
Third Quarter	$ 6.35	$ 3.40
Fourth Quarter	$ 4.97	$ 3.31

Stockholders

As of December 31, 2010, there were approximately 55 stockholders of record of our Common Stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial stockholders represented by these record holders.

Unregistered Sale of Securities

On October 1, 2010, as consideration for consulting services provided, we issued an aggregate of 15,687 shares of our common stock to Newport Coast Securities, Inc. These shares were issued without registration in reliance on the exemptions afforded by Section 4(2) of the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

We made no repurchases of our securities during the year ended December 31, 2010.

Item 6: Selected Financial Data

The following selected financial data has been derived from our audited financial statements. The information below is not necessarily indicative of the results of future operations and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and Item 1A, "Risk Factors,"

of this Form 10-K, and the financial statements and related notes thereto included in Item 8 of this Form 10-K, in order to fully understand factors that may affect the comparability of the information presented below:

SELECTED FINANCIAL DATA

	Year Ended December 31,				
	2010	2009	2008	2007	2006
Consolidated Statement of Operations Data:	(in thousands, except per share data)				
Total Operating Revenue	$15,332	$14,346	$4,706	$2,019	$1,708
Government contract or grant	15,332	12,696	4,586	1,729	1,503
Commercial	-	1,650	120	290	205
Net loss	$(26,672)(1)	$(12,826)(1)	$(14,026)(1)	$(26,997)(1)	$(7,223)
Net loss per share, basic and diluted	$(1.01)	$(0.82)	$(1.13)	$(2.34)	$(0.84)

	December 31,				
	2010	2009	2008	2007	2006
Consolidated Balance Sheet Data:	(in thousands)				
Total assets	$19,887	$6,554	$4,706	$17,422	$6,417
Long-term debt	-	-	-	-	50
Stockholder's equity (deficit)	(12,500)	(6,800)	538	14,194	5,593

We have not paid any dividends on common stock.

(1) Net loss in 2010, 2009, 2008, 2007 and 2006 included employee stock-based compensation costs of $4.6 million, $2.8 million, $1.5 million, $7.8 million and $0.5 million, net of tax, respectively, due to our adoption of the provisions of the Financial Accounting Standards Board Accounting Standards Codification on stock-based compensation on January 1, 2005. No employee stock-based compensation expense was recognized in reported amounts in any period prior to January 1, 2005.

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

This management's discussion and analysis of financial condition and results of operations and other portions of this filing contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking information. Factors that may cause such differences include, but are not limited to, availability and cost of financial resources, results of our R&D efforts and clinical trials, product demand, market acceptance and other factors discussed in this annual report under the heading "Risk Factors" and the Company's other Securities and Exchange Commission ("SEC") filings. This management's discussion and analysis of financial condition and results of operations should be read in conjunction with our financial statements and the related notes included elsewhere in this filing.

Financial Overview

Including several non-cash charges, our net loss increased from $12,826,409 for the year ended December 31, 2009 to $26,671,857 for the year ended December 31, 2010, an increase of $13,845,448 or 107.9%. For the years ended December 31, 2010 and 2009, we incurred non-cash charges of depreciation and amortization of $407,289 and $362,143 respectively, non-cash salaries and consulting fees of $4,640,150 and $2,760,446 respectively, and a change in the value of warrant liability of $16,011,769 and $6,267,665, respectively. Excluding these non-cash charges, our net loss increased from $3,436,155 for the year ended December 31, 2009 to $5,612,649 for the year ended December 31, 2010, an increase of $2,176,494 or 63.3%. This increase was primarily due to the R&D efforts of our consolidated subsidiary, Incuron.

Equity Overview

On March 16, 2007, we consummated a transaction with various accredited investors pursuant to which we agreed to sell to the investors, in a private placement, an aggregate of approximately 4,288,712 shares of Series B Convertible Preferred Stock and Series B Warrants to purchase approximately 2,144,356 shares of our common stock pursuant to a securities purchase agreement of the same date. The Series B Warrants expire on March 15, 2012 and had an initial per share exercise price of $10.36. The aggregate purchase price paid by the investors for the Series B Preferred and Series B Warrants was approximately $30,000,000. Also issued in the transaction as partial compensation for services rendered by the placement agents were Series C Warrants, which had an initial per share exercise price of $11.00 and were originally exercisable for 267,074 shares of common stock. The Series C Warrants also expire on March 15, 2012. After related fees and expenses, we received net proceeds of approximately $29,000,000. On September 16, 2009, the outstanding Series B Preferred shares reached their termination date and, in accordance with their terms, were automatically converted into shares of common stock.

On February 13, 2009, March 20, 2009, and March 27, 2009, we entered into purchase agreements with various accredited investors, pursuant to which we agreed to sell to these investors an aggregate of 542.84 shares of Series D Convertible Preferred Stock and Series D Warrants to purchase an aggregate of 3,877,386 shares of the Company's common stock. The warrants have a seven-year term and a per share exercise price of $1.60. Each share of Series D Preferred was convertible into the number of shares of common stock equal to (1) the stated value of the share ($10,000), divided by (2) the then-current conversion price (initially $1.40, but subject to adjustment as described below). At the initial conversion price of $1.40, each share of Series D Preferred was convertible into approximately 7,143 shares of common stock. The aggregate purchase price paid by the investors for the Series D Preferred and the Series D warrants was approximately $5,428,307 (representing $10,000 for each share together with a warrant). After related fees and expenses, we received net proceeds of approximately $4,460,000. In consideration for its services as exclusive placement agent, Garden State Securities received cash compensation and warrants to purchase an aggregate of approximately 387,736 shares of common stock.

The conversion price of the Series D Preferred was subject to certain automatic adjustments, pursuant to which it reduced from $1.40 to $1.33 on August 13, 2009 and from $1.33 to $1.28 on November 13, 2009. On December 31, 2009, the conversion price of the Series D Preferred reduced from $1.28 to $1.02 because the Company failed to meet a particular development milestone by the end of 2009. At the conversion price of $1.02, each shares of Series D Preferred was convertible into approximately 9,804 shares of common stock. Upon completion of the Series D Preferred transaction and upon each adjustment to the conversion price of the Series D Preferred, the exercise prices of the Company's Series B Warrants and Series C Warrants, and the exercise price of certain other warrants issued prior to the Company's initial public offering, were reduced pursuant to weighted-average anti-dilution provisions. In addition to the adjustment to the exercise prices of these warrants, the aggregate number of shares issuable upon exercise of these warrants increased on each such occasion. As a result, the Series B Warrants had an exercise price of $6.37 per share and an aggregate of 3,847,276 shares of common stock were issuable upon exercise of the Series B Warrants, the Series C Warrants had an exercise price of $6.76 per share and an aggregate of 434,596 shares were issuable upon exercise of the Series C Warrants, and such warrants issued prior to our initial public offering had an exercise price of $1.39 per share and an aggregate of 117,861 shares were issuable upon exercise of such warrants.

On February 9, 2010, all outstanding shares of Series D Preferred automatically converted into approximately 4,576,979 shares of common stock at the conversion price of $1.02, as a result of the Company's closing sales price being above a certain level for 20 consecutive trading days as well as the satisfaction of certain other conditions.

On February 25, 2010, we entered into a Securities Purchase Agreement (the "February 2010 Securities Purchase Agreement") with various accredited investors, pursuant to which we agreed to sell an aggregate of 1,538,462 shares of our common stock and warrants to purchase an aggregate of 1,015,384 shares of our common stock, for an aggregate purchase price of $5,000,002. The transaction closed on March 2, 2010. After related fees and expenses, the Company received net proceeds totaling $4,423,882. The common stock was sold at a price of $3.25 per share, and the warrants have an exercise price of $4.50 per share, subject to future adjustment for various events, such as stock splits or dilutive issuances. The warrants expire on March 2, 2015. For its services as placement agent, Rodman & Renshaw, LLC ("Rodman") received gross cash compensation in the amount of approximately $350,000, and it and its designees collectively received warrants to purchase 123,077 shares of common stock. The common stock and the shares of common stock underlying the warrants issued to the purchasers and Rodman have not been registered under the Securities Act of 1933.

Immediately after the completion of this transaction on March 2, 2010, pursuant to weighted-average anti-dilution provisions:

- the exercise price of the Series B Warrants reduced from $6.37 to $5.99, and the aggregate number of shares of common stock issuable upon exercise of the Series B Warrants increased from 3,847,276 to 4,091,345; and

- the exercise price of the Series C Warrants reduced from $6.76 to $6.35, and the aggregate number of shares of common stock issuable upon exercise of the Series C Warrants increased from 434,596 to 462,654.

On December 23, 2010, we entered into a Placement Agent Agreement with HFP Capital Markets, LLC ("HFP") relating to the sale by us to a single institutional accredited investor of 1,400,000 shares of our common stock in a "registered direct" offering ("December 2010 Offering"). The December 2010 Offering closed on December 29, 2010. The shares were sold at a purchase price of $5.99 per share. The sale of the shares was made pursuant to a Subscription Agreement, dated December 23, 2010 with the investor. HFP and Rodman acted as co-placement agents in connection with the December 2010 Offering. The net proceeds to us from the sale of the shares, after deducting for the placement agents' fees and offering expenses, was approximately $7.73 million.

As a result of the completion of the December 2010 Offering, the aggregate number of shares of common stock issuable to the holders of the Series C Warrants increased from 462,654 shares to 464,852 shares and the exercise price of the Series C Warrants decreased from $6.35 per share to $6.32 per share.

Also in connection with the December 2010 Offering, on December 23, 2010, the investors party to the February 2010 Securities Purchase Agreement, who purchased at least 75% of the aggregate original subscription amount, entered into an amendment to the February 2010 Securities Purchase Agreement with us. Such investors were granted the right to participate in certain future financing transactions ("Subsequent Financings") on or prior to the earlier of (i) the first trading day immediately following the date on which we complete Subsequent Financings resulting in aggregate gross proceeds in excess of $15 million, or (ii) December 31, 2011, and will have the right to participate in an amount of the Subsequent Financing equal to 100% of the Subsequent Financing amount, on the same terms, conditions and price provided for in the Subsequent Financing.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues, expenses and other reported disclosures. We believe that we consistently apply these judgments and estimates and the financial statements and accompanying

notes fairly represent all periods presented. However, any differences between these judgments and estimates and actual results could have a material impact on our statements of income and financial position. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances.

Note 2 to our financial statements includes disclosure of our significant accounting policies. Critical accounting estimates, as defined by the SEC, are those that are most important to the portrayal of our financial condition and results of operations and require our most difficult and subjective judgments and estimates of matters that are inherently uncertain. While all decisions regarding accounting policies are important, we believe that our policies regarding revenue recognition, R&D expenses, intellectual property related costs, stock-based compensation expense and fair value measurements could be considered critical, and are discussed in more detail below. For additional information, see our audited financial statements and notes thereto which are included with this Annual Report on Form 10-K, which contain accounting policies and estimates and other disclosures required by GAAP.

Revenue Recognition

Our revenue sources consist of government grants, government contracts and a commercial licensing and development contract.

Grant revenue is recognized using two different methods depending on the type of grant. Cost reimbursement grants require us to submit proof of costs incurred that are invoiced by us to the government agency, which then pays the invoice. In this case, grant revenue is recognized during the period that the costs were incurred.

Fixed-cost grants require no proof of costs and are paid as a request for payment is submitted for expenses. The grant revenue under these fixed cost grants is recognized using a percentage-of-completion method, which uses assumptions and estimates. These assumptions and estimates are developed in coordination with the principal investigator performing the work under the fixed-cost grants to determine key milestones, expenses incurred, and deliverables to perform a percentage-of-completion analysis to ensure that revenue is appropriately recognized. Critical estimates involved in this process include total costs incurred and anticipated to be incurred during the remaining life of the grant.

We recognize revenue related to the funds received from the State of New York under the sponsored research agreement with RPCI as allowable costs are incurred. We recognize revenue on research laboratory services and the subsequent use of related equipment. The amount paid as a payment toward future services related to the equipment is recognized as a prepaid asset and will be recognized as revenue ratably over the useful life of the asset.

Government contract revenue is recognized as allowable R&D expenses are incurred during the period and according to the terms of the contract.

Commercial revenue is recognized when the service or development is delivered or upon complying with the relevant terms of the commercial agreement including licensing agreements granting the rights to further develop technology leading to commercialization in certain territories.

Research and Development Expenses

R&D costs are expensed as incurred. These expenses consist primarily of our proprietary R&D efforts, including salaries and related expenses for personnel, costs of materials used in our R&D, costs of facilities, and costs incurred in connection with our third-party collaboration efforts. Pre-approved milestone payments made by us to third parties under contracted R&D arrangements are expensed when the specific milestone has been achieved. As of December 31, 2010, $50,000 has been paid to CCF for milestone payments relating to the filing of an IND with the FDA for Curaxin CBLC102, $250,000 has been paid to CCF as a result of commencing Phase II clinical trials for Curaxin CBLC102 and $50,000 has been paid to CCF relating to the filing of an IND with the FDA for Protectan CBLB502. Once a drug receives regulatory approval, we will record any subsequent milestone payments in identifiable intangible assets, less accumulated amortization, and amortize them evenly over the remaining agreement term or the expected drug life cycle, whichever is shorter. We expect our R&D expenses to increase as we continue to develop our drug candidates.

Intellectual Property Related Costs

We capitalize costs associated with the preparation, filing and maintenance of our intellectual property rights. Capitalized intellectual property is reviewed annually for impairment. If a patent application is approved, costs paid by us associated with the preparation, filing and maintenance of the patent will be amortized on a straight line basis over the shorter of 20 years from the initial application date or the anticipated useful life of the patent. If the patent application is not approved, costs paid by us associated with the preparation, filing and maintenance of the patent will be expensed as part of selling, general and administrative expenses at that time.

Through December 31, 2009, we capitalized $929,976 in expenditures less amortization associated with the preparation, filing and maintenance of certain of our patents. We capitalized an additional $250,735, amortized an

additional $17,850 and recognized a deferred loss of $574 related to foreign currency translation for the year ended December 31, 2010, resulting in a balance of capitalized intellectual property totaling $1,162,287.

Stock-based Compensation

All stock-based compensation, including grants of employee stock options, is recognized in the statement of operations based on its fair value.

The fair value of each stock option granted is estimated on the grant date using accepted valuation techniques such as the Black Scholes Option Valuation model or Monte Carlo Simulation depending on the terms and conditions present within the specific option being valued. The assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect our experience. We use a risk-free rate based on published rates from the St. Louis Federal Reserve at the time of the option grant; assume a forfeiture rate of zero; assume an expected dividend yield rate of zero based on our intent not to issue a dividend in the foreseeable future; use an expected life based on the safe harbor method; and presently compute an expected volatility based on a method layering in the volatility of our common stock with that of the volatility of similar high-growth, publicly-traded, biotechnology companies' common stock due to the limited trading history of our company. Compensation expense is recognized using the straight-line amortization method for all stock-based awards.

During the years ended December 31, 2010 and 2009, we granted 1,175,930 and 787,932 stock options, respectively. We recognized a total of $1,977,009 and $1,784,240 in expense related to stock options for the years ended December 31, 2010 and 2009, respectively. We also recaptured $39,483 and $50,197 of previously recognized expense due to the forfeiture of non-vested stock options during the years ended December 31, 2010 and 2009, respectively. For the year ended December 31, 2010, we incurred an additional $37,800 of expense for stock options awarded under the 2009 Executive Compensation Plan. These options were originally expensed in 2009 based on December 31, 2009 variables, but were not issued until May 18, 2010. The change in dates resulted in a difference in valuation assumptions used in the Black-Scholes model causing an increase in the grant date fair value. This increase in the grant date fair value from $2.31 to $2.40 per share resulted in the incurrence of $37,800 in expense. The net expense for options for the years ended December 31, 2010 and 2009 was $1,975,326 and $1,784,240, respectively.

We also recognized a total of $1,719,091 and $993,070 in expense for shares issued during the years ended December 31, 2010 and 2009, respectively.

Fair Value Measurement

The carrying amount of financial instruments, including cash and equivalents, short-term investments, accounts receivable, accounts payable and accrued expenses, approximate fair value as of December 31, 2010 and 2009. We value our financial instruments in accordance with accounting standards on disclosures which establish a valuation hierarchy for the inputs used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs in which little or no market data exists, therefore requiring a company to develop its own assumptions. We do not have any significant assets or liabilities measured at fair value using Level 1 or Level 2 inputs as of December 31, 2010.

We used level 3 inputs for valuation of our warranty liabilities. This included use of the Black-Scholes option pricing model and assumptions regarding expected term, discount rates, and dividends. As a result of this valuation methodology, we carry the warrants issued in the Series D Private Placement at fair value totaling $21,223,779 and $8,410,379 as of December 31, 2010 and December 31, 2009, respectively. We recognized a fair value measurement loss of $14,487,184 and $6,267,665 for the years ended December 31, 2010 and 2009, respectively.

As a result of this valuation methodology, we carry the warrants issued pursuant to the February 2010 Securities Purchase Agreement at fair value totaling $4,126,954 and $0 as of December 31, 2010 and December 31, 2009, respectively. We recognized a fair value measurement loss of $1,524,585 and $0 for the years ended December 31, 2010 and 2009, respectively.

We did not identify any other non-recurring assets and liabilities that are required to be presented on the balance sheets at fair value.

Recently Issued Accounting Pronouncements

In January 2010, the FASB issued updated guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. This update requires new disclosures on significant transfers of assets and liabilities between Level 1 and Level 2 of the fair value hierarchy (including the reasons for these transfers) and the reasons for any transfers in or out of Level 3. This update also requires a reconciliation of recurring Level 3 measurements about purchases, sales, issuances and settlements on a gross basis. In addition to these new disclosure requirements, this update clarifies certain existing disclosure requirements. For example, this update clarifies that reporting entities are required to provide fair value measurement disclosures for each class of assets and liabilities

rather than each major category of assets and liabilities. This update also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. This update became effective for the Company with the interim and annual reporting period beginning January 1, 2010, except for the requirement to provide the Level 3 activity of purchases, sales, issuances, and settlements on a gross basis, which will become effective for the Company with the interim and annual reporting period beginning January 1, 2011. The Company will not be required to provide the amended disclosures for any previous periods presented for comparative purposes. Other than requiring additional disclosures, adoption of this update did not have a material effect on the Company's financial statements.

In September 2009, the FASB provided updated guidance (1) on whether, in a revenue arrangement, multiple deliverables exist, how the deliverables should be separated, and how the consideration should be allocated; (2) requiring an entity to allocate revenue in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price; and (3) eliminating the use of the residual method and requiring an entity to allocate revenue using the relative selling price method. The update is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. Adoption may either be on a prospective basis or by retrospective application. The adoption of this guidance is not expected to have a material impact on the Company’s financial statements.

Results of Operations

The following is a summary of the quarterly consolidated results of operations for the years ended December 31, 2010 and December 31, 2009:

	Revenue	Operating Loss	Net Income (Loss)	Basic and Full Diluted Earnings Per Share Available for Common Shareholders
Year Ended December 31,2010				
First Quarter	$ 4,170,348	$ (1,456,933)	$ (3,364,011)	$ (0.14)
Second Quarter	4,210,763	(2,620,552)	(2,528,908)	(0.09)
Third Quarter	3,189,488	(967,705)	(7,285,539)	(0.27)
Fourth Quarter	3,760,968	(5,692,008)	(13,493,399)	(0.51)
Year	$ 15,331,567	$ (10,737,198)	$ (26,671,857)	(1.01)
Year Ended December 31, 2009				
First Quarter	$ 2,309,731	$ (1,315,040)	$ (2,958,929)	$ (0.24)
Second Quarter	4,189,978	(2,424,258)	(6,476,730)	(0.45)
Third Quarter	3,223,094	(1,091,084)	(5,189,279)	(0.33)
Fourth Quarter	4,623,105	(1,552,547)	1,798,529	0.20
Year	$ 14,345,908	$ (6,382,929)	$ (12,826,409)	(0.82)

The following table sets forth our statement of operations data for the years ended December 31, 2010, 2009 and 2008 and should be read in conjunction with our financial statements and the related notes appearing elsewhere in this annual report on Form 10-K.

	Year Ended December 31, 2010	Year Ended December 31, 2009	Year Ended December 31, 2008
Revenues	$ 15,331,567	$ 14,345,908	$ 4,705,597
Operating expenses	26,068,765	20,728,837	19,050,965
Other expense (income)	16,033,770	6,463,208	(59,597)
Net interest income	(99,111)	(19,728)	(259,844)
Net loss	$ (26,671,857)	$ (12,826,409)	$ (14,025,927)

Year Ended December 31, 2010 Compared to Year Ended December 31, 2009

Revenue

Revenue increased from $14,345,908 for the year ended December 31, 2009 to $15,331,567 for the year ended December 31, 2010, representing an increase of $985,659 or 6.9%. This increase resulted primarily from an increase in revenue from U.S. government contracts and grants.

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

Agency	Program	Contract Amount	Period of Performance	Revenue 2010	Revenue 2009

DoD	DTRA Contract	$	1,263,836	03/2007-02/2009	$	-	$ 183,613
AFRRI	Subcontractor	$	69,878	02/2010-11/2010	$	69,878	$ -
NY State/RPCI	Sponsored Research Agreement	$	3,000,000	03/2007-02/2012	$	12,398	$ 35,696
DoD	DOD Contract	$	9,590,000	05/2008-09/2010	$	564,432	$ 4,843,303
HHS	BARDA Contract	$	15,600,000	09/2008-02/2011	$	9,968,445	$ 5,374,535
NIH	NIAID Grant	$	1,232,695	09/2008-02/2010	$	560	$ 1,021,095
NIH	NIAID GO Grant	$	5,329,543	09/2009-09/2011	$	4,091,879	$ 1,237,666
DOD	CBMS-MITS Contract	$	14,800,000	09/2010-03/2013	$	623,975	$ -
				Totals	$	15,331,567	$ 12,695,908

We anticipate our revenue over the next year to continue to be derived mainly from government grants and contracts. We have been awarded 20 government contracts and grants totaling over $46 million in funding for R&D. We plan to submit or have submitted proposals for additional government contracts and grants over the next two years totaling over $100 million in funding. Many of the proposals will be submitted to government agencies that have awarded contracts and grants to us in the recent past, but there is no guarantee that any will be awarded to us.

If these awards are not funded in their entirety or if new grants and contracts are not awarded in the future, our ability to fund future R&D and implement technological improvements would be diminished, which would negatively impact our ability to compete in our industry.

Operating Expenses

Operating expenses have historically consisted of costs relating to R&D and general and administrative expenses. R&D expenses have consisted mainly of supporting our R&D teams, process development, sponsored research at RPCI and CCF, clinical trials and consulting fees. We plan to incur only those R&D costs that are properly funded, either through a government contract or grant or other capital sources. General and administrative expenses include all corporate and administrative functions that serve to support our current and future operations while also providing an infrastructure to support future growth. Major items in this category include management and staff salaries, rent/leases, professional services and travel-related expenses. Some of these costs will be funded through government contracts and grants that provide indirect cost reimbursement for certain indirect costs such as fringe benefits, overhead and general and administrative expenses.

Operating expenses increased from $20,728,837 for the year ended December 31, 2009 to $26,068,765 for the year ended December 31, 2010, representing an increase of $5,339,928 or 25.8%. We recognized a total of $2,760,446 of non-cash, stock-based compensation for the year December 31, 2009 compared to $4,640,150 for the year ended December 31, 2010. If these non-cash, stock-based compensation expenses were excluded, operating expenses would have increased from $17,968,391 for the year ended December 31, 2009 to $21,428,615 for the year ended December 31, 2010. This represents an increase in operating expenses of $3,460,224 or 19.3%, resulting primarily from increased Incuron activities as well as higher selling, general, and an administrative expense as our infrastructure continues to be strengthened.

A portion of this increase resulted from an increase in R&D expenses from $14,331,673 for the year ended December 31, 2009 to $16,141,040 for the year ended December 31, 2010, an increase of $1,809,367 or 12.6%. The increased R&D expenses were incurred primarily as a result of increasing the non-cash, stock-based compensation and additional R&D costs incurred to support the revenue increase. We recognized a total of $1,074,048 of non-cash compensation for R&D stock based compensation for the year ended December 31, 2009 compared to $1,430,754 for the year ended December 31, 2010. Without the non-cash, stock-based compensation, the R&D expenses increased from $13,257,625 for the year ended December 31, 2009 to $14,710,286 for the year ended December 31, 2010, an increase of $1,452,661 or 11.0%. The majority of this increase was due to R&D activities incurred by our consolidated subsidiary, Incuron.

The following table summarizes research and development expenses for the years ended December 31, 2010, 2009 and 2008 and since inception:

	Year Ended December 31, 2010	Year Ended December 31, 2009	Year Ended December 31, 2008	Total Since Inception
Research and development	$ 16,141,040	$ 14,331,673	$ 13,160,812	$ 73,850,472

General	$ 246,730	$ -	$ 931,441	$ 5,353,360
Protectan CBLB502 - non-medical applications	$ 14,316,540	$ 13,676,289	$ 7,264,813	$ 49,594,026
Protectan CBLB502 - medical applications	$ -	$ 56,127	$ 756,227	$ 1,833,056
Protectan CBLB612	$ 5,140	$ 6,567	$ 974,459	$ 3,142,081
Curaxin CBLC102	$ 399,068	$ 262,637	$ 1,741,194	$ 7,249,224
Other Curaxins	$ 1,173,562	$ 330,053	$ 1,492,678	$ 6,678,725

In addition, selling, general and administrative expenses increased from $6,397,164 for the year ended December 31, 2009 to $9,927,725 for the year ended December 31, 2010, representing an increase of $3,530,561 or 55.2%. We recognized a total of $1,686,398 of non-cash, stock-based compensation for general and administrative compensation for the year ended December 31, 2009 compared to $3,209,396 for the year ended December 31, 2010. Without the non-cash stock based compensation, the general and administrative expenses increased from $4,710,766 for the year ended December 31, 2009 to $6,718,329 for the year ended December 31, 2010, an increase of $2,007,563 or 42.6%. This increase is due to the selling, general and administrative expenses from Incuron as well as higher costs as the infrastructure of the organization continues to be strengthened.

Until we introduce a product to the market, expenses in the categories mentioned above will be the largest component of our income statement.

Year Ended December 31, 2009 Compared to Year Ended December 31, 2008

Revenue

Revenue increased from $4,705,597 for the year ended December 31, 2008 to $14,345,908 for the year ended December 31, 2009, representing an increase of $9,640,311 or 204.9%, resulting primarily from an increase in revenue from U.S. government contracts and grants, as well as the licensing agreement with Hisun.

Operating Expenses

Operating expenses increased from $19,050,965 for the year ended December 31, 2008 to $20,728,837 for the year ended December 31, 2009. This represents an increase of $1,677,872 or 8.8%. We recognized a total of $1,527,600 of non-cash, stock-based compensation for the year December 31, 2008 compared to $2,760,446 for the year ended December 31, 2009. If these non-cash, stock-based compensation expenses were excluded, operating expenses would have increased from $17,523,365 for the year ended December 31, 2008 to $17,968,391 for the year ended December 31, 2009. This represents an increase in operating expenses of $445,026 or 2.5%.

This increase resulted primarily from an increase in R&D expenses from $13,160,812 for the year ended December 31, 2008 to $14,331,673 for the year ended December 31, 2009, an increase of $1,170,861 or 8.9%. The increased R&D expenses were incurred primarily as a result of increasing the non-cash, stock-based compensation and additional R&D costs incurred to support the revenue increase. We recognized a total of $632,253 of non-cash compensation for R&D stock based compensation for the year ended December 31, 2008 compared to $1,074,048 for the year ended December 31, 2009. Without the non-cash, stock-based compensation, the R&D expenses increased from $12,528,559 for the year ended December 31, 2008 to $13,257,625 for the year ended December 31, 2009, an increase of $729,066 or 5.8%.

In addition, selling, general and administrative expenses increased from $5,890,153 for the year ended December 31, 2008 to $6,397,164 for the year ended December 31, 2009. This represents an increase of $507,011 or 8.6%. These higher selling, general and administrative expenses were incurred as a result of an increase in the non-cash, stock-based compensation for the selling, general and administrative area of the Company partially offset by cost containment efforts. We recognized a total of $895,347 of non-cash, stock-based compensation for general and administrative compensation for the year ended December 31, 2008 compared to $1,686,398 for the year ended December 31, 2009. Without the non-cash stock based compensation, the general and administrative expenses decreased from $4,994,806 for the year ended December 31, 2008 to $4,710,766 for the year ended December 31, 2009, a decrease of $284,040 or 5.7%.

Liquidity and Capital Resources

We have incurred annual operating losses since our inception, and, as of December 31, 2010, we had an accumulated deficit of $96,053,977. Our principal sources of liquidity have been cash provided by sales of our securities, government grants and contracts and licensing agreements. Our principal uses of cash have been R&D and working capital. We expect our future sources of liquidity to be primarily government contracts and grants, equity financing, licensing fees and milestone payments in the event we enter into licensing agreements with third parties, and research collaboration fees in the event we enter into research collaborations with third parties, which to date we have not.

Net cash used in operating activities totaled $5,899,331 for the year ended December 31, 2010, compared to $4,244,944 used in operating activities for the same period in 2009. This increase in cash used in operating activities resulted from the operating activities of Incuron. Net cash used in operating activities totaled $12,121,102 for the same period in 2008.

Net cash used in investing activities was $1,175,749 for the year ended December 31, 2010, compared to net cash provided by investing activities of $626,536 for the same period in 2009. The increase in cash used in investing activities resulted primarily from a short term investment of $459,364 in 2010 as compared to the liquidation of a $1,000,000 short-term investment in 2009. In addition, cash used in investing activities for the purchase of equipment increased from $136,400 in 2009 to $465,650 in 2010 primarily due to the creation of new animal research facilities at our Buffalo location. Net cash used in investing activities was $558,407 for the same period in 2008.

Net cash provided by financing activities totaled $17,065,094 for the year ended December 31, 2010,compared to $4,281,659 provided by financing activities for the same period in 2009. The increase in cash provided by financing activities was attributed to the investment in Incuron by BCV in April and June of 2010 and the two equity offerings in March and December 2010, as compared to the Series D Preferred and Series D Warrants offering during the same period in 2009. Net cash used in financing activities totaled $1,232,831 for the same period in 2008.

Under our exclusive license agreement with CCF, we may be responsible for making milestone payments to CCF in amounts ranging from $50,000 to $4,000,000. The milestones and corresponding payments for Protectan CBLB502 and Curaxin CBLC102 are set forth above under “Item 1 – Description of Business – Collaborative Research Agreements – Cleveland Clinic Foundation.”

Our agreement with CCF also provides for payment by us to CCF of royalty payments calculated as a percentage of the net sales of the drug candidates ranging from 1-2%, and sublicense royalty payments calculated as a percentage of the royalties received from the sublicenses ranging from 5-35%. However, any royalty payments and sublicense royalty payments assume that we will be able to commercialize our drug candidates, which are subject to numerous risks and uncertainties, including those associated with the regulatory approval process, our R&D process and other factors. Accrued milestone payments, royalty payments and sublicense royalty payments are payable upon achievement of the milestone.

We believe that although existing cash resources will be sufficient to finance our currently planned operations beyond the next twelve months, these amounts will not be sufficient to meet our longer-term cash requirements, including our cash requirements for the commercialization of certain of our drug candidates currently in development. We may be required to issue equity or debt securities or enter into other financial arrangements, including relationships with corporate and other partners, in order to raise additional capital. Depending upon market conditions, we may not be successful in raising sufficient additional capital for our long-term requirements. In such event, our business, prospects, financial condition and results of operations could be materially adversely affected.

Subsequent Events

On January 20, 2011 BCV contributed 68,000,000 Russian Rubles (approximately $2.3 million) which increased their ownership in the consolidated subsidiary, Incuron, LLC to 24.0% and decreased CBLI's ownership percentage to 76.0%.

Impact of Inflation

We believe that our results of operations are not dependent upon moderate changes in inflation rates.

Impact of Exchange Rate Fluctuations

We believe that our results of operations are somewhat dependent upon changes in foreign currency exchange rates. We have entered into agreements with foreign third parties to produce one of our drug compounds and are required to make payments in the foreign currency. As a result, our financial results could be affected by changes in foreign currency exchange rates. As of December 31, 2010, we are obligated to make payments under these agreements of 1,243,852 Euros. We have purchased 689,542 Euros and therefore, at December 31, 2010, had foreign currency risk of $742,886 for Euros given prevailing currency exchange spot rates.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

Contractual Obligations

	Payments Due by Period				
Contactual Oblibations	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating Lease Obligations (1)	$ 486,862	$ 315,342	$ 151,455	$ 2,065	$ -
Purchase Obligations (2)	2,209,242	1,826,866	382,376	-	-
Deferred Revenue (3)	2,347,218	349,111	1,968,107	-	-

Total	$ 5,043,322	$ 2,491,319	$ 2,501,938	$ 2,065	$ -

(1)We have operating lease commitments in place for facilities in Buffalo, New York and Chicago, Illinois as well as office equipment. The lease for the Buffalo, New York facility provides for two renewal periods of two years each at our option. We sublet a portion of the Buffalo facility through March 2012. The sublease agreements provide for a change in annual rents in the same proportion that the Gross Domestic Product Price Deflator changes for the preceding lease year. As of December 31, 2010, we expect to receive aggregate future minimum lease payments totaling $.1 million (not included in the table above) over the duration of the sublease agreements.

(2)We have net open purchase orders (defined as total open purchase orders less any accruals or invoices charged to or amounts paid against such purchase orders) totaling approximately $2.2 million. We do not plan to spend any significant amounts on capital expenditures during 2011.

(3)In January 2007, we entered into a Strategic Research Agreement with RPCI to develop our cancer and radioprotectant drug candidates. We received $3,000,000 in funds from RPCI funded by the State of New York as part of an incentive package for us to develop our cancer and radioprotectant drug candidates. The remaining balance of deferred revenue as a result of these funds is expected to be recognized during the years 2011 through 2013 based on the schedule of collaborations planned with RPCI over the life of the Strategic Research Agreement.

Item 7A: Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks, including changes to interest rates, foreign currency exchange rates and equity investment prices. To reduce the volatility related to these exposures, we may enter into various derivative hedging transactions pursuant to our investment and risk management policies. There are inherent risks that may only be partially offset by our hedging programs should there be unfavorable movements in interest rates, foreign currency exchange rates, or equity investment prices.

Interest Rate Risk. Our interest income is sensitive to changes in the general level of domestic interest rates, particularly since our investments are classified as short-term held to maturity. Due to our intention to hold our investments to maturity, we have concluded that there is no material interest rate risk exposure.

Our revolving credit facility also would have been affected by fluctuations in interest rates as it is based on prime minus 1%. As of December 31, 2010, we had not drawn on this facility.

Foreign Currency Risk. As of December 31, 2010, we have agreements with third parties that require payment in the foreign currency. As a result, our financial results could be affected by changes in foreign currency exchange rates. Currently, our exposure primarily exists with the Euro. As a consequence, movements in exchange rates could cause our foreign currency denominated expenses to fluctuate as a percentage of net revenue, affecting our profitability and cash flows.

As of December 31, 2010, we are obligated to make payments under these agreements of 1,243,852 Euros. We have purchased 689,542 Euros and therefore, at December 31, 2010, had foreign currency risk of $742,886 for Euros given prevailing currency exchange spot rates. At this time, our exposure to foreign currency fluctuations is not material.

In addition, our consolidated financial reports are presented in U.S. dollars, whereas the functional currency for Incuron is Russian rubles. As such, we are subject to translation risks relating to exchange rates between the U.S. dollar and the Russian ruble. Therefore, due to Incuron, our results may be affected by changes in the exchange rate between U.S. dollars and Russian rubles. Furthermore, 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 its ownership interest to BCV or make a cash contribution to Incuron. In such a case, if we choose to transfer a portion of its ownership interest to BCV, 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.

Finally, the indirect effect of fluctuations in interest rates and foreign currency exchange rates could have a material adverse effect on our business financial condition and results of operations. For example, currency exchange rate fluctuations could affect international demand for our products in the future. Furthermore, interest rate and currency exchange rate fluctuations may broadly influence the U.S. and foreign economies resulting in a material adverse effect on our business, financial condition and results of operations. As a result, we cannot give any assurance as to the effect that future changes in foreign currency rates will have on our financial position, results of operations or cash flows.

Item 8: Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders of Cleveland BioLabs, Inc.:

We have audited the accompanying balance sheets of CLEVELAND BIOLABS, INC. as of December 31, 2010 and 2009, and the related statements of income, stockholders' equity and comprehensive income, and cash flows for each of the years in the three-year period ended December 31, 2010. We also have audited Cleveland BioLabs' internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Cleveland BioLabs' management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on these financial statements and an opinion on the Company's internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Cleveland BioLabs, Inc. as of December 31, 2010 and 2009, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2010 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, Cleveland BioLabs, Inc. maintained, in all

material respects, effective internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

MEADEN & MOORE, LTD.
Certified Public Accountants

Cleveland, Ohio
March 11, 2011

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

December 31, 2010 and 2009

	December 31 2010	December 31 2009
ASSETS		
CURRENT ASSETS		
Cash and equivalents	$ 10,918,537	$ 963,100
Short-term investments	459,364	-
Accounts receivable	5,382,121	3,391,347
Other current assets	991,062	381,030
Total current assets	17,751,084	4,735,477
EQUIPMENT		
Computer equipment	400,892	323,961
Lab equipment	1,528,066	1,159,478
Furniture	397,013	376,882
	2,325,971	1,860,321
Less accumulated depreciation	1,384,847	995,408
	941,124	864,913
OTHER ASSETS		
Intellectual property	1,162,287	929,976
Deposits	32,108	23,482
	1,194,395	953,458
TOTAL ASSETS	$ 19,886,603	$ 6,553,848

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

December 31, 2010 and 2009

	December 31 2010	December 31 2009
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$1,261,493	$1,208,632
Deferred revenue	349,111	2,329,616
Accrued expenses	136,163	171,374
Accrued bonuses	3,321,131	1,234,341
Accrued warrant liability	25,350,733	8,410,379
Total current liabilities	30,418,631	13,354,342
LONG TERM LIABILITIES		
Deferred revenue	1,968,107	-
Total long term liabilities	1,968,107	-
Commitments and contingencies - See Note 7		
STOCKHOLDERS' EQUITY		
Preferred stock, $.005 par value		
Authorized - 10,000,000 shares at December 31, 2010 and 2009		
Series D convertible preferred stock, Issued and outstanding 0 and 466.85 shares at December 31, 2010 and 2009, respectively	-	2
Common stock, $.005 par value		
Authorized - 80,000,000 shares at December 31, 2010 and 2009		
Issued and outstanding 28,959,176 and 20,203,508 shares at December 31, 2010 and 2009, respectively	144,796	101,018
Additional paid-in capital	80,241,717	62,786,418
Accumulated other comprehensive loss	(30,544)	-
Accumulated deficit	(96,053,977)	(69,687,932)
Total Cleveland BioLabs, Inc. stockholders' equity	(15,698,008)	(6,800,494)
Noncontrolling Interest in stockholders' equity	3,197,873	-
Total stockholders' equity	(12,500,135)	(6,800,494)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$19,886,603	$6,553,848

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

Years Ended December 31, 2010, 2009, and 2008

	December 31 2010	December 31 2009	December 31 2008
REVENUES			
Grant and contract	$15,331,567	$12,695,908	$4,585,597
Service	-	1,650,000	120,000
	15,331,567	14,345,908	4,705,597
OPERATING EXPENSES			
Research and development	16,141,040	14,331,673	13,160,812
Selling, general and administrative	9,927,725	6,397,164	5,890,153
Total operating expenses	26,068,765	20,728,837	19,050,965
LOSS FROM OPERATIONS	(10,737,198)	(6,382,929)	(14,345,368)
OTHER INCOME			
Interest income	99,111	21,688	259,844
Other income	209,979	71,427	237,161
Total other income	309,090	93,115	497,005
OTHER EXPENSE			
Other expense	231,980	266,970	177,564
Interest expense	-	1,960	-
Change in value of warrant liability	16,011,769	6,267,665	-
Total other expense	16,243,749	6,536,595	177,564
NET LOSS	$(26,671,857)	$(12,826,409)	$(14,025,927)
LESS: LOSS ATTRIBUTABLE TO NONCONTROLLING INTERESTS	305,812	-	-
NET LOSS ATTRIBUTABLE TO CLEVELAND BIOLABS, INC.	$(26,366,045)	$(12,826,409)	$(14,025,927)
DIVIDENDS ON CONVERTIBLE PREFERRED STOCK	-	615,352	1,182,033
NET LOSS AVAILABLE TO COMMON STOCKHOLDERS	(26,366,045)	(13,441,761)	(15,207,960)
NET LOSS AVAILABLE TO COMMON SHAREHOLDERS PER SHARE OF COMMON STOCK - BASIC AND DILUTED	$(1.01)	$(0.82)	$(1.13)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATING NET LOSS PER SHARE, BASIC AND DILUTED	26,184,773	16,405,129	13,492,391

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

Period From January 1, 2008 to December 31, 2010

	Stockholders' Equity			
	Preferred Stock			
	Series B Shares	Series B Amount	Series D Shares	Series D Amount
Balance at January 1, 2008	3,870,267	$ 19,351	-	$ -
Issuance of options	-	-	-	-
Partial recapture of expense for options expensed in 2007 but issued in 2008	-	-	-	-
Issuance of shares	-	-	-	-
Amortization of restricted stock awards	-	-	-	-
Exercise of options	-	-	-	-
Conversion of Series B Preferred Shares to Common	(709,293)	(3,547)	-	-
Dividends on Series B Preferred shares	-	-	-	-
Net Loss	-	-	-	-
Balance at January 1, 2009	3,160,974	15,805	-	-
Issuance of options	-	-	-	-
Issuance of shares	-	-	-	-
Recapture of expense for nonvested options forfeited	-	-	-	-
Amortization of restricted stock awards	-	-	-	-
Exercise of options	-	-	-	-
Conversion of Series B Preferred Shares to Common	(3,160,974)	(15,805)	-	-
Dividends on Series B Preferred shares	-	-	-	-
Issuance of shares - Series D financing	-	-	543	3
Allocation of financing proceeds to fair value of Series D warrants	-	-	-	-
Fees associated with Series D Preferred offering	-	-	-	-
Conversion of Series D Preferred Shares to Common	-	-	(76)	(1)
Exercise of warrants	-	-	-	-
Net Loss	-	-	-	-
Balance at December 31, 2009	-	-	467	2
Issuance of options	-	-	-	-
Issuance of shares	-	-	-	-
Recapture of expense for nonvested options forfeited	-	-	-	-
Amortization of restricted stock awards	-	-	-	-
Exercise of options	-	-	-	-
Issuance of shares - February 2010 financing	-	-	-	-
Allocation of financing proceeds to fair value of warrants	-	-	-	-
Fees associated with February 2010 offering	-	-	-	-

Issuance of shares - December 2010 financing	-	-	-	-
Fees associated with December 2010 offering	-	-	-	-
Conversion of Series D Preferred Shares to Common	-	-	(467)	(2)
Exercise of warrants	-	-	-	-
Warrant exercise fees	-	-	-	-
Noncontrolling interest capital contribution to Incuron, LLC	-	-	-	-
Net Loss	-	-	-	-
Other comprehensive income				
Foreign currency translation	-	-	-	-
Balance at December 31, 2010	-	$ -	-	$ -

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

Period From January 1, 2008 to December 31, 2010

	Stockholders' Equity Common Stock	
	Shares	Amount
Balance at January 1, 2008	12,899,241	$64,496
Issuance of options	-	-
Partial recapture of expense for options expensed in 2007 but issued in 2008	-	-
Issuance of shares	130,000	650
Amortization of restricted stock awards	-	-
Exercise of options	37,271	186
Conversion of Series B Preferred Shares to Common	709,293	3,547
Dividends on Series B Preferred shares	-	-
Net Loss	-	-
Balance at January 1, 2009	13,775,805	68,879
Issuance of options	-	-
Issuance of shares	291,532	1,458
Recapture of expense for nonvested options forfeited	-	-
Amortization of restricted stock awards	-	-
Exercise of options	194,675	973
Conversion of Series B Preferred Shares to Common	4,693,530	23,468
Dividends on Series B Preferred shares	-	-
Issuance of shares - Series D financing	-	-
Allocation of financing proceeds to fair value of Series D warrants	-	-
Fees associated with Series D Preferred offering	-	-
Conversion of Series D Preferred Shares to Common	572,353	2,862
Exercise of warrants	675,613	3,378
Net Loss	-	-
Balance at December 31, 2009	20,203,508	101,018
Issuance of options	-	-
Issuance of shares	461,196	2,306
Recapture of expense for nonvested options forfeited	-	-
Amortization of restricted stock awards	-	-
Exercise of options	336,674	1,683
Issuance of shares - February 2010 financing	1,538,462	7,692
Allocation of financing proceeds to fair value of warrants	-	-
Fees associated with February 2010 offering	-	-
Issuance of shares - December 2010 financing	1,400,000	7,000
Fees associated with December 2010 offering	-	-
Conversion of Series D Preferred Shares to Common	4,576,979	22,885

Exercise of warrants	442,357	2,212
Warrant exercise fees	-	-
Noncontrolling interest capital contribution to Incuron, LLC	-	-
Net Loss	-	-
Other comprehensive income		
Foreign currency translation	-	-
Balance at December 31, 2010	28,959,176	$144,796

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

Period From January 1, 2008 to December 31, 2010

	Stockholders' Equity				
	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Noncontrolling Interests	Total
Balance at January 1, 2008	$ 55,148,608	$ -	$ (41,038,212)	$ -	$ 14,194,244
Issuance of options	2,287,803	-	-	-	2,287,803
Partial recapture of expense for options expensed in 2007 but issued in 2008	(1,459,425)	-	-	-	(1,459,425)
Issuance of shares	625,850	-	-	-	626,500
Amortization of restricted stock awards	72,722	-	-	-	72,722
Exercise of options	24,191	-	-	-	24,378
Conversion of Series B Preferred Shares to Common	-	-	-	-	-
Dividends on Series B Preferred shares	-	-	(1,182,033)	-	(1,182,033)
Net Loss	-	-	(14,025,927)	-	(14,025,927)
Balance at January 1, 2009	56,699,750	-	(56,246,172)	-	538,261
Issuance of options	1,784,240	-	-	-	1,784,240
Issuance of shares	991,612	-	-	-	993,070
Recapture of expense for nonvested options forfeited	(50,197)	-	-	-	(50,197)
Amortization of restricted stock awards	33,333	-	-	-	33,333
Exercise of options	361,884	-	-	-	362,857
Conversion of Series B Preferred Shares to Common	(7,663)	-	-	-	-
Dividends on Series B Preferred shares	-	-	(615,351)	-	(615,351)
Issuance of shares - Series D financing	5,428,304	-	-	-	5,428,307
Allocation of financing proceeds to fair value of Series D warrants	(3,016,834)	-	-	-	(3,016,834)
Fees associated with Series D Preferred offering	(720,175)	-	-	-	(720,175)
Conversion of Series D Preferred Shares to Common	(2,861)	-	-	-	-
Exercise of warrants	1,285,026	-	-	-	1,288,404
Net Loss	-	-	(12,826,409)	-	(12,826,409)

Balance at December 31, 2009	62,786,418	-	(69,687,932)	-	(6,800,494)
Issuance of options	2,947,209	-	-	-	2,947,209
Issuance of shares	1,716,785	-	-	-	1,719,091
Recapture of expense for nonvested options forfeited	(39,483)	-	-	-	(39,483)
Amortization of restricted stock awards	13,333	-	-	-	13,333
Exercise of options	900,228	-	-	-	901,911
Issuance of shares - February 2010 financing	4,992,310	-	-	-	5,000,002
Allocation of financing proceeds to fair value of warrants	(2,629,847)	-	-	-	(2,629,847)
Fees associated with February 2010 offering	(578,118)	-	-	-	(578,118)
Issuance of shares - December 2010 financing	8,379,000	-	-	-	8,386,000
Fees associated with December 2010 offering	(659,980)	-	-	-	(659,980)
Conversion of Series D Preferred Shares to Common	(22,883)	-	-	-	-
Exercise of warrants	2,438,558	-	-	-	2,440,770
Warrant exercise fees	(1,813)	-	-	-	(1,813)
Noncontrolling interest capital contribution to Incuron, LLC	-		-	3,509,564	3,509,564
Net Loss	-	-	(26,366,045)	(305,812)	(26,671,857)
Other comprehensive income					