CLEVELAND BIOLABS INC
Form 10-K
March 22, 2010

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, 2009

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 o 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 o	Accelerated filer o
Non-accelerated filer o	Smaller reporting company x

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates, computed by reference to the price at which the common equity was last sold or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter was $46,703,406. There were 26,632,040 shares of common stock outstanding as of March 5, 2010.

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant's Annual Meeting of Stockholders, to be held on June 8, 2010, is incorporated by reference in Part III to the extent described therein.

CLEVELAND BIOLABS, INC.
FORM 10-K
03/22/10

Cleveland BioLabs, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2009

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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. The actual future results for Cleveland BioLabs, Inc. 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 indicated, “CBLI,” the “Company,” “we,” “our” and “us” refers to Cleveland BioLabs, Inc.

PART I

Item 1. Description of 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. We were 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 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, or 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, or 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 and that there will be many new drugs entering the market.

These drug candidates demonstrate the value of our scientific foundation. Based on the expedited approval process currently available for non-medical applications such as protection from exposure to radiation, our most advanced drug candidate, Protectan CBLB502 may be approved for such applications within 18 - 24 months. Another drug candidate, Curaxin CBLC102, demonstrated activity and safety in a Phase IIa clinical trial concluded in late 2008.

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, or Pharma, companies joined the biotech arena through licensing, sponsored research, and corporate agreement relationships. As of April 2008, biotech is a $360 billion industry (based on total market capitalization of U.S. public companies tracked by BioWorld) and includes large companies such as Amgen, Inc. and Genentech, Inc.

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.

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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 Food and Drug Administration, or 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 of the potential military and defense implications of such a drug, the normally lengthy FDA approval process for these non-medical applications is substantially abbreviated resulting in a large cost savings to us. We expect to complete development of Protectan CBLB502 for these non-medical applications and complete submission of the Biologic License Application, or BLA, with the FDA in the first half of 2011.
- Leveraging our relationship with leading research and clinical development institutions. The Cleveland Clinic, one of the top research medical facilities in the world, is one of our co-founders. In addition to providing us with drug leads and technologies, the Cleveland Clinic will share valuable expertise with us as development efforts are performed on our drug candidates. In January 2007, we entered into a strategic research partnership with Roswell Park Cancer Institute, or RPCI, in Buffalo, New York. This partnership 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 Armed Forces Radiobiology Research Institute, or AFRRI.
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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. 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 over 1,000,000 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, 2009, we spent $57,588,395 on R&D.

Our ability to complete our R&D on schedule is, however, subject to a number of risks and uncertainties, which are discussed below under Item 1A – Risk Factors. 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 United States 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 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 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 United States 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).

Nine sets of patent applications have been filed over the past six 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 recently 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 already granted by the nine member countries of the Eurasian Patent Organization, and the Ukraine. 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.

We spent approximately $13,738,983 and $8,995,500 on R&D for protectans for all applications in the fiscal years ended December 31, 2009 and 2008, respectively. From our inception to December 31, 2009, we have spent approximately $40,247,483 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, or ARS, in defense scenarios, and protection from acute organ failure. Protectan CBLB502 is administered through intramuscular injection.

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

We spent approximately $13,732,416 and $8,021,040 on R&D for Protectan CBLB502 in the fiscal years ended December 31, 2009 and 2008, respectively. From our inception to December 31, 2009, we have spent approximately $37,110,541 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, or 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 and 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 and pharmacodynamics studies are the only stage of human testing required for approval in this indication.

We have successfully established current Good Manufacturing Practices, or cGMP, quality manufacturing for Protectan CBLB502 and have completed an initial Phase I human safety study 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 for CBLB502. This safety study will include a total of 100 healthy volunteers randomized among four dosing regimens of CBLB502. Our goal is for dosing and data analysis of this trial to be concluded in June 2010. We would then anticipate moving forward with the double-blind definitive safety study in a larger group of healthy volunteers. We believe the addition of the intermediate 100 subject trial will be very beneficial for both the potential commercialization of CBLB502 and our regulatory process towards FDA licensure.

Participants in the 100 subject study will be assessed for adverse side effects and blood samples will be obtained to assess the effects of CBLB502 on various biomarkers. The primary objectives of this study are to gather additional data on safety, pharmacokinetics, and cytokine biomarkers in a larger and broader subject population in order to finalize an appropriate dose to take forward and determine the size of a definitive human safety study. We are working towards filing a BLA for FDA licensure of Protectan CBLB502 for non-medical applications in the first half of 2011.

The Defense Threat Reduction Agency of the U.S. Department of Defense, or 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 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, or BAA, for selected tasks in the advanced development of Protectan CBLB502 as a Medical Radiation Countermeasure, or MRC, to treat radiation injury following exposure to radiation from nuclear or radiological weapons. 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.

In September 2008, we were awarded a $774,183 grant from the National Institute of Allergy and Infectious Diseases, or NIAID, of the National Institutes of Health, or 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, the Biomedical Advanced Research and Development Authority, or BARDA, of the Department of Health and Human Services, or HHS, 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. 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 by $2.3 million to $15.6 million and awarded the first milestone option of $6.3 million. 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.

We spent approximately $13,676,289 and $7,264,813 on R&D for the non-medical applications of Protectan CBLB502 in the fiscal years ended December 31, 2009 and 2008, respectively. From our inception to December 31, 2009, we have spent approximately $35,277,485 on R&D for the non-medical applications of Protectan CBLB502.

Protectan CBLB502 is a candidate for procurement by the DoD, HHS/BARDA and other countries 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 agencies 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.

In February 2010, we responded to a Request for Proposal, or RFP, issued by the DoD for the advanced development, FDA licensure and delivery of a MRC. As stated in the RFP, the ultimate goal of the MRC project is to select, develop, and manufacture a FDA-approved drug/biologic to increase survival and decrease incapacity such that forces can maintain operational effectiveness within a contaminated area following radiation exposure. The solicitation specifically sought a drug/biologic intended for use following exposure to ionizing radiation to prevent/reduce the extent of radiation injury, specifically targeting the GI tract that is safe and efficacious when administered at least four hours following the radiation exposure and has a minimal logistical burden in terms of storage, delivery and administration. Potential candidates were required to submit data demonstrating safety in humans and efficacy in animal models as required to obtain an FDA license under the animal efficacy rule. A further requirement was evidence of progress toward achieving cGMP compliance as part of their technical proposal. If awarded, exercise of contract options could result in purchase and delivery of products to meet the initial requirements established by the DoD in order to protect service members exposed to ionizing radiation.

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 will be 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, 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 Investigational New Drug, or IND, applications, New Drug Applications, or NDA and Biologic License Applications, or BLA and to provide for accelerated review and licensure of certain medical products for counterterrorism applications, including granting eligible applications “Fast Track” status. Based on concurrence from the FDA reached during a December 2009 meeting, we will be applying for Fast Track status. 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 CBLB502 development plan and preparation and approval of the BLA.

In cases where priority review is given to Fast Track applications, the applicant is permitted to submit applications on a rolling basis.

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 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, or potentially many more, depending on the final therapeutic dose to be used, which will be determined through our Phase I safety trial. 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. We expect to complete these studies in 2010. The studies have an approximate cost of $2,500,000 and are covered by a government development contract.

- Performing a second Phase I safety study in approximately 100 healthy human volunteers started in January 2010. This study has an approximate cost of $1,400,000 and is covered by a government development contract

- 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 this study in early 2011 at 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 complete in the first half of 2011. At the present time, the costs of the filing cannot be approximated with any level of certainty.

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 a $1,500,000 research grant pursuant to this law.

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 40% of the roughly $50 billion annually spent on cancer treatment represents supportive care addressing toxicities of various treatments, including chemotherapy.

Consistent with this strategy, we plan to initiate a Phase I/II study for Protectan CBLB502 in head and neck cancer patients who are undergoing radiotherapy and radio-sensitizing chemotherapy in the first half of 2010 for the medical indication of CBLB502. The primary goal of this trial will be to demonstrate safety and tolerability of CBLB502 in cancer patients with a secondary goal of demonstrating potential efficacy of CBLB502 in a clinical setting. The primary endpoint of the study will be the reduction of toxicities of radiation and chemotherapy, such as mucositis (a painful inflammation and ulceration of oral mucosa causing difficulties with speaking and eating). Mucositis weakens the patient by not allowing for the oral intake of nutrients and fluids and forces the temporary suspension of radiotherapy and chemotherapy until the tissues of the mouth and throat have healed. Due to the ability of head and neck cancer cells to regrow during periods of interrupted treatment, any interruption in radiotherapy should be avoided. Since the main cause of treatment interruptions in radiotherapy or combinations of chemotherapy and radiotherapy treatment regimens of head and neck cancer is acute mucositis, the ability to prevent mucositis, and therefore, interruptions in treatment, could potentially result in better outcomes for patients with cancers of the head and neck.

In other studies, we have demonstrated the potential of Protectan CBLB502 to be applicable to ischemic conditions. Our researchers, in collaboration with investigators from the Cleveland Clinic, 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 the Cleveland Clinic 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 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:

- Submitting an amendment to our CBLB502 IND application and receiving allowance from the FDA. We expect to submit the amendment in the first half of 2010. We estimate that the approximate cost of filing will be less than $100,000 which is covered by a government grant.

- Performing a Phase I/II human efficacy study on a small number of head and neck cancer patients. We expect to complete this study two years from the receipt of allowance from the FDA of the IND amendment at an approximate cost of $1,500,000 which is covered by a government development grant.

- 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.

We spent approximately $56,127 and $756,227 on R&D for the medical applications of Protectan CBLB502 in the fiscal years ended December 31, 2009 and 2008, respectively. From our inception to December 31, 2009, we have spent approximately $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 Protection 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, or 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. 100% of the deficient mice transplanted with blood from 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 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 sets of patent applications have been filed for Protectan CBLB612.

In September 2009, we executed a license agreement granting Zhejiang Hisun Pharmaceutical Co. Ltd., or Hisun, a leading pharmaceutical manufacturer in the People's Republic of China exclusive rights to develop and commercialize 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 CBLB612 are not granted. We retain all rights to 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 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 CBLB612 selected from the previous studies previously shown to be safe in humans and efficacious in animals; and

- Filing a New Drug Application.

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 $6,567 and $974,459 on R&D for Protectan CBLB612 in the fiscal years ended December 31, 2009 and December 31, 2008, respectively. From our inception to December 31, 2009, we have spent approximately $3,136,941 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.

Nine sets of patent applications have been filed around the curaxin family of compounds.

We spent approximately $592,690 and $3,233,872 on R&D for curaxins overall in the fiscal years ended December 31, 2009 and 2008, respectively. From our inception to December 31, 2009, we have spent approximately $12,234,282 on R&D for curaxins.

In December 2009, we entered into a joint venture, Incuron, with Bioprocess Capital Ventures, or BCV, a Russian Federation venture capital fund, to develop our curaxin compounds for cancer applications. According to the terms of the agreement, we will transfer the rights of curaxin anticancer molecules to the new joint venture, and BCV will contribute approximately $18 million over three payments to support development of the compounds. The first payment of $5.8 million is due upon formation of the Incuron entity, which is expected to occur in April 2010. The ensuing payments are based upon achievement of predetermined development milestones. The first milestone payment of $6.4 million shall be made upon approval to begin clinical trials on oncology patients with a selected lead curaxin compound, or upon progression of a clinical program of CBLC102. The second milestone payment shall be made upon completion of at least one Phase I/II trial in cancer patients. We will serve as a subcontractor to Incuron to support certain mechanistic studies and oversee clinical development.

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 the Cleveland Clinic 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 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, 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 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 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. 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 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 CBLC102 will be explored in conjunction with our strategic partners at RPCI and through the Incuron joint venture.

New 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 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 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 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 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 sets 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 $262,637 and $1,741,194 on R&D for Curaxin CBLC102 in the fiscal years ended December 31, 2009 and 2008, respectively. From our inception to December 31, 2008, we have spent approximately $6,729,120 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 CBLC137, which is a drug candidate with proprietary composition of matter intellectual property protection belonging to our next generation of highly improved curaxins. CBLC137 has demonstrated reliable anti-tumor effects in animal models of colon, breast, renal and prostate cancers. 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 CBLC102, but significantly exceeds the former compound's activity and efficacy in preclinical tumor models. Further development of CBLC137 will continue through the Incuron joint venture.

Six sets of patent applications have been filed for other curaxins.

We spent approximately $330,053 and $1,492,678 on R&D for other curaxins in the fiscal years ended December 31, 2009 and 2008, respectively. From our inception to December 31, 2008, we have spent approximately $5,505,163 on R&D for other curaxins.

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 the Cleveland Clinic. Pursuant to an agreement we entered into with the Cleveland Clinic effective as of July 1, 2004, we were granted an exclusive license to the Cleveland Clinic'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 the Cleveland Clinic 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 the Cleveland Clinic with notice within 60 days after receiving an invention disclosure report from the Cleveland Clinic 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 the Cleveland Clinic will play a critical role in validating therapeutic concepts and in conducting trials. The Cleveland Clinic 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, or 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) the Cleveland Clinic, 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.

In February 2008, the terms of the agreement were extended by an additional two years expiring August 15, 2010, 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.

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 the Cleveland Clinic, 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 the Cleveland Clinic 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, provides us with continual access to 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 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 CBLC137, which is a drug candidate belonging to our next generation of highly improved curaxins with proprietary composition of matter and intellectual property protection. CBLC137 has demonstrated reliable anti-tumor effects in animal models of colon, breast, renal and prostate cancers. 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 CBLC102, but significantly exceeds that compound’s activity and efficacy in preclinical tumor models.

PATENTS

As a result of the license agreement with the Cleveland Clinic, we currently have filed, on the Cleveland Clinic’s behalf, ten patent applications 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 CBLB502.

Our intellectual property platform is based primarily on these ten patent applications exclusively licensed to us by the Cleveland Clinic, four patent applications we have filed and own exclusively, three patents filed in collaboration with RPCI per the Sponsored Research Agreement and one in collaboration with ChemBridge Corporation.

In 2009, five patent applications were introduced and filed for approval with the U.S. Patent Office and counterpart agencies in several other nations. Two of the patent applications are licensed from the Cleveland Clinic and three are licensed to us in collaboration with RPCI.

We review our patent applications on a continuing basis. In 2009, six patents were combined into two separate patent applications and two patent applications were abandoned due to the determination that the technology forecasted no financial return.

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., 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 CBLC102, we have contracted with Regis Technologies, Inc. to manufacture sufficient amounts for clinical trials.

GOVERNMENT REGULATION

The R&D, manufacturing and marketing of drug candidates are subject to regulation, primarily by the FDA in the U.S. and by comparable authorities in other countries. These national agencies and other federal, state, local and foreign entities regulate, among other things, R&D activities (including testing in primates and in humans) and the testing, manufacturing, handling, labeling, storage, record keeping, approval, advertising and promotion of the products that we are developing. Noncompliance with applicable requirements can result in various adverse consequences, including approval delays or refusals to approve drug licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, recalls or seizures of products, injunctions against shipping drugs, and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts.

The process of obtaining FDA approval for a new drug may take many years and generally involves the expenditure of substantial resources. The steps required before a new drug can be produced and marketed for human use include clinical trials and the approval of an NDA or BLA and typically proceed as follows:

Preclinical Testing

In the preclinical phase of development, the promising compound is subjected to extensive laboratory and animal testing to determine if the compound is biologically active and safe.

Investigational New Drug (IND)

Before human tests can start, the drug sponsor must file an IND application with the FDA, showing how the drug is made and the results of animal testing. IND status allows initiation of clinical investigation within 30 days of filing if the FDA does not respond with questions during the 30-day period.

Human Clinical Testing

The human clinical testing program usually involves three phases that generally are conducted sequentially, but which, particularly in the case of anti-cancer and other life-saving drugs, may overlap or be combined. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA as part of the IND filing. Each clinical study is conducted under the direction of an independent Institutional Review Board, or IRB, for each institution at which the study will be conducted. The IRB will consider, among other things, all existing pharmacology and toxicology information on the product, ethical factors, the risk to human subjects and the potential benefits of therapy relative to risk.

In Phase I clinical trials, studies usually are conducted on healthy volunteers or, in the case of certain terminal illnesses such as advanced prostate cancer, patients with the disease who have failed to respond to other treatment, to determine the maximum tolerated dose, side effects and pharmacokinetics of a product. Phase II studies are conducted on a small number of patients having a specific disease to determine initial efficacy in humans for that specific disease, the most effective doses and schedules of administration, and possible adverse effects and safety risks. Phase II/III differs from Phase II in that the trials involved may include more patients and, at the sole discretion of the FDA, be considered the “pivotal” trials, or trials that will form the basis for FDA approval. Phase III normally involves the pivotal trials of a drug, consisting of wide-scale studies on patients with the same disease, in order to evaluate the overall benefits and risks of the drug for the treated disease compared with other available therapies. The FDA continually reviews the clinical trial plans and results, and may suggest design changes or may discontinue the trials at any time if significant safety or other issues arise.

As described above, for several of the product opportunities we are pursuing, we may apply for approval based upon a rule adopted by the FDA in 2002, titled “Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible” (Part 314, Subpart I), which is also referred to as the animal efficacy rule. Pursuant to this new rule, in situations where it would be unethical to conduct traditional Phase II and Phase III efficacy studies in humans, as is the case with countermeasures to a number of weapons of mass destruction, the FDA will review new drugs for approval on the basis of safety in humans and efficacy in relevant animal models.

New Drug Application (NDA) / Biologic License Application (BLA)

Upon successful completion of Phase III clinical trials, the drug sponsor files an NDA or BLA with the FDA for approval, containing all information that has been gathered. The NDA or BLA must include the chemical composition of the drug, scientific rationale, purpose, animal and laboratory studies, results of human tests, formation and

production details, and proposed labeling.

Post-Approval Regulation

Following any initial regulatory approval of any drugs we may develop, we will also be subject to continuing regulatory review, including the review of adverse experiences and clinical results that are reported after our drug candidates are made commercially available. This will include results from any post-marketing tests or vigilance required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug candidates will also be subject to periodic review and inspection by the FDA. The discovery of any previously unknown problems with the drug, manufacturer or facility may result in restrictions on the drug, manufacturer or facility, including withdrawal of the drug from the market. We do not have, and currently do not intend to develop, the ability to manufacture material for our clinical trials or on a commercial scale. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured drugs ourselves, including reliance on the third-party manufacturer for regulatory compliance, and which are discussed in more detail below under Item 1A – Risk Factors. Our drug promotion and advertising is also subject to regulatory requirements and continuing FDA review.

The testing and approval process is likely to require substantial time and effort, and there can be no assurance that any FDA approval will be granted on a timely basis, if at all. The approval process is affected by a number of factors, primarily the side effects of the drug (safety) and its therapeutic benefits (efficacy). Additional preclinical or clinical trials may be required during the FDA review period and may delay marketing approval. The FDA may also deny an NDA if applicable regulatory criteria are not met.

The FDA reviews the results of the clinical trials and may order the temporary or permanent discontinuation of clinical trials at any time if it believes the drug candidate exposes clinical subjects to an unacceptable health risk.

Sales outside the U.S. of products that we develop will also be subject to regulatory requirements governing human clinical trials and marketing for drugs and biological products and devices. The requirements vary widely from country to country, but typically the registration and approval process takes several years and requires significant resources. In most cases, even if the FDA has not approved a product for sale in the U.S., the product may be exported to any country if it complies with the laws of that country and has valid marketing authorization by the appropriate authority. There are specific FDA regulations that govern this process.

EMPLOYEES

As of March 5, 2010, we had 38 employees, 36 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, the Company currently has no known exposures to any current or proposed climate change legislation which could negatively impact the Company's 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, or NCI, 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.

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.

We receive over 85% of our revenues from grant and contract development work in connection with grants from the DoD, NIH, BARDA and NASA.

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.

We can provide no assurance of the successful and timely development of 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 there can be no assurance that we or our collaborators will 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 there can be no assurance that such use will not 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 which carry their own set of risks.

Projects that appear promising in the early phases of development may fail to reach the market for several reasons including:

- pre-clinical or clinical study 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 a NDA/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 cause the product to be not economically unfeasible; and

- the proprietary rights of others and their competing products and technologies that may prevent the 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 studies we are planning to conduct; for example, our R&D expenses may increase based on the number of late-stage clinical studies 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.

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 gathered 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 may receive reports of observations or warning letters 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 precluded from conducting any ongoing or any future clinical trials, 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 cannot assure that our products will obtain regulatory approval or that the results of clinical studies will 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 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 patent applications from the Cleveland Clinic and have filed seven patent applications on our own or in collaboration with RPCI and ChemBridge. 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, there can be no assurance that our technology will not 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 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 Cleveland Clinic's patent applications as described above and certain processes, products and information of others, we cannot be certain that these licenses will not be terminated or expire during critical periods, that we will be able to obtain licenses for other rights that may be important to us, or, if obtained, that such licenses will 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, we cannot assure that the patents underlying any licenses will 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 Cleveland Clinic 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 complying 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 two 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.

The successful development of biopharmaceuticals is highly uncertain.

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 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 a 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 the product from being commercialized.

Success in pre-clinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product to the next, and may be difficult to predict.

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 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 United States 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 the Cleveland Clinic, 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 United States 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 in the public markets 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, 2009, we had 20,203,508 shares of our common stock and 467 shares of our preferred stock issued and outstanding, excluding shares issuable upon the exercise of our outstanding warrants and options. In February 2010, the preferred stock converted into 4,576,979 shares of common stock. As of March 5, 2010, we had 26,632,040 shares of our common stock and 0 shares of our preferred stock issued and outstanding and 9,793,405 warrants and 2,600,745 options outstanding, of which 2,299,120 options are currently fully vested. 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 addition, 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.

Item 1B. Unresolved Staff Comments

None

Item 2. Description of Property

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. 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

As of March 5, 2010, we were not a party to any litigation or other legal proceeding.

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 Stock Market and/or NASDAQ Capital Market, as applicable, for each quarter during 2009 and 2008. On March 5, 2010, the last reported sale price of our common stock was $3.96 per share.

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

2008	High	Low
First Quarter	$ 8.79	$ 2.03
Second Quarter	$ 6.40	$ 3.82
Third Quarter	$ 5.65	$ 3.70
Fourth Quarter	$ 4.59	$ 1.51

Common Stockholders

As of December 31, 2009, there were approximately 40 stockholders of record of our Common Stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial stockholders represented by these record holders.

We made no repurchases of our securities during the year ended December 31, 2009.

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
(in thousands, except per share data)

	2009	2008	2007	2006	2005
Total Operating Revenue	$ 14,346	$ 4,706	$ 2,019	$ 1,708	$ 1,139

Government contract or grant	12,696	4,586	1,729	1,503	1,000
Commercial	1,650	120	290	205	139
Net loss	$ (12,826)(1)	$ (14,026)(1)	$ (26,997)(1)	$ (7,223)(1)	$ (2,678)
Net loss per share, basic and diluted	$ (0.82)	$ (1.13)	$ (2.34)	$ (0.84)	$ (0.43)
Total assets	$ 6,554	$ 4,706	$ 17,422	$ 6,417	$ 4,253
Long-term debt	-	-	-	50	303
Stockholder's equity (deficit)	(6,800)	538	14,194	5,593	3,557

We have not paid any dividends on common stock.

(1) Net loss in 2009, 2008, 2007 and 2006 included employee stock-based compensation costs of $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 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, or 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 decreased from $14,025,927 for the year ended December 31, 2008 to $12,826,409 for the year ended December 31, 2009, a decrease of $1,199,518 or 8.6%. For the years ended December 31, 2009 and 2008, we incurred non-cash charges of depreciation and amortization of $362,143 and $324,351, non-cash salaries and consulting fees of $2,760,446 and $1,527,600 and a change in value of Series D warrants of $6,267,665 and $0, respectively. Excluding these non-cash charges, our net loss decreased $8,737,821 or 71.8% from $12,173,976 for the year ended December 31, 2008 to $3,436,155 for the year ended December 31, 2009. This decrease was due to increased government funding and our cost containment efforts.

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, par value $0.005 per share, 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 warrants expire on March 15, 2012. 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. 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 Preferred and 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 $1.33, but subject to adjustment as described below). At the time of its issuance, each share of Series D Preferred was convertible into approximately 7,519 shares of Common Stock.

The aggregate purchase price paid by the investors for the Series D Preferred and the 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.

At the time of its issuance, the Series D Preferred ranked junior to our Series B Preferred and senior to all our shares of Common Stock and other capital stock.

Upon completion of the Series D Preferred transaction, the exercise prices of the Company's Series B Warrants and Series C Warrants were adjusted, pursuant to weighted-average anti-dilution provisions, to $6.79 and $7.20 respectively, from the original exercise prices of $10.36 and $11.00. In addition to the adjustment to the exercise prices of the Series B Warrants and the Series C Warrants, the aggregate number of shares issuable upon exercise of the Series B Warrants and the Series C Warrants increased to 3,609,300 and 408,036, respectively, from 2,365,528 and 267,074. Certain other warrants issued prior to the Company's initial public offering were also adjusted pursuant to anti-dilution provisions contained in those warrants such that their per share exercise price reduced from $2.00 to $1.48 and the aggregate number of shares of Common Stock issuable increased from 281,042 to 379,792.

Pursuant to the terms of the Certificate of Designation of Preferences, Rights and Limitations of the Series D Preferred, the Conversion Price of the Series D Preferred was automatically reduced from $1.40 to $1.33 on August 13, 2009. This adjustment caused the number of shares of Common Stock into which the 542.84 outstanding shares of Series D Preferred could be converted to increase from 3,877,386 to 4,081,445. In addition, pursuant to the weighted-average anti-dilution provisions of the Series B Warrants and the Series C Warrants, this adjustment caused:

- the exercise price of the Series B Warrants to be reduced from $6.79 to $6.73, and the aggregate number of shares of Common Stock issuable upon exercise of the Series B Warrants to increase from 3,609,300 to 3,641,479; and

- the exercise price of the Series C Warrants to be reduced from $7.20 to $7.13, and the aggregate number of shares of Common Stock issuable upon exercise of the Series C Warrants to increase from 408,036 to 412,042.

Certain other warrants issued prior to the Company's initial public offering were also affected by this adjustment, which caused their exercise price to reduce from $1.48 to $1.47 and the aggregate number of shares of Common Stock issuable to increase from 343,537 to 345,855.

On November 13, 2009, the Conversion Price of the Series D Preferred automatically reduced from $1.33 to $1.28. This second adjustment caused the number of shares of Common Stock into which the 470.25 outstanding shares of Series D Preferred could be converted to increase from 3,627,041 to 3,673,844.

In addition, pursuant to the weighted-average anti-dilution provisions of the Series B Warrants and the Series C Warrants, the second adjustment caused:

- the exercise price of the Series B Warrants to be reduced from $6.73 to $6.68, and the aggregate number of shares of Common Stock issuable upon exercise of the Series B Warrants to increase from 3,641,479 to 3,668,727; and

- the exercise price of the Series C Warrants to be reduced from $7.13 to $7.08, and the aggregate number of shares of Common Stock issuable upon exercise of the Series C Warrants to increase from 412,042 to 414,952.

Certain other warrants issued prior to the Company's initial public offering were also affected by this second adjustment, which caused their exercise price to reduce from $1.47 to $1.46 and the aggregate number of shares of Common Stock issuable to increase from 111,447 to 112,210.

On December 31, 2009, the Conversion Price of the Series D Preferred again automatically reduced from $1.33 to $1.02 because the Company failed to meet a particular development milestone by the end of 2009. This milestone-based adjustment caused the number of shares of Common Stock into which the 466.85 outstanding shares of Series D Preferred could be converted to increase from 3,647,281 to 4,576,979.

In addition, pursuant to the weighted-average anti-dilution provisions of the Series B Warrants and the Series C Warrants, the milestone adjustment caused:

- the exercise price of the Series B Warrants to be reduced from $6.68 to $6.37, and the aggregate number of shares of Common Stock issuable upon exercise of the Series B Warrants to increase from 3,668,727 to 3,847,276; and

- the exercise price of the Series C Warrants to be reduced from $7.08 to $6.76, and the aggregate number of shares of Common Stock issuable upon exercise of the Series C Warrants to increase from 414,952 to 434,956.

Certain other warrants issued prior to the Company's initial public offering were also affected by the milestone adjustment causing their exercise price to reduce from $1.46 to $1.39 and the aggregate number of shares of Common Stock issuable to increase from 112,210 to 117,861.

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, discussed in more detail below under "Subsequent Events."

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 generally accepted accounting principles in the U.S., or 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. 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 accounting principles generally accepted in the United States.

Accounting policies that we deem to be most critical include policies relating to: revenue recognition, research and development expenses, intellectual property costs, stock based compensation expenses, and fair value measurement of financial instruments, and are discussed in more detail below.

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.

The Company recognizes revenue related to the funds received from the State of New York under the sponsored research agreement with the RPCI as allowable costs are incurred. The Company recognizes 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, 2009, $50,000 has been paid to the Cleveland Clinic for milestone payments relating to the filing of an IND with

the FDA for Curaxin CBLC102, $250,000 has been paid to the Cleveland Clinic as a result of commencing Phase II clinical trials for Curaxin CBLC102 and $50,000 has been paid to the Cleveland Clinic 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 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, 2008, we capitalized $733,051 in expenditures associated with the preparation, filing and maintenance of certain of our patents, which were incurred through the year ended December 31, 2009. We capitalized an additional $237,064, amortized $4,575 and expensed $35,564 of previously capitalized expenditures relating to these costs incurred for the year ended December 31, 2009, resulting in a balance of capitalized intellectual property totaling $929,976.

Stock-based Compensation

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

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 the Company along with that of similar high-growth, publicly-traded, biotechnology companies due to the limited trading history of the Company. Compensation expense is recognized using the straight-line amortization method for all stock-based awards.

During the year ended December 31, 2009, the Company granted 787,932 stock options. The Company recognized a total of $1,784,240 in expense related to options for the year ended December 31, 2009. The Company also recaptured $50,197 of previously recognized expense due to stock option forfeitures. During the year ended December 31, 2008, the Company granted 997,721 stock options pursuant to stock award agreements. We recognized a total of $828,377 in expense related to options for the year ended December 31, 2008. The weighted average, estimated grant date fair values of stock options granted during the year ended December 31, 2009 and 2008 was $1.95 and $3.16, respectively.

For the year ended December 31, 2009 the Company also recognized a total of $991,612 expense for shares issued under the Company’s Equity Incentive Plan and a total of $33,333 in expense related to the amortization of restricted shares.

Fair Value Measurement

The Company values its financial instruments based on fair value measurements and disclosures which establishes a valuation hierarchy for disclosure of the inputs to valuation 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. The Company does not have any significant assets or liabilities measured at fair value using Level 1 or Level 2 inputs as of December 31, 2009.

The Company analyzed all financial instruments with features of both liabilities and equity.

The Company carries the warrants issued in the Series D Private Placement at fair value using Level 3 inputs for its valuation methodology totaling $8,410,379 and $0 as of December 31, 2009 and 2008, respectively. The Company recognized a fair value measurement loss of $6,267,665 and $0 for the year ended December 31, 2009 and 2008,

respectively.

The Company 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

See Note 2U to financial statements in Item 8.

Results of Operations

The following table sets forth our statement of operations data for the years ended December 31, 2009, 2008 and 2007 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, 2009	Year Ended December 31, 2008	Year Ended December 31, 2007
Revenues	$ 14,345,908	$ 4,705,597	$ 2,018,558
Operating expenses	20,728,837	19,050,965	27,960,590
Other expense (income)	6,463,208	(59,597)	2,058,236
Net interest expense (income)	(19,728)	(259,844)	(1,003,766)
Net income (loss)	$ (12,826,409)	$ (14,025,927)	$ (26,996,502)

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.

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

Agency	Program	Amount	Period of Performance	Revenue 2009	Revenue 2008
DoD	DTRA Contract	$ 1,263,836	03/2007-02/2009	$ 183,613	$ 613,901
NIH	Phase II NIH SBIR program	$ 750,000	07/2006-06/2008	$ -	$ 77,971
NY State/RPCI	Sponsored Research Agreement	$ 3,000,000	03/2007-02/2012	$ 35,696	$ 305,298
NIH	NCI Contract	$ 750,000	09/2006-08/2008	$ -	$ 219,618
DoD	DOD Contract	$ 8,900,000	05/2008-09/2009	$ 4,843,303	$ 2,938,357
HHS	BARDA Contract	$ 13,300,000	09/2008-09/2011	$ 5,374,535	$ 219,412
NIH	NIAID Grant	$ 1,232,695	09/2008-02/2010	$ 1,021,095	$ 211,040
NIH	NIAID GO Grant	$ 5,329,543	09/2009-09/2011	$ 1,237,666	$ -
			Totals	$ 12,695,908	$ 4,585,597

We anticipate our revenue over the next year to continue to be derived mainly from government grants and contracts. We have been awarded 19 government contracts and grants totaling over $27 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 $50 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 the Cleveland Clinic, 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 $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, 2008. 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%.

The following table summarizes research and development expenses for the years ended December 31, 2009, 2008 and 2007 and since inception:

	Year Ended December 31, 2009	Year Ended December 31, 2008	Year Ended December 31, 2007	Total Since Inception
Research and development	$ 14,331,673	$ 13,160,812	$ 17,429,652	$ 57,588,395
General	$ -	$ 931,441	$ 892,456	$ 5,106,630
Protectan CBLB502 - non-medical applications	$ 13,676,289	$ 7,264,813	$ 9,885,776	$ 35,277,485
Protectan CBLB502 - medical applications	$ 56,127	$ 756,227	$ 815,399	$ 1,833,056
Protectan CBLB612	$ 6,567	$ 974,459	$ 1,127,248	$ 3,136,941
Curaxin CBLC102	$ 262,637	$ 1,741,194	$ 2,712,521	$ 6,729,120
Other Curaxins	$ 330,053	$ 1,492,678	$ 1,996,252	$ 5,505,163

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%.

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, 2008 Compared to Year Ended December 31, 2007

Revenue

Revenue increased from $2,018,558 for the year ended December 31, 2007 to $4,705,597 for the year ended December 31, 2008, representing an increase of $2,687,039 or 133.1%, resulting primarily from an increase in revenue from the DoD contract, the BARDA contract and the NIAID grant.

Operating Expenses

Operating expenses decreased from $27,960,590 for the year ended December 31, 2007 to $19,050,965 for the year ended December 31, 2008. This represents a decrease of $8,909,625 or 31.9%. We recognized a total of $7,789,305 of non-cash, stock-based compensation for the year December 31, 2007 compared to $1,527,600 for the year ended December 31, 2008. If these non-cash, stock-based compensation expenses were excluded, operating expenses would have decreased from $20,171,285 for the year ended December 31, 2007 to $17,523,365 for the year ended December 31, 2008. This represents a decrease in operating expenses of $2,647,920 or 13.1%.

This decrease resulted primarily from a decrease in R&D expenses from $17,429,652 for the year ended December 31, 2007 to $13,160,812 for the year ended December 31, 2008, a decrease of $4,268,840 or 24.5%. The reduced R&D expenses were incurred primarily as a result of decreasing the number of R&D subcontracts and other costs until sufficient funding was obtained. We recognized a total of $1,836,787 of non-cash compensation for R&D stock-based compensation for the year ended December 31, 2007 compared to $632,253 for the year ended December 31, 2008. Without the non-cash, stock-based compensation, the R&D expenses decreased from $15,592,865 for the year ended December 31, 2007 to $12,528,559 for the year ended December 31, 2008; a decrease of $3,064,306 or 19.7%.

In addition, selling, general and administrative expenses decreased from $10,530,938 for the year ended December 31, 2007 to $5,890,153, for the year ended December 31, 2008. This represents a decrease of $4,640,785 or 44.1%. These lower selling, general and administrative expenses were incurred as a result of a substantial reduction in the non-cash, stock-based compensation for the selling, general and administrative area of the Company. We recognized a total of $5,952,517 of non-cash, stock-based compensation for general and administrative compensation for the year ended December 31, 2007 compared to $895,347 for the year ended December 31, 2008. Without the non-cash, stock-based compensation, the general and administrative expenses increased from $4,578,421 for the year ended December 31, 2007 to $4,994,806 for the year ended December 31, 2008; an increase of $416,385 or 9.1%.

Liquidity and Capital Resources

We have incurred annual operating losses since our inception, and, as of December 31, 2009 we had an accumulated deficit of $69,687,932. 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 $4,244,944 for the year ended December 31, 2009, compared to $12,121,102 used in operating activities for the same period in 2008. This decrease in cash used in operating activities resulted from a reduction in our net loss due to increase contract and grant revenues. In addition, the cost containment efforts combined with focusing our R&D efforts on projects where grant and contract funding was awarded contributed to this decrease in cash used in operating activities. Net cash used in operating activities totaled $16,607,922 for the same period in 2007.

Net cash provided by investing activities was $626,536 for the year ended December 31, 2009, compared to net cash used in investing activities of $558,407 for the same period in 2008. The increase in cash provided by investing activities resulted primarily from the liquidation of a short-term investment in 2009. Net cash used in investing activities was $442,523 for the same period in 2007.

Net cash provided by financing activities totaled $4,281,659 for the year ended December 31, 2009, compared to $1,232,831 used by financing activities for the same period in 2008. The increase in cash provided by financial activities was attributed to the issuance of the Series D Preferred Shares and Series D Warrants as compared to the cash used in financing activities to pay dividends on the Series B Preferred during the same period in 2008. Net cash provided by financing activities totaled $28,200,591 for the same period in 2007. The decrease in cash provided by financing activities was attributed to the dividends paid on the Series B Preferred in 2008 as compared to the proceeds from the issuance of Series B Preferred in connection with our private placement offering in 2007.

Under our exclusive license agreement with the Cleveland Clinic Foundation, or 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

As discussed above, as a result of the satisfaction of certain conditions contained in Section 8(a) of the Certificate of Designation of Preferences, Rights and Limitations of the Series D Preferred, filed with the Secretary of State of Delaware on February 13, 2009, including that the closing sale price of the Company's Common Stock on the NASDAQ Capital Market has exceeded 300% of the conversion price of the Series D Preferred ($1.02) for 20 consecutive trading days, on February 9, 2010, 466.85 shares of Series D Preferred, which represented all outstanding Series D Preferred, converted into 4,576,979 shares of common stock.

On February 25, 2010, we entered into a 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 1,015,385 shares of our common stock, for an aggregate purchase price of $5,000,000. The transaction closed on March 2, 2010. After related fees and expenses, the Company received net proceeds totaling approximately $4,500,000. The Company intends to use the proceeds of the private placement for working capital purposes.

The common stock was sold at a price of $3.25 per share, and the warrants had an exercise price of $4.50 per share, subject to future adjustment for various events, such as stock splits or dilutive issuances. The warrants are exercisable commencing six months following issuance and expire on March 2, 2015.

For its services as placement agent, Rodman & Renshaw, LLC 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 and Renshaw have not been and will not be registered under the Securities Act of 1933.

Immediately after the completion of this transaction, 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.

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, 2009, we are obligated to make payments under these agreements of 790,242 Euros. We have established means to purchase forward contracts to hedge against this risk.

Off-Balance Sheet Arrangements

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

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, 2009, we had not drawn on this facility.

Foreign Currency Risk. As of December 31, 2009, 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, the Company's 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. At this time, our exposure to foreign currency fluctuations is not material.

In addition, 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, 2009 and 2008, and the related statements of operations, stockholders' equity and comprehensive income, and cash flows for each of the years in the three-year period ended December 31, 2009. Cleveland BioLabs, Inc.'s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes 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, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Cleveland BioLabs Inc. as of December 31, 2009 and 2008, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2009 in conformity with accounting principles generally accepted in the United States of America.

MEADEN & MOORE, LTD.
Certified Public Accountants

Cleveland, Ohio
March 15, 2010

CLEVELAND BIOLABS, INC.

BALANCE SHEETS

December 31, 2009 and December 31, 2008

	December 31 2009	December 31 2008
ASSETS		
CURRENT ASSETS		
Cash and equivalents	$ 963,100	$ 299,849
Short-term investments	-	1,000,000
Accounts receivable:		
Trade	3,391,347	1,043,821
Interest	-	9,488
Other current assets	381,030	510,707
Total current assets	4,735,477	2,863,865
EQUIPMENT		
Computer equipment	323,961	309,323
Lab equipment	1,159,478	1,102,465
Furniture	376,882	312,134
	1,860,321	1,723,922
Less accumulated depreciation	995,408	637,840
	864,913	1,086,082
OTHER ASSETS		
Intellectual property	929,976	733,051
Deposits	23,482	23,482
	953,458	756,533
TOTAL ASSETS	$ 6,553,848	$ 4,706,480

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CLEVELAND BIOLABS, INC.

BALANCE SHEETS

December 31, 2009 and December 31, 2008

	December 31 2009	December 31 2008
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,208,632	$ 1,101,961
Deferred revenue	2,329,616	2,365,312
Dividends payable	-	321,293
Accrued expenses	1,405,715	379,653
Accrued warrant liability	8,410,379	-
Total current liabilities	13,354,342	4,168,219
STOCKHOLDERS' EQUITY		
Preferred stock, $.005 par value Authorized - 10,000,000 shares at December 31, 2009 and December 31, 2008		
Series B convertible preferred stock, Issued and outstanding 0 and 3,160,974 shares at December 31, 2009 and December 31, 2008, respectively	-	15,805
Series D convertible preferred stock, Issued and outstanding 466.85 and 0 shares at December 31, 2009 and December 31, 2008, respectively	2	-
Common stock, $.005 par value Authorized - 80,000,000 and 40,000,000 shares at December 31, 2009 and December 31, 2008, respectively		
Issued and outstanding 20,203,508 and 13,775,805 shares at December 31, 2009 and December 31, 2008, respectively	101,018	68,879
Additional paid-in capital	62,786,418	56,699,750
Accumulated deficit	(69,687,932)	(56,246,173)
Total stockholders' equity	(6,800,494)	538,261
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 6,553,848	$ 4,706,480

CLEVELAND BIOLABS, INC.

STATEMENTS OF OPERATIONS

Years Ended December 31, 2009, 2008, and 2007

	December 31 2009	December 31 2008	December 31 2007
REVENUES			
Grant and Contract	$ 12,695,908	$ 4,585,597	$ 1,728,558
Commercial	1,650,000	120,000	290,000
	14,345,908	4,705,597	2,018,558
OPERATING EXPENSES			
Research and development	14,331,673	13,160,812	17,429,652
Selling, general and administrative	6,397,164	5,890,153	10,530,938
Total operating expenses	20,728,837	19,050,965	27,960,590
LOSS FROM OPERATIONS	(6,382,929)	(14,345,368)	(25,942,032)
OTHER INCOME			
Interest income	21,688	259,844	1,004,853
Buffalo relocation reimbursement	-	220,000	-
Sublease revenue	71,427	12,475	4,427
Gain on disposal of fixed assets	-	1,394	-
Gain on investment	-	3,292	-
Total other income	93,115	497,005	1,009,280
OTHER EXPENSE			
Warrant issuance costs	266,970	-	-
Interest expense	1,960	-	1,087
Corporate relocation	-	177,564	1,741,609
Loss on disposal of fixed assets	-	-	15,575
Loss on investment	-	-	305,479
Change in value of warrant liability	6,267,665	-	-
	6,536,595	177,564	2,063,750
NET LOSS	(12,826,409)	(14,025,927)	(26,996,502)
DIVIDENDS ON CONVERTIBLE PREFERRED STOCK	(615,352)	(1,182,033)	(1,265,800)
NET LOSS AVAILABLE TO COMMON STOCKHOLDERS	$ (13,441,761)	$ (15,207,960)	$ (28,262,302)
NET LOSS AVAILABLE TO COMMON STOCKHOLDERS PER SHARE OF COMMON STOCK - BASIC AND DILUTED	$ (0.82)	$ (1.13)	$ (2.34)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATING NET LOSS PER SHARE, BASIC AND DILUTED	16,405,129	13,492,391	12,090,430

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CLEVELAND BIOLABS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2007 to December 31, 2009

	Stockholders' Equity Common Stock Shares	Amount
Balance at January 1, 2007	11,826,389	$ 59,132
Issuance of options	-	-
Options to be issued in 2008	-	-
Issuance of shares - Series B financing	-	-
Fees associated with Series B Preferred offering	-	-
Issuance of restricted shares	190,000	950
Exercise of options	126,046	630
Exercise of warrants	48,063	240
Conversion of Series B Preferred Shares to Common	708,743	3,544
Dividends on Series B Preferred shares	-	-
Net Loss	-	-
Other comprehensive income		
Unrealized gains (losses) on short term investments		
Changes in unrealized holding gains (losses) arising during period	-	-
Less reclassification adjustment for (gains) losses included in net loss	-	-
Comprehensive loss		
Balance at December 31, 2007	12,899,241	$ 64,496
Issuance of options	-	-
Partial recapture of expense for options expensed in 2007 but issued in 2008	-	-
Issuance of restricted shares	130,000	650
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 December 31, 2008	13,775,805	$ 68,879
Issuance of options	-	-
Issuance of restricted shares	291,532	1,458
Recapture of expense for nonvested options forfeited	-	-
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

CLEVELAND BIOLABS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2007 to December 31, 2009

	Stockholders' Equity			
	Preferred Stock			
	Series B	Amount	Series D	Amount
Balance at January 1, 2007	-	$ -	-	$ -
Issuance of options	-	-	-	-
Options to be issued in 2008	-	-	-	-
Issuance of shares - Series B financing	4,579,010	22,895	4,579,010	22,895
Fees associated with Series B Preferred offering	-	-	-	-
Issuance of restricted shares	-	-	-	-
Exercise of options	-	-	-	-
Exercise of warrants	-	-	-	-
Conversion of Series B Preferred Shares to Common	(708,743)	(3,544)	708,743	3,544
Dividends on Series B Preferred shares	-	-	-	-
Net Loss	-	-	-	-
Other comprehensive income				
Unrealized gains (losses) on short term investments				
Changes in unrealized holding gains (losses) arising during period	-	-	-	-
Less reclassification adjustment for (gains) losses included in net loss Comprehensive loss	-	-	-	-
Balance at December 31, 2007	3,870,267	$ 19,351	-	$ -
Issuance of options	-	-	-	-
Partial recapture of expense for options expensed in 2007 but issued in 2008	-	-	-	-
Issuance of restricted shares	-	-	-	-
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 December 31, 2008	3,160,974	$ 15,805	-	$ -
Issuance of options	-	-	-	-
Issuance of restricted shares	-	-	-	-
Recapture of expense for nonvested options forfeited	-	-	-	-
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

	Stockholders' Equity				
	Additional Paid-in Capital	Other Comprehensive Income/(Loss)	Accumulated Deficit	Total	Comprehensive Income (Loss)
Balance at January 1, 2007	$ 18,314,097	$ (4,165)	$ (12,775,910)	$ 5,653,754	
Issuance of options	3,401,499	-	-	3,401,499	
Options to be issued in 2008	2,687,355	-	-	2,687,355	
Issuance of shares - Series B financing	-	-	-	4,624,800	
Fees associated with Series B Preferred offering	-	-	-	-	
Issuance of restricted shares	1,699,500	-	-	1,700,450	
Exercise of options	110,650	-	-	111,280	
Exercise of warrants	90,275	-	-	90,515	
Conversion of Series B Preferred Shares to Common	4,461,537	-	-	5,173,824	
Dividends on Series B Preferred shares	-	-	(1,265,800)	(1,265,800)	
Net Loss	-	-	(26,996,502)	(26,996,502)	(26,996,502)
Other comprehensive income					
Unrealized gains (losses) on short term investments					
Changes in unrealized holding gains (losses) arising during period	-	-	-	-	$ -
Less reclassification adjustment for (gains) losses included in net loss Comprehensive loss	-	4,165	-	4,165	$ 4,165
Balance at December 31, 2007	$ 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 restricted shares	625,850	-	-	626,500	
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)	$ (14,025,927)
Balance at December 31, 2008	$ 56,699,750	$ -	$ (56,246,172)	$ 538,261	
Issuance of options	1,784,240	-	-	1,784,240	
Issuance of restricted shares	991,612	-	-	993,070	
Recapture of expense for nonvested options forfeited	(50,197)	-	-	(50,197)	
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)	$ (12,826,409)
Balance at December 31, 2009	$ 62,786,418	$ -	$ (69,687,932)	$ (6,800,494)	

CLEVELAND BIOLABS, INC.

STATEMENTS OF CASH FLOWS

For the Years Ended December 31, 2009, 2008 and 2007

	2009	2008	2007
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (12,826,409)	$ (14,025,927)	$ (26,996,502)
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation	357,568	324,351	188,395
Amortization	4,575	-	-
Noncash salaries and consulting expense	2,760,446	1,527,600	7,789,305
Series D warrant issuance costs	266,970	-	-
Change in value of warrant liability	6,267,665	-	-
Loss on disposal of fixed assets	-	-	15,575
Loss on investments		-	305,479
Loss on abandoned patents	35,564	60,045	-
Changes in operating assets and liabilities:			
Accounts receivable - trade	(2,347,526)	(880,419)	(3,652)
Accounts receivable - interest	9,488	40,553	(12,870)
Other current assets	129,677	(185,081)	109,049
Deposits	-	1,963	(10,390)
Accounts payable	106,672	391,232	65,923
Deferred revenue	(35,696)	694,702	1,670,610
Accrued expenses	1,026,062	(70,121)	321,206
Milestone payments	-	-	(50,000)
Total adjustments	8,581,465	1,904,825	10,388,630
Net cash (used by) provided by operating activities	(4,244,944)	(12,121,102)	(16,607,872)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of short-term investments	-	(2,000,000)	(1,000,000)
Sale of short-term investments	1,000,000	2,000,000	2,000,000
Issuance of notes receivable	-	-	(250,000)
Purchase of equipment	(136,400)	(224,413)	(987,649)
Sale of equipment	-	-	1,250
Costs of patents pending	(237,064)	(333,994)	(206,124)
Net cash (used in) provided by investing activities	626,536	(558,407)	(442,523)
CASH FLOWS FROM FINANCING ACTIVITIES			
Issuance of preferred stock	5,428,307	-	30,020,984
Financing costs on preferred stock	(720,175)	-	(1,152,857)
Series D warrant issuance costs	(266,970)		
Dividends	(936,644)	(1,257,209)	(869,331)
Exercise of stock options	362,857	24,378	111,280
Exercise of warrants	414,284	-	90,515
Net cash (used in) provided by financing activities	4,281,659	(1,232,831)	28,200,591

INCREASE (DECREASE) IN CASH AND EQUIVALENTS	663,251	(13,912,340)	11,150,196
CASH AND EQUIVALENTS AT BEGINNING OF PERIOD	299,849	14,212,189	3,061,993
CASH AND EQUIVALENTS AT END OF PERIOD	$ 963,100	$ 299,849	$ 14,212,189

CLEVELAND BIOLABS, INC.

STATEMENTS OF CASH FLOWS

For the Years Ended December 31, 2009, 2008 and 2007

	2009	2008	2007
Supplemental disclosures of cash flow information:			
Cash paid during the period for interest	$ 1,960	$ -	$ 1,087
Cash paid during the period for income taxes	$ -	$ -	$ -
Supplemental schedule of noncash financing activities:			
Issuance of stock options to employees, consultants, and independent board members	$ 1,784,240	$ 2,287,803	$ 3,401,499
Expense recapture of expense for options expensed in 2007 but issued in 2008	$ -	$ (1,459,425)	$ -
Expense recapture of expense for options that were nonvested and forfeited	$ (50,197)	$ -	$ -
Stock options due to employees and a consultant	$ -	$ -	$ 2,687,355
Issuance of shares to consultants and employees	$ 993,070	$ 626,500	$ 1,700,450
Amortization of restricted shares to be issued to employees and consultants	$ 33,333	$ 72,722	$ -
Issuance of non-cash financing fees	$ -	$ -	$ 2,032,086
Accrual of Series B preferred stock dividends	$ -	$ 321,293	$ 396,469
Conversion of warrant liability to equity due to exercise of warrants	$ 874,119	$ -	$ -

CLEVELAND BIOLABS, INC.

NOTES TO FINANCIAL STATEMENTS

Note 1. Organization

Cleveland BioLabs, Inc. (“CBLI” or “Company”) is a drug discovery and development company leveraging its proprietary discoveries around programmed cell death to develop treatments for cancer and protection of normal tissues from radiation and other stresses. The Company was incorporated under the laws of the State of Delaware on June 5, 2003 and is headquartered in Buffalo, New York.

The Company’s financial statements have been prepared on the accrual basis of accounting in accordance with accounting principles generally accepted in the United States of America and on a going concern basis which contemplates the realization of assets and the liquidation of liabilities in the ordinary course of business. The Company has incurred substantial losses from operations which raises a question about its ability to continue as a going concern. The Company sustained a net loss of $12,826,409 for the fiscal year ended December 31, 2009.

The Company continues to explore investment and licensing arrangements and also plans to submit proposals for government contracts and grants over the next two years totaling over $10 million and have three applications totaling nearly $43 million that are pending approval. Many of the proposals will be submitted to government agencies that have awarded contracts and grants to the Company in the recent past. Finally, the Company has implemented cost containment efforts that permit the incurrence of those costs that are properly funded, either through a government contract or grant or other capital sources. It is expected that the successful implementation of the financing and cost containment efforts identified above will allow the Company to continue to realize its assets and liquidate its liabilities in the ordinary course of business.

Note 2. Summary of Significant Accounting Policies

A. Cash and Equivalents - The Company considers highly liquid investments with a maturity date of three months or less to be cash equivalents. In addition, the Company maintains cash and equivalents at financial institutions, which may exceed federally insured amounts at times and which may, at times, significantly exceed balance sheet amounts due to outstanding checks.

B. Marketable Securities and Short Term Investments - The Company considers investments with a maturity date of more than three months to be short-term investments and has classified these securities as available-for-sale. Such investments are carried at fair value, with unrealized gains and losses included as accumulated other comprehensive income (loss) in stockholders' equity. The cost of available-for-sale securities sold is determined based on the specific identification method.

C. Accounts Receivable - The Company extends unsecured credit to customers under normal trade agreements, which generally require payment within 30 days. Management estimates an allowance for doubtful accounts which is based upon management's review of delinquent accounts and an assessment of the Company's historical evidence of collections. There is no allowance for doubtful accounts as of December 31, 2009 and December 31, 2008.

D. Equipment - Equipment is stated at cost and depreciated over the estimated useful lives of the assets (generally five years) using the straight-line method. Leasehold improvements are depreciated on the straight-line method over the shorter of the lease term or the estimated useful lives of the assets. Expenditures for maintenance and repairs are charged to expense as incurred. Major expenditures for renewals and betterments are capitalized and depreciated. Depreciation expense was $357,568, $324,351, and $188,395 for the years ended December 31, 2009, 2008 and 2007, respectively.

E. Impairment of Long-Lived Assets - Long-lived assets to be held and used, including equipment and intangible assets subject to depreciation and amortization, are reviewed for impairment at least annually and whenever events or changes in circumstances indicate that the carrying amounts of the assets or related asset group may not be recoverable. Determination of recoverability is based on an estimate of discounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset or asset group, the carrying amount of the asset is written down to its estimated net realizable value.

F. Intellectual Property - The Company capitalizes the costs associated with the preparation, filing, and maintenance of patent applications relating to intellectual property. If the patent applications are approved, costs paid by the Company associated with the preparation, filing, and maintenance of the patents will be amortized on a straight-line basis over the shorter of 20 years or the anticipated useful life of the patent. If the patent application is not approved, the costs associated the patent application will be expensed as part of selling, general and administrative expenses at that time. Capitalized intellectual property is reviewed annually for impairment.

A portion of this intellectual property is owned by the Cleveland Clinic Foundation ("CCF") and granted to the Company through an exclusive licensing agreement. As part of the licensing agreement, CBLI agrees to bear the costs associated with the preparation, filing and maintenance of patent applications relating to this intellectual property. Gross capitalized patents and patents pending costs were $688,355 and $629,363 for ten and thirteen patent applications as of December 31, 2009 and December 31, 2008, respectively. One of the CCF patent applications was approved by several nations and is being amortized on a straight-line basis over the weighted average estimated remaining life of approximately fifteen years. The remainder of the CCF patent applications are still pending approval. During 2009, the Company abandoned two patent applications due to developing an improved drug for the same application and expensed $35,564 in selling, general and administrative expenses. During 2008, the Company abandoned one patent application due to developing another drug for the same application and expensed $44,790 in selling, general and administrative expenses. The Company recognized $4,575, $0 and $0 in amortization expense for the years ended December 31, 2009, 2008 and 2007, respectively.

The Company also has submitted patent applications as a result of intellectual property exclusively developed and owned by the Company. Gross capitalized patents pending costs were $199,371 and $103,688 for four and five patent applications as of December 31, 2009 and December 31, 2008, respectively. The patent applications are still pending approval. During 2008, the Company abandoned one patent application due to discovering that the patent would provide no future economic benefit and expensed $15,256 in selling, general and administrative expenses.

The Company has also submitted two patent applications as a result of the collaborative research agreement with the Roswell Park Cancer Institute ("RPCI"). As part of this collaborative agreement, CBLI agrees to bear the costs associated with the preparation, filing and maintenance of patent applications related to the intellectual property being developed. Gross capitalized patents pending costs were $8,340 and 0 for two patent applications as of December 31, 2009 and 2008, respectively.

The Company has also submitted one patent application as a result of the collaborative research agreement with the ChemBridge Corporation ("ChemBridge"). As part of this collaborative agreement, CBLI agrees to bear the costs associated with the preparation, filing and maintenance of patent applications related to the intellectual property being developed. Gross capitalized patents pending costs were $38,484 and $22,441 for this patent application as of December 31, 2009 and 2008, respectively.

Below is a summary of the major identifiable intangible assets and weighted average amortization periods for each identifiable asset:

	As of December 31, 2009			
Intangible Assets	Cost	Accumulated Amortization	Net Intangible Asset	Weighted Average Amortization Period (Years)
Patents	$ 150,888	$ 4,574	$ 146,314	14.9
Patent Applications	783,662	-	783,663	n.a.
	$ 934,550	$ 4,574	$ 929,976	

The estimated amortization expense for the next five years for approved patents is as follows:

2010	$ 9,801
2011	$ 9,801
2012	$ 9,801
2013	$ 9,801

2014	$	9,801

G. Line of Credit - The Company has a working capital line of credit that is fully secured by cash equivalents and short-term investments. This fully-secured, working capital line of credit carries an interest rate of prime minus 1%, a borrowing limit of $600,000, and expires on May 31, 2010. At December 31, 2009 and 2008, there were no outstanding borrowings under this credit facility.

H. Fair Value of Financial Instruments - Financial instruments, including cash and equivalents, accounts receivable, notes receivable, accounts payable and accrued liabilities, are carried at net realizable value

The Company values its financial instruments in accordance with the FASB Accounting Standards Codification ("Codification") on fair value measurements and disclosures which establishes a valuation hierarchy for disclosure of the inputs to valuation 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. The Company does not have any significant assets or liabilities measured at fair value using Level 1 or Level 2 inputs as of December 31, 2009.

The Company analyzed all financial instruments with features of both liabilities and equity in accordance with the Codification on distinguishing liabilities from equity and derivatives from hedging.

The Company carries its warrants issued in connection with the Series D Private Placement at fair value totaling $8,410,379 and $0 as of December 31, 2009 and December 31, 2008, respectively. The Company used Level 3 inputs for its valuation methodology for the warrant liability, and the fair values were determined using the Black-Scholes option pricing model based on the following assumptions:

	Warrant Value at December 31, 2009
Stock price	$ 3.31
Exercise price	$ 1.60
Term in years	1.25
Volatility	105.81%
Annual rate of quarterly dividends	-
Discount rate- bond equivalent yield	0.52%

	Fair Value As of December 31, 2009	Fair Value Measurements at December 31, 2009 Using Fair Value Hierarchy		
Liabilities		Level 1	Level 2	Level 3
Warrant liability	$ 8,410,379	$ -	$ -	$ 8,410,379

I. Use of Estimates - The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company bases its estimates on historical experience and on various other assumptions that the Company believes to be reasonable under these circumstances. Actual results could differ from those estimates.

J. Revenue Recognition - Revenue sources consist of government grants, government contracts and commercial licensing and development contracts.

Revenues from government grants and contracts are for research and development purposes and are recognized in accordance with the terms of the award and the government agency. Grant revenue is recognized in one of two different ways depending on the 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 according to the terms of the government grant. Fixed cost grants require no

proof of costs at the time of invoicing, but proof is required for audit purposes and grant revenue is recognized during the period that the costs were incurred according to the terms of the government grant. The grant revenue under these fixed costs 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.

Government contract revenue is recognized as allowable research and development expenses are incurred during the period and according to the terms of the government contract.

The Company recognizes revenue related to the funds received from the State of New York under the sponsored research agreement with RPCI as allowable costs are incurred. The Company recognizes revenue on research laboratory services and the use of related equipment. The amount paid 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.

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

K. Deferred Revenue – Deferred revenue results when payment is received in advance of revenue being earned. The Company makes a determination as to whether the revenue has been earned by applying a percentage-of-completion analysis to compute the need to recognize deferred revenue. The percentage of completion method is based upon (1) the total income projected for the project at the time of completion and (2) the expenses incurred to date. The percentage-of-completion can be measured using the proportion of costs incurred versus the total estimated cost to complete the contract.

The Company received $2,000,000 in funds from the State of New York through RPCI during the second quarter of 2007. The Company received an additional $1,000,000 in funds from the State of New York through RPCI during the second quarter of 2008. The Company is recognizing this revenue over the terms and conditions of the sponsored research agreement. The Company recognizes revenue on research laboratory services and the purchase and subsequent use of related equipment. The amount paid toward future services related to the equipment is recognized as a prepaid asset and will be recognized as revenue as depreciated over the estimated useful life of the equipment.

The following table summarizes the deferred revenue activity for the years ended December 31, 2009 and 2008, respectively:

		Activity
Beginning Balance, December 31, 2007	$	1,670,610
Funds Recived From State of NY	$	1,000,000
Funds Recognized as Revenue	$	(305,298)
Ending Balance, December 31, 2008	$	2,365,312
Funds Recived From State of NY	$	-
Funds Recognized as Revenue	$	(35,696)
Ending Balance, December 31, 2009	$	2,329,616

L. Research and Development - Research and development expenses consist primarily of costs associated with salaries and related expenses for personnel, costs of materials used in research and development, costs of facilities and costs incurred in connection with third-party efforts. Expenditures relating to research and development are expensed as incurred.

M. Equity Incentive Plan - On May 26, 2006, the Company's Board of Directors adopted the 2006 Equity Incentive Plan (“Plan”) to attract and retain persons eligible to participate in the Plan, motivate participants to achieve long-term Company goals, and further align participants' interests with those of the Company's other stockholders. The Plan was to expire on May 26, 2016 and the aggregate number of shares of stock which could be delivered under the Plan may not exceed 2,000,000 shares. On February 14, 2007, these 2,000,000 shares were registered with the SEC by filing a Form S-8 registration statement. On April 29, 2008, the stockholders of the Company approved an amendment and restatement of the Plan (“Amended Plan”). The Amended Plan increased the number of

shares available for issuance by an additional 2,000,000 shares, clarified other aspects of the Plan, contained updates that reflected changes and developments in federal tax laws and extended the expiration date to April 29, 2018. As of December 31, 2009 there were 2,490,653 stock options and 446,532 shares granted under the Amended Plan and 43,177 shares forfeited leaving 1,105,992 shares of stock to be awarded under the Amended Plan.

N. Executive Compensation Plan - On May 11, 2007, the Compensation Committee of the Board of Directors ("Compensation Committee") approved an executive compensation program designed to reward each of the Company's Chief Executive Officer, Chief Operating Officer, Chief Financial Officer and Chief Scientific Officer ("Executive Officers") for the achievement of certain pre-determined milestones. The purpose of the program is to link each Executive Officer's compensation to the achievement of key Company milestones that the Compensation Committee believes have a strong potential to create long-term stockholder value.

Under the terms of this program, after each fiscal year beginning with the fiscal year ended December 31, 2007, each component of the Executive Officers' compensation packages - base salary, cash bonus and stock option awards - will be measured against the Company's achievement of (1) stock performance milestones, (2) scientific milestones, (3) business milestones (4) financial milestones and (5) corporate governance, each of which will be weighted by the Compensation Committee. The milestones will be set at the beginning of each fiscal year. Each set of milestones has a minimum threshold performance level, a target level and a high performance level. For base salary, increases will range between 2% for threshold performance to 6% for high performance. For cash bonuses, increases will range between 15% for threshold performance and 60% for high performance. For stock option awards, awards will range between 50,000 stock options for threshold performance and 200,000 for high performance.

For the year ended December 31, 2009 the Compensation Committee awarded $264,141 in cash bonuses and $970,200 in non-cash, stock-based compensation for stock option awards to be granted in 2010 under this executive compensation program ("ECP"). For the year ended December 31, 2008, the Compensation Committee made no awards under the ECP.

O. Stock-Based Compensation - The Company recognizes and values stock-based compensation under the provisions of the Codification on stock compensation.

The fair value of each stock option granted is estimated on the grant date. The Black Scholes model is used for standard stock options, but if market conditions are present within the stock options, the Company utilizes Monte Carlo simulation to value the stock options. The assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect the Company's experience. The Company uses a risk-free rate published by the St. Louis Federal Reserve at the time of the option grant, assumes a forfeiture rate of zero, assumes an expected dividend yield rate of zero based on the Company's intent not to issue a dividend in the foreseeable future, uses an expected life based on the safe harbor method and computes an expected volatility based on the volatility of the Company's common stock and on the common stock similar high-growth, publicly-traded, biotechnology companies. In 2008, the Company began to include the use of its own common stock in the volatility calculation and is layering in the volatility of the common stock of the Company with that of the common stock comparable companies since there is not adequate trading history to rely solely on the volatility of the Company's common stock. The Company recognizes the fair value of stock-based compensation in net income on a straight-line basis over the requisite service period.

The Company issued 787,932, 997,721 and 660,000 stock options during the years ended December 31, 2009, 2008, and 2007, respectively, pursuant to various stock award agreements. The Company recognized a total of $1,784,240, $828,377, and $3,401,499 in expense related to options and recaptured $50,197, $0 and $0 of previously recognized expense due to the forfeiture of non-vested options for the years ended December 31, 2009, 2008, and 2007, respectively. The weighted average, estimated grant date fair values of stock options granted was $1.95, $3.16, and $6.08 during the years ended December 31, 2009, 2008, and 2007, respectively.

The assumptions used to value these option grants using the Black-Scholes option valuation model are as follows:

	2009	2008	2007
Risk-free interest rate	1.87-2.74%	2.43-3.58%	3.38-5.11%
Expected dividend yield	0%	0%	0%
Expected life	5-6 years	5-6 years	2.74-6 years
Expected volatility	84.13-90.06%	64.25-82.47%	71.86-76.29%

The following tables summarize the stock option activity for the years ended December 31, 2009 and 2008, respectively.

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)
Outstanding, December 31, 2008	1,948,874	$ 6.17	
Granted	787,932	$ 2.82	
Exercised	(194,675)	$ 1.86	
Forfeited, Canceled	(25,124)	$ 5.52	
Outstanding, December 31, 2009	2,517,007	$ 5.46	8.02
Exercisable, December 31, 2009	2,185,632	$ 5.12	7.99

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)
Outstanding, December 31, 2007	1,011,740	$ 7.29	
Granted	997,721	$ 3.16	
Exercised	(42,534)	$ 1.04	
Forfeited, Canceled	(18,053)	$ 9.00	
Outstanding, December 31, 2008	1,948,874	$ 6.17	