CLEVELAND BIOLABS INC
Form 10-K
March 30, 2009

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, 2008

or

¨ Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from _____to _____

Commission file number 001-32954

CLEVELAND BIOLABS, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	20-0077155
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
73 High Street, Buffalo, NY 14203	(716) 849-6810
(Address of principal executive offices)	Telephone No.

Securities Registered Pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange which registered
Common Stock, par value $0.005 per share	NASDAQ Capital Market

Securities Registered Pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

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

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

Indicate by check mark 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 $37,767,484. There were 14,014,137 shares of common stock outstanding as of March 16, 2009.

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant's Annual Meeting of Stockholders, to be held on June 25, 2009, is incorporated by reference in Part III to the extent described therein.

CLEVELAND BIOLABS, INC.
FORM 10-K
03/30/09

Cleveland BioLabs, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2008

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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 and specifically decline 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

We were incorporated in Delaware and commenced business operations in June 2003 as a development-stage, biotechnology company, with a very specific and targeted focus on radiation drug discovery. 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. After our initial public offering, our common stock was listed on the NASDAQ Capital Market under the symbol “CBLI” and on the Boston Stock Exchange under the symbol “CFB.” Our trading symbol on the Boston Stock Exchange was later changed to “CBLI.” On August 28, 2007, trading of our common stock transferred from the NASDAQ Capital Market to the NASDAQ Global Market. In September 2007, we ceased our listing on the Boston Stock Exchange. On November 28, 2008, trading of our common stock transferred from the NASDAQ Global Market back to the NASDAQ Capital Market.

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. At the present time, the primary focus of our research is on the protection of healthy tissues against external exposures resulting from military or defense activities.

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. At the present time, our research efforts in this area are limited as we dedicate the majority of our resources to military and defense applications.

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 and tumors 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 100% or even 50% of all cancer patients. This means that there likely will be a need for additional anticancer drugs for each type of cancer.

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 24 months. Another drug candidate, Curaxin CBLC102, demonstrated efficacy and safety in a Phase IIa clinical trial concluded in late 2008.

INDUSTRY

CBLI is a biotechnology, or biotech, company focused on developing cancer treatment, tissue protection and biodefense 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. Today biotech is a $296 billion industry (based on total market capitalization) 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.

- 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 in the market 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 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 NIH;

- 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 by the end of 2010.

Leveraging our relationship with leading research and clinical development institutions. The Cleveland Clinic Foundation, 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 clinical trials 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.

Utilizing 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.

PRODUCTS IN DEVELOPMENT

Protectans

We are exploring a new natural source of factors that suppress the programmed cell death (apoptosis) response in human cells, which can be rapidly developed into therapeutic products. These inhibitors are anti-apoptotic factors developed by microorganisms of human microflora throughout millions of years of co-evolution with mammalian host. We are using the same strategy that was applied for the discovery of antibiotics, one of the biggest medical achievements of the 20 th century. We have established a technological pipeline for screening of such factors, named protectans, and their rapid preclinical evaluation. Such inhibitors can be used as protection from cancer treatment side effects and antidotes against injuries induced by radiation and other stresses associated with severe pathologies (i.e., heart attack or stroke).

Fourteen families of patents have been filed over the past five 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, including Protectan CBLB502, was recently granted by the Eurasian Patent Organization (nine countries) and two other countries.

We spent approximately $8,995,500 and $11,828,423 on R&D for protectans for all applications in the fiscal years ended December 31, 2008 and December 31, 2007, respectively. From our inception to December 31, 2008, we spent approximately $26,508,500 on R&D for protectans.

Protectan CBLB502

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

We spent approximately $8,021,040 and $10,701,175 on R&D for Protectan CBLB502 in the fiscal years ended December 31, 2008 and December 31, 2007, respectively. From our inception to December 31, 2008, we spent approximately $23,378,126 on R&D for Protectan CBLB502.

We intend to enter into negotiations for contracts to purchase Protectan CBLB502 with various U.S. and international government agencies in the third quarter of 2009. If the U.S. government makes significant future contract awards for the supply of its emergency stockpile to our competitors, our business will be harmed and it is unlikely that we will be able to ultimately commercialize our competitive product.

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.

We have successfully established cGMP quality manufacturing for Protectan CBLB502 and are nearing completion of the first of two Phase I human safety studies for Protectan CBLB502 in ARS. Protectan CBLB502 is being developed under the FDA's animal efficacy rule to treat radiation injury following exposure to radiation from nuclear or radiological weapons, or from nuclear accident. This approval pathway requires demonstration of efficacy in two animal species and safety and drug metabolism testing in a representative sample of healthy human volunteers. Protectan CBLB502 has demonstrated activity as a radioprotectant in several animal species, including non-human primates. Phase I is the only stage of human testing required for approval in this indication.

The FDA gave us permission to start safety testing on humans on August 7, 2008. The first healthy volunteer in the dose escalation safety study was dosed on October 14, 2008. The initial safety study will involve single injections of Protectan CBLB502 in ascending dose groups of six healthy volunteers each. Participants in the study are being assessed for adverse side effects over two-week time period and blood samples are being obtained to assess the effects of Protectan CBLB502 on various biomarkers. The study is currently projected to be completed in spring 2009. The second safety study in a larger number of healthy volunteers is planned to start in the third quarter of 2009.

We are working towards filing a BLA for FDA approval of Protectan CBLB502 for non-medical applications by the end of 2010.

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 the Armed Forces Radiobiology Research Institute, which has also received significant independent funding for work on Protectan CBLB502.

In March 2008, the U.S. Department of Defense, or DoD, awarded us a contract valued at up to $8.9 million 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 to treat radiation injury following exposure to radiation from nuclear or radiological weapons.

On September 12, 2008, we were awarded a $774,183 grant from the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), to further study certain mitigating properties of Protectan CBLB502 in the context of hematopoietic damage from radiation exposure. The grant program, Medical Countermeasures to Enhance Platelet Regeneration and Increase Survival Following Radiation Exposure, is funded through the Project BioShield Act of 2004 and administered by the Department of Health and Human Services.

On September 16, 2008, the Biomedical Advanced Research and Development Authority (BARDA) of the Department of Health and Human Services (HHS) awarded us a contract under the Broad Agency Announcement 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 is $13.3 million over a three-year period, with the first year's award of $3.4 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.

Protectan CBLB502's unprecedented efficacy, unique ability to address both hematopoietic and GI damage, broad time window of use, and mitigation effects that do not require additional supportive care and set it apart from any other existing or therapies.

We spent approximately $7,264,813 and $9,885,776 on R&D for the non-medical applications of Protectan CBLB502 in the fiscal years ended December 31, 2008 and December 31, 2007, respectively. From our inception to December 31, 2008, we spent approximately $21,601,196 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 even more imminent 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 from BARDA emphasize the government’s focus on acquiring adequate protection against nuclear and radiation threats for military and civilian populations. Upon FDA approval, our Protectan CBLB502 will 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.

Regulatory Status

Extraordinary radioprotective properties, an excellent toxicity profile, outstanding stability and cost efficient production of Protectan CBLB502 make it a primary candidate for entering formal preclinical and clinical studies. Initially, Protectan CBLB502 will be developed for non-medical purposes — as a radioprotectant antidote for the protection of people from severe 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 (rodents and non-human primates). Based upon this expedited approval process, Protectan CBLB502 could be approved for non-medical applications within 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 and New Drug Applications, or NDAs, and to provide for accelerated review or approval of certain medical products for counterterrorism applications, including granting eligible applications “Fast Track” approval status. The Fast Track designation ordinarily allows a product to be considered for accelerated approval through the use of surrogate endpoints to demonstrate effectiveness. As a result of these provisions, the FDA has broader authority to consider evidence of partial tumor shrinkage or other surrogate endpoints of clinical benefit in deciding on approval. This new policy is intended to facilitate the study of cancer therapies and shorten the total time required for marketing approvals. 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 approval for Protectan CBLB502 for non-medical applications, we have completed Good Manufacturing Practices compliant (cGMP) manufacturing of Protectan CBLB502. The yields from the process and the purity of the final product exceeded our expectations. We were able to develop a complicated, high-yield manufacturing process for CBLB502 was and were able to 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 receiving final FDA approval for Protectan CBLB502 for non-medical applications, we will need to complete several interim steps, including:

- Performing a Phase I dose-escalation human study on a small number of volunteers. We expect to complete this study in March 2009 at an approximate cost of $1,500,000.

- Conducting pivotal animal efficacy studies with the cGMP manufactured drug candidate. We expect to complete these studies in mid 2010. At the present time, the costs of these studies cannot be approximated with any level of certainty.

- Performing a 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 late 2010 at an approximate cost of $5,300,000 based on 500 subjects tested in four locations.

- Filing a BLA which we expect to complete in late 2010. 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.

The DoD also awarded a $1 million grant to our founding partner, the Cleveland Clinic, 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.

Medical Applications

While our current focus remains on its military and other 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.

Specifically, 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 paradigm shift 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 in mid-2009. The 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 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.

Moreover, studies funded by a grant from the DoD and conducted at the Cleveland Clinic, 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 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 approval 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 cannot estimate with any certainty when the FDA may allow the application. We expect to submit the amendment upon the receipt of dedicated federal funding. We estimate that the approximate cost of filing will be less than $100,000.

- Performing a Phase I/II human efficacy study on a small number of 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.

- 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 the scope of these steps cannot be approximated with any level of certainty.

We spent approximately $756,227 and $815,399 on R&D for the medical applications of Protectan CBLB502 in the fiscal years ended December 31, 2008 and December 31, 2007, respectively. From our inception to December 31, 2008, we spent approximately $1,776,929 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®, Amgen, Inc., Thousand Oaks, California), 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) (a recently FDA approved stem cell mobilizer from Genzyme Corporation (Cambridge, Massachusetts)), 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, 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 (SCID), 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 Department of Defense.

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 GMP-manufactured CBLB612.
- Submitting an IND application and receiving approval from the FDA;
- Performing a Phase I dose-escalation human study;
- Performing a Phase II and Phase III human efficacy study 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.

At this time, none of the above costs are reasonably estimitable.

We spent approximately $974,459 and $1,127,248 on R&D for Protectan CBLB612 in the fiscal years ended December 31, 2008 and December 31, 2007, respectively. From our inception to December 31, 2008, we spent

approximately $3,130,374 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 destroy tumor cells by simultaneously targeting two regulators of apoptosis. Our initial test results indicate that curaxins can be effective against a number of malignancies, including renal cell carcinoma, or 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 a recently achieved 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 new 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.

We spent approximately $3,233,872 and $4,708,773 on R&D for curaxins overall in the fiscal years ended December 31, 2008 and December 31, 2007, respectively. From our inception to December 31, 2008, we spent approximately $11,641,592 on R&D for curaxins.

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. It has favorable pharmacological and toxicological profiles and demonstrates the anticancer effect in transplants of human cancer cells into primates.

We have applied for a patent covering the use of Curaxin CBLC102 as an anticancer agent.

We have an agreement with Regis Technologies, Inc., a GMP manufacturer, to produce sufficient quantities of Curaxin CBLC102 according to the process previously used for the production of this drug when it was in common use.

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 a 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 Roswell Park Cancer Institute.

We anticipate that additional clinical efficacy studies will be required before we are able to apply for FDA approval. 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 $1,741,194 and $2,712,521 on R&D for Curaxin CBLC102 in the fiscal years ended December 31, 2008 and December 31, 2007, respectively. From our inception to December 31, 2008, we spent approximately $6,466,483 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. CBLC137 is currently undergoing manufacturing and preclinical toxicology studies in preparation for clinic trials in 2010.

We spent approximately $1,492,678 and $1,996,252 on R&D for other curaxins in the fiscal years ended December 31, 2008 and December 31, 2007, respectively. From our inception to December 31, 2008, we spent approximately $5,175,110 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
Complete Phase I studies for Protectan CBLB502	$	100,000
File NDA 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.

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 the Armed Forces Radiobiology Research Institute, or 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 Armed Forces Radiobiology Research Institute 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 Roswell Park Cancer Institute, or 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 will provide us with up to $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. As is December 31, 2008 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, 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 have filed, on the Cleveland Clinic's behalf, thirteen patent applications covering new classes of anticancer and radiation-protecting compounds, their utility and mode of action.

Our intellectual property platform is based primarily on these thirteen patent applications exclusively licensed to us by the Cleveland Clinic and five patent applications, which we have filed and own exclusively.

The aforementioned thirteen patent applications licensed from the Cleveland Clinic are as follows:

- Methods of Inhibiting Apoptosis Using Latent TFGß;
- Methods of Identifying Modulators of Apoptosis From Parasites and Uses Thereof;
- Methods of Inhibiting Apoptosis Using Inducers of NF-kB;
- Methods of Protecting Against Radiation Using Inducers of NF-kB;
- Methods of Protecting Against Radiation Using Flagellin;
- Small Molecules Inhibitors of MRP1 and Other Multidrug Transporters;
- Flagellin Related Polypeptides and Uses Thereof;
- Modulation of Apoptosis Using Aminoacridines;
- Modulation of Immune Responses;
- Methods of Protecting Against Apoptosis Using Lipopeptides;
- Modulation of Cell Growth;
- Mitochondrial Cytochrome B; and
- Methods of Reducing the Effects of Reperfusion.

The aforementioned five patent applications, which we filed, are as follows:

- Modulation of Androgen Receptor for Treatment of Prostate Cancer;
- Method of Increasing Hematopoietic Stem Cells;
- Method for Reducing the Effects of Chemotherapy Using Flagellin Related Polypeptides;
- Modulation of Heat Shock Response; and
- Carbozole Compounds and Therapeutic Uses of the Compounds.

In 2008, four patent applications were introduced and filed for approval with the U.S. Patent Office. One of the patent applications is licensed from the Cleveland Clinic and three are licensed to us.

We review our patent applications on a continuing basis. In 2008, two patent applications were abandoned. The first was an application licensed from the Cleveland Clinic titled ‘Activation of p53 and Inhibition of NF-kB for Cancer Treatment’. This patent application was abandoned due to developing another Curaxin for the same application. The second patent application was licensed to us and titled ‘Quinacrine Isomers”. The patent application was abandoned

due to the discovery of improved technology.

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. or SynCo, a leading biopharmaceutical manufacturer, to produce Protectan CBLB502 under cGMP specifications, and have completed an agreement to produce sufficient amounts for clinical trials and a commercial launch. As discussed above, the yields from the established manufacturing process at SynCo have been very high and the current process is expected to handle up to several million estimated human doses per year without need for any additional scale up.. For CBLC102, we have contracted with Regis Technologies, Inc. to manufacture sufficient amounts for clinical trials.

Reliance on third party manufacturing presents several risks, however, including the following:

- Delays in the delivery of quantities needed for multiple clinical trials or failure to manufacture such quantities to our specifications, either of which could cause delays in clinical trials, regulatory submissions or commercialization of our drug candidates;

- Inability to fulfill our needs in the event market demand for our drug candidates suddenly increases, which may require us to seek new manufacturing arrangements, which, in turn, could be expensive and time consuming; and

    - Ongoing inspections by the FDA or other regulators and other regulatory authorities for compliance with rules, regulations and standards, the failure to comply with which may subject us to, among other things, product seizures, recalls, fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecution.

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 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 two animal 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)

Upon successful completion of Phase III clinical trials, the drug sponsor files an NDA with the FDA for approval, containing all information that has been gathered. The NDA 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. 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.

We also are subject to the following risks and obligations relating to government regulation, among others:

- The FDA or foreign regulators may interpret data from pre-clinical testing and clinical trials differently than we interpret them;

- If regulatory approval of a product is granted, the approval may be limited to specific indications or limited with respect to its distribution. In addition, many foreign countries control pricing and coverage under their respective national social security systems;

- The FDA or foreign regulators may not approve our manufacturing processes or manufacturing facilities;

- The FDA or foreign regulators may change their approval policies or adopt new regulations;

- Even if regulatory approval for any product is obtained, the marketing license will be subject to continual review, and newly discovered or developed safety or effectiveness data may result in suspension or revocation of the marketing license;

- If regulatory approval of the product candidate is granted, the marketing of that product would be subject to adverse event reporting requirements and a general prohibition against promoting products for unapproved or “off-label” uses;

- In some foreign countries, we may be subject to official release requirements that require each batch of the product we produce to be officially released by regulatory authorities prior to its distribution by us; and

- We will be subject to continual regulatory review and periodic inspection and approval of manufacturing modifications, including compliance with current GMP regulations.

EMPLOYEES

As of March 16, 2009, we had 33 employees, 31 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.

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., Onconova Therapeutics, Inc 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 level of development advancement is the critical factor in the marketing of an effective medical radiation countermeasure 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.

Anticancer Applications

The arsenal of medical radiation-protectors is limited to ETHYOL™ (amifostine), sold by MedImmune, and recently 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 (Neupogen® and Neulast@, Amgen, Inc., Thousand Oaks, California) 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.

Mozibil (Genzyme Corporation (Cambridge, Massachusetts)is a newly 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., Wayne, New Jersey) 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 FDA 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 90% of our revenues from grant and contract development work in connection with grants from the Department of Defense, NIH, NASA and the Defense Advanced Research Projects Agency, or DARPA.

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 make the product not economical; and
- the proprietary rights of others and their competing products and technologies that may prevent the product from being commercialized.

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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 research and development 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 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.

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.

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 thirteen patent applications from the Cleveland Clinic and have filed five patent applications on our own. There can be no assurance that any of these patent applications 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. Further, we 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 nor are they 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 from the Cleveland Clinic. 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. 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 assure you that such 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 preclude 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 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, 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 assure that we will be able to obtain financing when it is needed. Over the past year, 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 economical; 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 Department of Defense, 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.

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, Roswell Park Cancer Institute 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 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.

We are currently authorized to issue 40,000,000 shares of our common stock and 10,000,000 of our preferred stock As of December 31, 2008, we had 13,775,805 shares of our common stock and 3,160,974 shares of our preferred stock issued and outstanding, excluding shares issuable upon the exercise of our outstanding warrants and options. As of March 16, 2009, we had 14,014,137 shares of our common stock and 3,024,144 shares of our preferred stock issued and outstanding and 4,797,396 warrants and 1,938,742 options outstanding. To the extent the shares of common stock are issued or options and warrants are exercised, holders of our common stock will experience dilution. In addition, in the event of any future financing 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 16, 2009, we were not a party to any litigation or other legal proceeding.

Item 4. Submission of Matters to a Vote of Security Holders

Not applicable.

Executive Officers of the Registrant as of March 16, 2009

Name	Age	Position
Michael Fonstein. Ph.D.	49	President and Chief Executive Officer
Andrei Gudkov, Ph.D., D.Sci.	52	Chief Scientific Officer
Yakov Kogan, Ph.D.	35	Chief Operating Officer
John A. Marhofer, Jr., CMA, CFM	46	Chief Financial Officer

The Board of Directors appoints all executive officers annually and such officers serve at the discretion of the Board of Directors. There is no family relationship between or among any of the executive officers or directors.

Michael Fonstein, Ph.D. Dr. Fonstein has served as our Chief Executive Officer, President, and as one of our directors since our inception in June 2003. He served as Director of the DNA Sequencing Center at the University of Chicago from its creation in 1994 to 1998, when he left to found Integrated Genomics, Inc. located in Chicago, Illinois. He served as CEO and President of Integrated Genomics from 1997 to 2003. Dr. Fonstein has won several

business awards, including the Incubator of the Year Award from the Association of University Related Research Parks. He was also the winner of a coveted KPMG Illinois High Tech Award.

Andrei Gudkov, Ph.D., D. Sci. Dr. Gudkov has served as one of our directors and as our Chief Scientific Officer since our inception in June 2003. Prior to 1990, he worked at The National Cancer Research Center in Moscow, where he led a broad research program focused on virology and cancer drug resistance. In 1990, he reestablished his lab at the University of Illinois at Chicago where he became a tenured faculty member in the Department of Molecular Genetics. His lab concentrated on the development of new functional gene discovery methodologies and the identification of new candidate cancer treatment targets. In 1999, he defined p53 as a major determinant of cancer treatment side effects and suggested this protein as a target for therapeutic suppression. In 2001, Dr. Gudkov moved his laboratory to the Lerner Research Institute at the Cleveland Clinic where he became Chairman of the Department of Molecular Biology and Professor of Biochemistry at Case Western Reserve University. In May 2007, Dr. Gudkov became Senior Vice President of Research Programming and Development for Roswell Park Cancer Institute. He continues in his capacity as a consultant with CBLI.

Yakov Kogan, Ph.D. Dr. Kogan has served as one of our directors since our inception in June 2003, as Secretary since March 2006, and as Chief Operating Officer since February 2008. Dr. Kogan also served as our Executive Vice President of Business Development from our inception until February 2008. From 2002 to 2003, as Director for Business Development at Integrated Genomics, he was responsible for commercial sales and expansion of the company's capital base. Prior to his tenure in business development, Dr. Kogan worked as a Group Leader/Senior Scientist at Integrated Genomics and ThermoGen, Inc. and as Research Associate at the University of Chicago. Dr. Kogan holds a Ph.D. degree in Molecular Biology from All-Union Research Institute of Genetics and Selection of Industrial Microorganisms (VNIIGenetika) (Moscow, Russia), as well as an MBA degree from the University of Chicago Graduate School Of Business.

John (Jack) A. Marhofer, Jr., CMA, CFM Mr. Marhofer joined us as Controller and General Manager in February 2005 and was subsequently appointed to be our Chief Financial Officer in August 2005. He was Corporate Controller of Litehouse Products, Inc. from June 2001 to February 2005. Mr. Marhofer earned his Bachelor of Science in Accounting and Marketing from Miami University in Ohio in 1984, and his Masters in Business Administration in Finance from Akron University in Ohio in 1997, where he was named to the National Honor Society of the Financial Management Association.

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.

Common Stockholders

As of December 31, 2008, 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, 2008.

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 2008 and 2007. On March 16, 2009, the last reported sale price of our common stock was $1.40 per share.

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

2007	High	Low
First Quarter	$ 13.99	$ 4.49
Second Quarter	$ 11.98	$ 8.00
Third Quarter	$ 13.89	$ 9.10
Fourth Quarter	$ 13.07	$ 6.64

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)

	2008	2007	2006	2005	2004
Total Operating Revenue	$ 4,706	$ 2,019	$ 1,708	$ 1,139	$ 636
Government contract or grant	4,586	1,729	1,503	1,000	531
Commercial	120	290	205	139	105
Net loss	$ (14,026) (1)	$ (26,997) (1)	$ (7,223) (1)	$ (2,678) (1)	$ (2,523)
Net loss per share, basic and diluted	$ (1.13)	$ (2.34)	$ (0.84)	$ (0.43)	$ (0.55)
Total assets	$ 4,706	$ 17,422	$ 6,417	$ 4,253	$ 382
Long-term debt	-	-	50	303	334
Stockholder's equity (deficit)	538	14,194	5,593	3,557	(374)

We have not paid any dividends on common stock.
All per share amounts reflect the 596-to-1 stock split that was effected in 2004.

(1) Net loss in 2008, 2007, 2006 and 2005 included employee stock-based compensation costs of $1.5 million, $7.8 million, $0.5 million and $0.3 million, net of tax, respectively, due to our adoption of Statement of Financial Accounting Standards No. 123(R),"Share-Based Payment," on a modified prospective basis 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 and the Company's other SEC filings under the heading "Risk Factors." 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.

Overview

We incorporated in Delaware and commenced business operations in June 2003. We secured a $6,000,000 investment via a private placement of Series A Preferred Stock in March 2005. On July 20, 2006, we sold 1,700,000 shares of common stock in our initial public offering at $6.00 per share. The net proceeds from this offering were approximately $8,300,000. Beginning July 21, 2006, our common stock was listed on the NASDAQ Capital Market and on the Boston Stock Exchange under the symbols "CBLI" and "CFB" respectively. On August 28, 2007, trading of our stock moved from the NASDAQ Capital Market to the NASDAQ Global Market. In September 2007, we ceased our listing on the Boston Stock Exchange. On November 28, 2008, trading of our common stock transferred from the NASDAQ Global Market to the NASDAQ Capital Market.

On September 21, 2006, the SEC declared effective a registration statement of the Company registering up to 4,453,601 shares of common stock for resale from time to time by the selling stockholders named in the prospectus contained in the registration statement. We will not receive any proceeds from the sale of the underlying shares of common stock, although to the extent the selling stockholders exercise warrants for the underlying shares of common stock, we will receive the exercise price of those warrants. The registration statement was filed to satisfy registration rights that we had previously granted in connection with our Series A Preferred transaction.

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 aggregate purchase price paid by the investors for the Series B Preferred and Series B Warrants was approximately $30,000,000. After related fees and expenses, we received net proceeds of approximately $29,000,000. We intend to use the proceeds for general corporate and working capital purposes.

The Series B Preferred have an initial conversion price of $7.00 per share, and in the event of a conversion at such conversion price, one share of Series B Preferred would convert into one share of common stock. Based on the closing price of our stock on March 16, 2007 of $10.19, the Series B Preferred sold to investors and issued to certain of the Agents had a market value of $46,660,112. The Series B Warrants have an exercise price of $10.36 per share, the closing bid price on the day prior to the private placement. To the extent, however, that the conversion price of the Series B Preferred or the exercise price of the Series B Warrants is reduced as a result of certain anti-dilution protections, the number of shares of common stock into which the Series B Preferred are convertible and for which the Series B Warrants are exercisable may increase.

We also issued to the placement agents in the private placement, as compensation for their services, Series B Preferred, Series B Warrants, and Series C Warrants. The agents collectively received Series B Preferred that are convertible into an aggregate of 290,298 shares of common stock, Series B Warrants that are exercisable for an aggregate of 221,172 shares of our common stock, and Series C Warrants that are exercisable for 267,074 shares of

our common stock. The Series C Warrants have an exercise price of $11.00 per share, and are also subject to antidilution protections that could increase the number of shares of common stock for which they are exercisable.

In total, the securities issued in the private placement were convertible into, or exercisable for, up to approximately 7,211,612 shares of common stock (subject to adjustments for stock splits, anti-dilution, etc.). As of March 16, 2009 the securities issued in the transaction, in the aggregate, were convertible into or exercisable for approximately 6,249,469 shares of common stock that remain outstanding (subject to adjustments for stock splits, anti-dilution, etc.).

Proceeds from these transactions, together with grants we have received, have supported our R&D activities through December 31, 2008. We are actively seeking new grants and co-development contacts with premier pharmaceutical partners to support further development of other promising leads resulting from our R&D program.

On December 11, 2007, the SEC declared effective a registration statement of the Company registering up to 5,514,999 shares of common stock for resale from time to time by the selling stockholders named in the prospectus contained in the registration statement. This number represents 5,514,999 shares of common stock issuable upon the conversion or exercise of the securities issued the Company's March 2007 private placement at the current conversion and exercise prices. Of these 5,514,999 shares of common stock, 3,717,515 shares are issuable upon conversion of Series B Preferred and 1,797,484 shares are issuable upon exercise of the Series B Warrants. We will not receive any proceeds from the sale of the underlying shares of common stock, although to the extent the selling stockholders exercise warrants for the underlying shares of common stock, we will receive the exercise price of those warrants. The registration statement was filed to satisfy registration rights that we had previously granted. Subsequent to the effectiveness of the registration statement, 1,418,036 Series B Preferred were converted and $321,293 in dividends earned have been accrued as of December 31, 2008.

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 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 include disclosure of our significant accounting policies. 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 income taxes could be considered critical.

Revenue Recognition

We recognize revenue in accordance with Staff Accounting Bulletin No. 104, "Revenue Recognition", and Statement of Financial Accounting Standards No. 116, or SFAS 116. Our revenue sources consist of government contracts, government grants and a commercial development contract.

Government contract and grant revenue is recognized using two different methods depending on the type of contract or grant. Cost reimbursement contracts and 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, 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 government fixed-cost grants to determine key milestones, expenses incurred, and deliverables to perform a percentage-of-completion analysis to ensure that revenue is appropriately recognized. Critical estimates involved in this process include total costs incurred and anticipated to be incurred during the remaining life of the grant.

We recognize revenue related to the funds received in 2007 from the State of New York under the sponsored research agreement with the Roswell Park Cancer Institute in accordance with SFAS 116. The principles of SFAS 116 result in the recognition of revenue as allowable costs are incurred. We recognize revenue on research laboratory services and the purchase and subsequent use of related equipment. The amount paid as a payment toward future use related to the equipment is recognized as a prepaid asset and will be recognized as revenue as the equipment is amortized over its useful life and the prepaid asset is recognized as expense.

Government contract revenue is recognized as allowable research and development expenses are incurred during the period and according to the terms of the contract. Commercial development revenues are recognized when the service or development is delivered.

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, 2008, $50,000 has been paid to CCF for milestone payments relating to the filing of an IND with the FDA for Curaxin CBLC102, $250,000 has been paid to CCF as a result of commencing Phase II clinical trials for Curaxin CBLC102 and $50,000 has been paid to CCF relating to the filing of an IND with the FDA for Protectan CBLB502. Once a drug receives regulatory approval, we will record any subsequent milestone payments in identifiable intangible assets, less accumulated amortization, and amortize them evenly over the remaining agreement term or the expected drug life cycle, whichever is shorter.

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 general and administrative expenses at that time.

Through December 31, 2007, we had capitalized $459,102 in expenditures associated with the preparation, filing and maintenance of certain of our patents. For the year ending December 31, 2008, we capitalized an additional $333,995. In addition, the company abandoned two patent applications and expensed $60,046 to selling, general and administrative expenses. This resulted in a balance of $733,051 in expenditures associated with the filing and maintenance of certain patents as a December 31, 2008 capitalized balance for intellectual property.

Stock-based Compensation

The Financial Accounting Standards Board (FASB) issued SFAS No. 123(R) requiring all share-based payments to employees, including grants of employee stock options, be recognized in the statement of operations based at their fair values. Accordingly, effective January 1, 2005, we value employee stock based compensation under the provisions of SFAS 123(R) and related interpretations.

The fair value of each stock option granted is estimated on the grant date using the Black-Scholes option valuation model or the Monte Carlo Simulation depending on the terms and conditions present within the specific option being valued. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, the Black-Scholes valuations model requires the input of highly subjective assumptions including the expected stock price volatility. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in subjective input assumptions can materially affect the fair value estimate, in management’s opinion, the existing models do not necessarily provide a reliable single measure of the fair value of our options. For those stock options where market conditions are present within the stock options, we utilize Monte Carlo simulation to value the stock options. There was one issuance in the fiscal year ended December 31, 2007, for a total of 90,000 options to an outside consultant where Monte Carlo simulation was used to value the issuance.

On March 1, 2006, we granted 116,750 options pursuant to stock award agreements to certain employees and key consultants. On July 20, 2006, we granted a total of 45,000 fully-vested, stock options to our new independent board members (Messrs. Antal, Kasten, and Perez) pursuant to stock award agreements.

In the fiscal year ended December 31, 2007, we granted 520,000 options pursuant to stock award agreements to certain employees and key consultants. On June 12, 2007 we granted 140,000 fully- vested stock options to the independent board members (Messrs. Antal, DiCorleto, Kasten, and Perez) pursuant to stock award agreements.

In the fiscal year ended December 31, 2008, we granted 857,721 options pursuant to stock award agreements to certain employees and key consultants. On April 29, 2008 we granted 140,000 fully-vested stock options to the independent board members (Messrs. Antal, DiCorleto, Kasten, and Perez) pursuant to stock award agreements. In addition, during the fiscal year ended December 31, 2008, we issued 130,000 restricted shares to certain key employees and key consultants and granted an additional 15,000 restricted shares to a key employee that vest over a three year period.

We recognized a total of $828,377, $3,401,499, and $506,078 in expense for options for the years ended December 31, 2008, 2007 and 2006 respectively. For the year ended December 31, 2008, we recognized a total of $626,500 in expense for shares issued and a total of $72,722 in expense related to the amortization of restricted shares. For the year ended December 31, 2007 and 2006, the Company recognized a total of $1,700,450 and $0, respectively, in expense for shares issued to various consultants.

The weighted average, estimated grant date fair values of stock options granted during the years ended December 31, 2008, 2007 and 2006 were $3.16, $6.08 and $3.14, respectively.

Income Taxes

The Company accounts for income taxes in accordance with Statement of Financial Accounting Standards No. 109 “Accounting for Income Taxes,” which requires an asset and liability approach to financial accounting and reporting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to operating loss and tax credit carryforwards, and temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those operating loss carryforwards and temporary differences are expected to be recovered or settled. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is established, if necessary, to reduce the deferred tax asset to the amount that will, more likely than not, be realized. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes.

Impact of Recently Issued Accounting Pronouncements

In June 2008, the Financial Accounting Standards Board ("FASB") issued EITF Issue No. 07-5 ("EITF 07-5"), Determining whether an Instrument (or Embedded Feature) is indexed to an Entity's Own Stock. EITF No. 07-5 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early application is not permitted. Paragraph 11(a) of SFAS No. 133 - specifies that a contract that would otherwise meet the definition of a derivative but is both (a) indexed to the Company's own stock and (b) classified in stockholders' equity in the statement of financial position would not be considered a derivative financial instrument. EITF 07-5 provides a new two-step model to be applied in determining whether a financial instrument or an embedded feature is indexed to an issuer's own stock and thus able to qualify for the SFAS No. 133 paragraph 11(a) scope exception. The adoption of EITF 07-5 is not anticipated to materially impact our financial statements.

In June 2008, the FASB issued EITF 08-4, "Transition Guidance for Conforming Changes to Issue No. 98-5." The objective of EITF 08-4 is to provide transition guidance for conforming changes made to EITF No. 98-5, "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios," that result from EITF No. 00-27 "Application of Issue No. 98-5 to Certain Convertible Instruments," and SFAS 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This Issue is effective for financial statements issued for fiscal years ending after December 15, 2008. Early application is permitted. We are currently evaluating the impact of adoption of EITF 08-4.

In May 2008, the FASB issued SFAS No. 162, Hierarchy of Generally Accepted Accounting Principles (“SFAS No. 162”). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements. The implementation of this standard did not have an impact on our financial statements.

In April 2008, the FASB issued FASB Staff Position No. FAS 142-3, “Determination of the Useful Life of Intangible Assets” (“FSP FAS 142-3”). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, “Goodwill and Other Intangible Assets”. The FSP is intended to improve the consistency between the useful life of a recognized intangible asset under Statement 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141(R) and other U.S. generally accepted accounting principles. The new standard is effective for financial statements issued for fiscal years and interim periods beginning after December 15, 2008. We are currently evaluating the impact, if any of FSP FAS 142-3 upon adoption on our financial statements.

In March 2008, the FASB issued SFAS No. 161. "Disclosures about Derivative Instruments and Hedging Activities," (SFAS No. 161). SFAS No. 161 amends and expands the disclosure requirements of SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS No. 161 requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of gains and losses on derivative instruments and disclosures about credit-risk-related contingent features in derivative agreements. SFAS No. 161 is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2008. The adoption of SFAS No.161 will not affect our financial condition and results of operations, but may require additional disclosures if we enter into derivative and hedging activities.

In December 2007, the FASB issued Statement No. 160, Noncontrolling Interests in Consolidated Financial Statements — An Amendment of ARB No. 51, or SFAS 160. SFAS 160 establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. Specifically, SFAS 160 requires the recognition of a noncontrolling interest (minority interest) as equity in the consolidated financial statements and separate from the parent's equity. The amount of net income attributable to the noncontrolling interest will be included in consolidated net income on the face of the income statement. In addition, SFAS 160 requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. Such gain or loss will be measured using the fair value of the noncontrolling equity investment on the deconsolidation date. SFAS 160 also includes expanded disclosure requirements regarding the interests of the parent and its noncontrolling interest. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. We do not expect a material impact from the adoption of SFAS 160.

In December 2007, the FASB issued Statement No. 141 (revised 2007), Business Combinations ("SFAS 141(R)"), which replaces SFAS 141. SFAS 141(R) requires an acquiring entity to recognize all the assets acquired and liabilities assumed in a transaction at the acquisition-date fair value with limited exceptions. In addition, SFAS 141(R) will require acquisition costs to be expensed as incurred, acquired contingent liabilities will be recorded at fair value at the acquisition date and subsequently measured at either the higher of such amount or the amount determined under existing guidance for non-acquired contingencies, in-process research and development will be recorded at fair value as an indefinite-lived intangible asset at the acquisition date, restructuring costs associated with a business combination will be generally expensed subsequent to the acquisition date and changes in deferred tax asset valuation allowances and income tax uncertainties after the acquisition date generally will affect income tax expense. SFAS 141(R) also includes a substantial number of new disclosure requirements. SFAS 141(R) is effective prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We anticipate that the prospective application of the provisions of SFAS 141(R) could have a material impact on the fair values assigned to assets and liabilities of any future acquisitions.

In October 2008, the FASB issued FAS 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active (FAS 157-3). FAS 157-3 clarifies the application of FASB Statement No. 157, Fair Value Measurements, in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. The FSP is effective upon issuance, including for prior periods for which financial statements have not been issued. Revisions resulting from a change in the valuation technique or its application should be accounted for as a change in accounting estimate following the guidance in FASB Statement No. 154, Accounting Changes and Error Corrections. However, the disclosure provisions in Statement 154 for a change in accounting estimate are not required for revisions resulting from a change in valuation technique or its application. We believe the impact of this pronouncement on our financial statements to be immaterial.

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard ("SFAS") No. 157, "Fair Value Measurements." SFAS No. 157 provides enhanced guidance for using fair value

to measure assets and liabilities and expands disclosure with respect to fair value measurement. This statement was originally effective for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued Staff Position FSP 157-2 which allows companies to elect a one year deferral of adoption of SFAS No. 157 for non-financial assets and non-financial liabilities that are recognized or disclosed at fair values in the financial statements on a non-recurring basis. The Company has adopted SFAS No. 157 as of January 1, 2008. There has been no material impact to our financial statements due to the adoptions of SFAS No. 157.

Results of Operations

Our operating results for the past three fiscal years have been nominal. The following table sets forth our statement of operations data for the years ended December 31, 2008, 2007 and 2006 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, 2008	Year Ended December 31, 2007	Year Ended December 31, 2006
Revenues	$ 4,705,597	$ 2,018,558	$ 1,708,214
Operating expenses	19,050,965	27,960,590	9,126,315
Other expense (income)	(59,597)	2,058,236	-
Net interest expense (income)	(259,844)	(1,003,766)	(195,457)
Net income (loss)	$ (14,025,927)	$ (26,996,502)	$ (7,222,644)

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.

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

Agency	Program	Amount	Period of Performance	Revenue 2008	Revenue 2007
DoD	DTRA Contract	$ 1,263,836	03/2007-02/2009	$ 613,901	$ 466,322
NIH	Phase II NIH SBIR program	$ 750,000	07/2006-06/2008	$ 77,971	$ 459,621
NASA	Phase I NASA STTR program	$ 100,000	01/2006-01/2007	$ -	$ 33,197
NY State/RPCI	Sponsored Research Agreement	$ 3,000,000	03/2007-02/2012	$ 305,298	$ 329,390
NIH	NCI Contract	$ 750,000	09/2006-08/2008	$ 219,618	$ 440,028
DoD	DOD Contract	$ 8,900,000	05/2008 - 09/2009	$ 2,938,357	$ -
HHS	BARDA Contract	$ 13,300,000	09/2008-09/2011	$ 219,412	$ -
NIH	NIAID Grant	$ 774,183	09/2008-02/2010	$ 211,040	$ -
			Totals	$ 4,585,597	$ 1,728,558

We anticipate our revenue over the next year to be derived mainly from government grants and contracts. We have been awarded 17 government contracts and grants totaling over $30 million in funding for R&D. We plan to submit proposals for additional government contracts and grants over the next two years totaling over $30 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 the Roswell Park Cancer Institute 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 such as direct investment. 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 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 $1,527,598 of non-cash compensation for stock based compensation for the year December 31, 2008 compared to $7,789,305 for the year ended December 31, 2007. 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 $17,523,367 for the year ended December 31, 2008. This represents a decrease in operating expenses of $2,647,918 or 15.1%.

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 is 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 $632,252 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 $12,528,560 for the year ended December 31, 2008; a decrease of $3,064,305 or 19.7%.

The following table summarizes research and development expenses for the years ended December 31, 2008, 2007 and 2006 and since inception:

	Year Ended December 31, 2008	Year Ended December 31, 2007	Year Ended December 31, 2006	Total Since Inception
Research and development	$ 13,160,812	$ 17,429,652	$ 6,989,804	$ 43,256,722
General	$ 931,441	$ 892,456	$ 378,113	$ 5,106,630
Protectan CBLB502 - non-medical applications	$ 7,264,813	$ 9,885,776	$ 3,574,593	$ 21,601,196
Protectan CBLB502 - medical applications	$ 756,227	$ 815,399	$ 144,369	$ 1,776,929
Protectan CBLB612	$ 974,459	$ 1,127,248	$ 466,715	$ 3,130,374
Curaxin CBLC102	$ 1,741,194	$ 2,712,521	$ 1,372,998	$ 6,466,483
Other Curaxins	$ 1,492,678	$ 1,996,252	$ 1,053,016	$ 5,175,110

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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 $895,346 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 $4,994,807 for the year ended December 31, 2008; an increase of $416,386 or 9.1%.

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, 2007 Compared to Year Ended December 31, 2006

Revenue

Revenue increased from $1,708,214 for the year ended December 31, 2006 to $2,018,558 for the year ended December 31, 2007, representing an increase of $310,344 or 18.2%, resulting primarily from an increase in revenue from various grants including the sponsored research agreement with RPCI, the DTRA contract, and the NCI contract. As the term of the BioShield grant ended, the proceeds from the BioShield grant were $0 for the year ended December 31, 2007 as compared to $1,100,293 for the year ended December 31, 2006.

Operating Expenses

Operating expenses increased from $9,126,315 for the year ended December 31, 2006 to $27,960,590 for the year ended December 31, 2007. This represents an increase of $18,834,275 or 206.4%. We recognized a total of $7,789,305 of non-cash compensation for stock based compensation for the year December 31, 2007 compared to $506,078 for the year ended December 31, 2006. If these non-cash stock based compensation expenses were excluded, operating expenses would have increased from $8,620,237 for the year ended December 31, 2006 to $20,171,285 for the year ended December 31, 2007. This represents an increase in operating expenses of $11,551,048 or 134.0%.

This increase resulted primarily from an increase in R&D expenses from $6,989,804 for the year ended December 31, 2006 to $17,429,652 for the year ended December 31, 2007, an increase of $10,439,848 or 149.4%. The higher R&D expenses were incurred as a result of increasing the number of research and development personnel, commencing clinical trials for CBLC102 and completing the cGMP manufacturing of CBLB502. We recognized a total of $250,682 of non-cash compensation for R&D stock based compensation for the year ended December 31, 2006 compared to $1,836,787 for the year ended December 31, 2007. Without the non-cash stock based compensation, the R&D expenses increased from $6,739,122 for the year ended December 31, 2006 to $15,592,865 for the year ended December 31, 2007; an increase of $8,853,743 or 131.4%.

In addition, general and administrative expenses increased from $2,136,511 for the year ended December 31, 2006 to $10,530,938, for the year ended December 31, 2007. This represents an increase of $8,394,427 or 392.9%. These higher general and administrative expenses were incurred as a result of creating and improving the infrastructure of the company and the costs associated with being a publicly traded company. We recognized a total of $255,396 of non-cash stock-based compensation for general and administrative compensation for the year ended December 31, 2006 compared to $5,952,517 for the year ended December 31, 2007. Without the non-cash stock based compensation, the general and administrative expenses increased from $1,881,115 for the year ended December 31, 2006 to $4,578,421 for the year ended December 31, 2007; an increase of $2,697,306 or 143.4%.

Liquidity and Capital Resources

We have incurred annual operating losses since our inception, and, as of December 31, 2008 we had an accumulated deficit of $56,246,173. Our principal sources of liquidity have been cash provided by sales of our securities, and government grants, contracts and 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.

Net cash used in operating activities totaled $12,121,102 for the year ended December 31, 2008, compared to $16,607,922 used in operating activities for the same period in 2007. This decrease in cash used in operating activities resulted from a reduction in our net loss due to increase contract and grant revenues. Net cash used in operating activities totaled $6,653,602 for the same period in 2006.

Net cash used in investing activities was $558,407 for the year ended December 31, 2008 and $442,523 used for the same period in 2007. The increase in cash used for investing activities resulted primarily from an increase in the investment in intellectual property and the reduction in proceeds from the maturity of short term investment as compared to 2007. Net cash used in investing activities was $14,281 for the same period in 2006.

Net cash used in financing activities totaled $1,232,831 for the year ended December 31, 2008, compared to $28,200,591 provided by financing activities 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. Net cash provided by financing activities totaled $8,523,414 for the same period in 2006. The funds provided for the year ended December 31, 2006 were attributable primarily to the net proceeds from our initial public offering in July 2006.

Under our exclusive license agreement with the Cleveland Clinic, we may be responsible for making milestone payments to the Cleveland Clinic in amounts ranging from $50,000 to $4,000,000. The milestones and corresponding payments for Protectan CBLB502 and Curaxin CBLC102 are set forth below:

File IND application for Protectan CBLB502 (completed February 2008)	$	50,000
Complete Phase I studies for Protectan CBLB502	$	100,000
File NDA 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

As of December 31, 2008, we had accrued and paid $50,000 for the milestone payment relating to the filing of the IND application for Curaxin CBLC102, $50,000 for the milestone related to the filing of the IND application for Protectan CBLB502 and $250,000 for the milestone payment relating to starting a Phase II hormone-refractory prostate cancer clinical trial for Curaxin CBLC102.

Our agreement with CCF also provides for payment by us to the 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.

To more effectively match short-term investment maturities with cash flow requirements, we have obtained a working capital line of credit, which is fully secured by our short-term investments. This line of credit has an interest rate of prime, a borrowing limit of $1,000,000 and expires on September 25, 2009. At December 31, 2008, there were no outstanding borrowings under this credit facility.

We believe that existing cash resources will be sufficient to finance our currently planned operations for the near-term (approximately 12-24 months), such 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.

The following factors, among others, could cause actual results to differ from those indicated in the above forward-looking statements: the results of our R&D efforts, the timing and success of preclinical testing, the timing and success of any clinical trials we may commence in the future, the timing of and responses to regulatory submissions, the amount of cash generated by our operations, the amount of competition we face, and how successful we are in obtaining any required licenses and entering into collaboration arrangements.

Subsequent Event

On February 13, 2009, March 20, 2009, and March 27, 2009, the Company entered into Securities Purchase Agreements (the "Purchase Agreement") with various accredited investors (the "Purchasers"), pursuant to which the Company agreed to sell to the Purchasers an aggregate of 542.84 shares (the "Shares") of Series D Convertible Preferred Stock, with a par value of $0.005 per share and a stated value of $10,000 per share ("Series D Preferred"), and Common Stock Purchase Warrants (the "Warrants") to purchase an aggregate of 3,877,386 shares of the Company's Common Stock, par value $0.005 per share ("Common Stock"). The Warrants have a seven-year term and an exercise price of $1.60. Each share of Series D Preferred is convertible into approximately 7,143 shares of Common Stock, subject to the adjustment as described below.

The aggregate purchase price paid by the Purchasers for the Shares and the Warrants was approximately $5,428,307 (representing $10,000 for each Share together with a Warrant). After related fees and expenses, the Company received net proceeds of approximately $4,460,000. The Company intends to use the proceeds for working capital purposes.

In consideration for its services as exclusive placement agent, Garden State Securities, Inc. ("GSS"), received cash compensation and Warrants to purchase an aggregate of approximately 387,736 shares of Common Stock. In the aggregate, Series D Preferred and Warrants issued in the transaction (including those issued to GSS) are convertible into, and exercisable for, approximately 8,142,508 shares of Common Stock. Each share of Series D Preferred is convertible into a number of shares of Common Stock equal to (1) the stated value of the share ($10,000), divided by (2) $1.40, subject to adjustment as discussed below (the "Conversion Price").

The Series D Preferred ranks junior to the Company's Series B Convertible Preferred Stock ("Series B Preferred") and senior to all shares of Common Stock and other capital stock of the Company.

If the Company does not meet certain milestones, the Conversion Price will, unless the closing price of the Common Stock is greater than $3.69 on the date the Milestone is missed, be reduced to 80% of the Conversion Price in effect on that date (the "Milestone Adjustment"). In addition to the Milestone Adjustment, (a) on August 13, 2009 (the "Initial Adjustment Date"), the Conversion Price shall be reduced to 95% of the then Conversion Price, and (b) on each three month anniversary of the Initial Adjustment Date (each, an "Adjustment Date"), the then Conversion Price shall be reduced by $0.05 (subject to adjustment) until maturity. The Conversion Price is also subject to proportional adjustment in the event of any stock split, stock dividend, reclassification or similar event with respect to the Common Stock and to anti-dilution adjustment in the event of any Dilutive Issuance (as defined in the Certificate of Designation).

If the closing price for each of any 20 consecutive trading days after the effective date of the initial registration statement filed pursuant to the Registration Rights Agreement (as defined below) (the "Effective Date") exceeds 300% of the then effective Conversion Price and various other equity conditions are satisfied, the Series D Preferred will automatically convert into shares of Common Stock.

At any time after February 13, 2012, the Company may, if various equity conditions are satisfied, elect either to redeem any outstanding Series D Preferred in cash or to convert any outstanding Series D Preferred into shares of Common Stock at the conversion rate then in effect.

If the Company receives any cash funds after February 13, 2009 from fees, royalties or revenues as a result of the license of any of its intellectual property (such net proceeds the “IP Proceeds”), cash funds from development grants from any government agency for the development of anti-cancer applications of any of the Company’s curaxin compounds or anti-cancer or biodefense applications for the Company’s CBLB502 compound (the “Governmental Grant Proceeds”) or allocates cash proceeds to its Escrow Account (as defined in the Purchase Agreement) (the “Company Allocation”), then the Company must deposit 40% of the IP Proceeds, 20% of the Governmental Grant Proceeds and the Company Allocation into an escrow account (the “Sinking Fund”). At any time after the later of the Effective Date and the 6-month anniversary of the initial contribution by the Company to the Sinking Fund, but no more than once in every six-month period, the Company will be required to use the funds then in the Sinking Fund to redeem outstanding shares of Series D Preferred, from the holders on a pro rata basis, at a premium of 15% to the stated value through February 13, 2010, and 20% thereafter.

Immediately after the completion of the transactions contemplated by the Purchase Agreement, the conversion price of the Company's Series B Preferred was adjusted, pursuant to weighted-average anti-dilution provisions, to $4.67, causing the conversion rate of Series B Preferred into Common Stock to change to approximately 1-to-1.49893. In addition, 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 3,609,261 and 408,032, 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 approximately 281,042 to approximately 379,787.

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, 2008, we are obligated to make payments under these agreements of 916,354 Euros and 39,100 Great British Pounds. 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 in 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% or the Federal Funds Effective Rate in effect plus 0.50%. As of December 31, 2008, we had not drawn on this facility.

Foreign Currency Risk. As of December 31, 2008, 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 and the British Pound. 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 United States 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 consolidated 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, 2008 and 2007, 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, 2008. 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, 2008 and 2007, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America.

MEADEN & MOORE, LTD.
Certified Public Accountants

Cleveland, Ohio
March 27, 2009

CLEVELAND BIOLABS, INC.

BALANCE SHEETS

December 31, 2008 and December 31, 2007

	December 31 2008	December 31 2007
ASSETS		
CURRENT ASSETS		
Cash and equivalents	$ 299,849	$ 14,212,189
Short-term investments	1,000,000	1,000,000
Accounts receivable:		
Trade	1,043,821	163,402
Interest	9,488	50,042
Other prepaid expenses	510,707	325,626
Total current assets	2,863,865	15,751,259
EQUIPMENT		
Computer equipment	309,323	258,089
Lab equipment	1,102,465	966,517
Furniture	312,134	274,903
	1,723,922	1,499,509
Less accumulated depreciation	637,840	313,489
	1,086,082	1,186,020
OTHER ASSETS		
Intellectual property	733,051	459,102
Deposits	23,482	25,445
	756,533	484,547
TOTAL ASSETS	$ 4,706,480	$ 17,421,826

CLEVELAND BIOLABS, INC.

BALANCE SHEETS

December 31, 2008 and December 31, 2007

	December 31 2008	December 31 2007
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,101,961	$ 710,729
Deferred revenue	2,365,312	1,670,610
Dividends payable	321,293	396,469
Accrued expenses	379,653	449,774
Total current liabilities	4,168,219	3,227,582
STOCKHOLDERS' EQUITY		
Series B convertible preferred stock, $.005 par value		
Authorized - 10,000,000 shares at December 31, 2008		
and December 31, 2007		
Issued and outstanding 3,160,974 and 3,870,267		
shares at December 31, 2008 and December 31, 2007, respectively	15,805	19,351
Additional paid-in capital	19,918,696	24,383,695
Common stock, $.005 par value		
Authorized - 40,000,000 shares at December 31, 2008		
and December 31, 2007		
Issued and outstanding 13,775,805 and 12,899,241		
shares at December 31, 2008 and December 31, 2007, respectively	68,879	64,496
Additional paid-in capital	36,781,054	30,764,914
Accumulated deficit	(56,246,173)	(41,038,212)
Total stockholders' equity	538,261	14,194,244
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 4,706,480	$ 17,421,826

CLEVELAND BIOLABS, INC.

STATEMENTS OF OPERATIONS

Years Ended December 31, 2008, 2007, and 2006

	December 31 2008	December 31 2007	December 31 2006
REVENUES			
Contract and Grant	$ 4,585,597	$ 1,728,558	$ 1,503,214
Service	120,000	290,000	205,000
	4,705,597	2,018,558	1,708,214
OPERATING EXPENSES			
Research and development	13,160,812	17,429,652	6,989,804
Selling, general and administrative	5,890,153	10,530,938	2,136,511
Total operating expenses	19,050,965	27,960,590	9,126,315
LOSS FROM OPERATIONS	(14,345,368)	(25,942,032)	(7,418,101)
OTHER INCOME			
Interest income	259,844	1,004,853	206,655
Buffalo relocation reimbursement	220,000	-	-
Sublease revenue	12,475	4,427	-
Gain on disposal of fixed assets	1,394	-	-
Gain on investment	3,292	-	-
Total other income	497,005	1,009,280	206,655
OTHER EXPENSE			
Interest expense	-	1,087	11,198
Corporate relocation	177,564	1,741,609	-
Loss on disposal of fixed assets	-	15,575	-
Loss on investment	-	305,479	-
	177,564	2,063,750	11,198
NET LOSS	(14,025,927)	(26,996,502)	(7,222,644)
DIVIDENDS ON CONVERTIBLE PREFERRED STOCK	(1,182,033)	(1,265,800)	(214,928)
NET LOSS AVAILABLE TO COMMON STOCKHOLDERS	$ (15,207,960)	$ (28,262,302)	$ (7,437,572)
NET LOSS AVAILABLE TO COMMON STOCKHOLDERS PER SHARE OF COMMON STOCK - BASIC AND DILUTED	$ (1.13)	$ (2.34)	$ (0.84)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATING NET LOSS PER SHARE, BASIC AND			

DILUTED	13,492,391	12,090,430	8,906,266

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CLEVELAND BIOLABS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS
Period From January 1, 2006 to December 31, 2008

	Common Stock		Additional Paid-in	Penalty
	Shares	Amount	Capital	Shares
Balance at January 1, 2006	6,396,801	31,984	3,338,020	81,125
Issuance of shares - previously accrued penalty shares	54,060	270	80,855	(81,125)
Issuance of shares - stock dividend	184,183	922	367,445	-
Issuance of penalty shares	15,295	76	(76)	-
Issuance of shares - initial public offering	1,700,000	8,500	10,191,500	-
Fees associated with initital public offering	-	-	(1,890,444)	-
Conversion of preferred stock to common stock	3,351,219	16,756	5,291,385	-
Conversion of notes payable to common stock	124,206	621	312,382	-
Issuance of options	-	-	506,078	-
Exercise of options	625	3	2,810	-
Issuance of warrants	-	-	114,032	-
Proceeds from sales of warrants	-	-	110	-
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, 2006	11,826,389	$ 59,132	$ 18,314,097	$ -
Issuance of options	-	-	3,401,499	-
Options to be issued in 2008	-	-	2,687,355	-
Issuance of shares - Series B financing	-	-	-	-
Fees associated with Series B Preferred offering	-	-	-	-
Issuance of restricted shares	190,000	950	1,699,500	-
Exercise of options	126,046	630	110,650	-
Exercise of warrants	48,063	240	90,275	-
Conversion of Series B Preferred Shares to Common	708,743	3,544	4,461,537	-
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	$ 30,764,914	$ -
Issuance of options	-	-	2,287,803	-
Partial recapture of expense for options expensed in 2007 but issued in 2008	-	-	(1,459,425)	-

Issuance of restricted shares	130,000	650	625,850	-
Restricted stock awards	-	-	72,722	-
Exercise of options	37,271	186	24,191	-
Conversion of Series B Preferred Shares to Common	709,293	3,547	4,464,999	-
Dividends on Series B Preferred shares	-	-	-	-
Net Loss	-	-	-	-