CLEVELAND BIOLABS INC
Form 10-K
March 21, 2008

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, 2007

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 Global 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 $74,961,490. There were 13,158,477 shares of common stock outstanding as of March 1, 2008.

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant's Annual Meeting of Stockholders, to be held on April 29, 2008, is incorporated by reference in Part III to the extent described therein.

CLEVELAND BIOLABS, INC.
FORM 10-K
03/21/08

Cleveland BioLabs, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2007

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. In particular, statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are contained or incorporated by reference in this report. 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. 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," "we," "our" and "us" refers to Cleveland BioLabs, Inc.

PART I

Item 1. Description of Business

GENERAL OVERVIEW

CBLI was 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. CBLI's 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 developed 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 agents.

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.

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.

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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 often severe side effects of anticancer drugs and radiation that cause collateral damage to healthy tissues during cancer treatment. Because the severe side effects of anticancer drugs and radiation often limit their dosage in cancer patients, an apoptosis suppressant drug may enable a more aggressive treatment regimen using anticancer drugs and radiation and thereby increase their effectiveness.

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

Through our research and development, or R&D, and our strategic partnerships, we have established a technological foundation for the development of new pharmaceuticals and their rapid preclinical evaluation. We spent $17,429,652 and $6,989,804 on R&D in the fiscal years ended December 31, 2007 and December 31, 2006, respectively.

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 side effects.

- 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 renal cell carcinoma, or RCC (a highly fatal form of kidney cancer), soft-tissue sarcoma, and hormone-refractory prostate cancer.

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 to 36 months. Another drug candidate, Curaxin CBLC102, entered Phase IIa clinical trials earlier this year.

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 $300 billion industry (based on total market capitalization) and includes large companies such as Amgen, Inc. and Genentech, Inc.

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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. 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 scaled down 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.

While there are a number of biotech and Pharma companies that are attempting to develop new anti-radiation and anti-cancer drugs to treat these medical conditions, these areas are nevertheless considered unmet medical needs, which means that there are currently no existing methods to satisfactorily treat these medical conditions.

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 anticipate having a developed drug available for these non-medical applications within 18-30 months. The FDA approval process is estimated to take an additional six months.

- *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 20th 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).

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 protecting 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 intestine. Potential applications for Protectan CBLB502 include reduction of radiation therapy or chemotherapy side effects 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.

Biodefense 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 are 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. 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. Manufacture of Protectan CBLB502 is relatively inexpensive, due to its high yield bacterial producing strain and simple purification process.

Our research has also demonstrated that a single injection of less than 1% of the maximum tolerable dose of Protectan CBLB502 protected greater than 80% of National Institutes of Health, or NIH, Swiss mice from exposure to as high as 13 Gy of total body irradiation. No other known compounds in development show this degree of protective effect from this level of radiation exposure.

Protectan CBLB502 also showed strong radioprotective efficacy as a single therapy in non-human primates, enabling the survival of 70% of the CBLB502-treated animals that received whole-body radiation versus the non-treated control group, in which 75% of the animals died. Of the non-human primates in the control group that survived, none were without significant abnormalities. In contrast, the surviving non-human primates treated with CBLB502 possessed no significant structural abnormalities in their bone marrow, immune system organs, or small intestines after 40 days. This is consistent with data previously obtained from trials on mice. Irradiated mice treated with CBLB502 survived to their normal life span without developing any significant abnormalities and while preserving the normal formation of blood cells (hematopoiesis). This data suggests that CBLB502 may offer true protection from gamma-irradiation induced ARS, including the lethal effects on both the GI and hematopoietic systems.

A study completed in late 2007 demonstrated the efficacy of Protectan CBLB502 as a mitigator of hematopoietic (bone marrow/blood production) damage up to 48 hours after radiation exposure. This was the first primate study pointing towards CBLB502's high utility in protection of civil populations, where countermeasures would be stockpiled and then distributed.

In the study, five groups of ten rhesus primates received 5 Gy (approximately 20% of lethal dose) of gamma radiation. The control group received a placebo, while the four experimental groups received a single intramuscular injection of Protectan CBLB502 at one of the following times: 1, 16, 24 or 48 hours after irradiation. No mortality was observed in CBLB502-treated groups after 30 days, while 20% mortality was observed in the control group. Thrombocytopenia has been shown to be the best predictor of primate post-irradiation mortality in recent studies.

The duration and occurrence of severe thrombocytopenia (a decrease of platelet*s*, the blood cells that prevent bleeding) was strongly reduced by CBLB502. The average number of severe thrombocytopenia (< 50,000 platelets/ul) days per primate was drastically reduced from 4.3 in the control group to 0.6-1.5 in all four CBLB502-treated groups.

In addition, duration and occurrence of severe neutropenia (a decrease in white blood cells, which serve as the primary defense against infections) was also reduced by CBLB502. For example, an average number of days of extremely severe neutropenia (< 100 neutrophils/ul) per primate was reduced from 2.7 in the control group to 0.3-1.5 in the experimental groups.

We submitted Protectan CBLB502 in response to a Request for Information, or RFI, from the Department of Health and Human Services, or HHS, in July 2007, which noted the agency's intention to pursue an initial acquisition of 100,000 treatment courses of a medical countermeasure for neutropenia arising as a consequence of ARS. The RFI further stated that there would be options for up to an additional 100,000 treatment courses to meet HHS’s requirement of at least 200,000 treatment courses.

We intend to initiate a human safety study in the first half of 2008 for Protectan CBLB502 in ARS, which is the only stage of human testing required for approval in this indication.

Regulatory Status

Extraordinary radioprotective properties, an excellent toxicity profile, outstanding stability and inexpensive 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 to 36 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 because of the excellent work of our in-house team and consultants, and our subcontractor, SynCo Bio Partners B.V, which was able to prototype the process and resolve multiple challenges during the industrial development. We currently have drug substance corresponding to over 100,000 projected human doses, or potentially many more, depending on the final therapeutic dose to be used, which will be determined in the coming months 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.

In order for us to receive final FDA approval for Protectan CBLB502 for non-medical applications, we need to:

- Submit an IND application and receive approval from the FDA;
- Perform a Phase I dose-escalation human study on a small number of volunteers;
- Conduct pivotal animal efficacy studies with the GMP manufactured drug candidate;
- Perform a human safety study in a larger number of volunteers using the dose of CBLB502 previously shown to be safe in humans and efficacious in animals; and
- File a Biologic License Application, or BLA.

In our most optimistic business scenario, all of these steps could be accomplished in 18 months. In a more conservative business scenario, it may take up to 30 months or more to complete the development and file the BLA for the approval of Protectan CBLB502 for non-medical applications.

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 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.

The DoD also recently 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.

Market Opportunities

Protectan CBLB502 is a candidate for procurement by the DoD. In general, the procurement process is conducted on the basis of full and open competition that cannot be limited, unless the DoD determines that the public requesting policy would otherwise seriously jeopardize national security.

Prior to determining the best treatment, the DoD issues a Request for Information, or RFI, for treatments available or in development for a specific condition resulting from an identified threat. The RFI provides an incentive for companies to research and develop countermeasures that are superior to those selected for stockpiling. Through the RFI, companies may compete for future contracts that will revise and update stockpile content for emerging threats and to discover advanced technologies and new countermeasures.

Following its review of the responses it receives, the DoD issues a Request for Proposal, or RFP. The RFP solicits proposals for the manufacturing of specified treatments for a defined number of doses to be delivered within a specified time frame (a maximum of eight years). A contract may be awarded once the review of the RFP responses has been completed, though payments by the government are made only upon product delivery.

If the product or the use indicated in the RFP of an approved product is not approved, licensed, or cleared for commercial distribution at completion of the review, the DoD has the authority to procure the required amount if it has:

- Determined that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years after the date of a determination, and
- Determined that the product is authorized for emergency use.

In February 2007, the DoD, through the U.S. Army Space and Missile Defense Command, issued a RFP for the Advanced Development of Medical Radiation Countermeasures, or MRC. According to the RFP, the objective of the MRC project is to develop a post-exposure MRC through a Phase I clinical trial and, pending successful completion of the Phase I clinical trial, develop the MRC product through approval/licensure with the FDA and procure quantities of the MRC sufficient to achieve Initial Operational Capability, or IOC. The RFP stated that the MRC must have the following characteristics: be safe, efficacious, quick acting, free from performance-decrementing side effects, relatively non-invasive, compatible with current military countermeasures, and usable on the battle field. The MRC also should not require refrigeration, nor have other significant logistical burdens, and should have a relatively long shelf life. The solicitation specifically requested a drug/biologic intended for use after exposure to ionized radiation, or IR, has occurred.

In January 2008, we learned that Protectan CBLB502 was not selected for award under the RFP. We intend to further develop CBLB502 and obtain FDA approval and will respond to future DoD solicitations as they are announced. We plan to continue our discussions with the DoD, HHS, and other friendly governments, who are interested in CBLB502's potential to protect against terrorist threats and nuclear disaster. Our goal is to achieve FDA approval for CBLB502 in 2009 and market it as an effective and affordable radiation protector for defense use on the battlefield or for first responders of civilian emergencies.

Medical Applications

In addition to its military or other non-medical applications, we have found that 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.

Another recent study demonstrated the ability of Protectan CBLB502 to reduce the side effects of a chemotherapeutic drug, Platinol (cisplatin), broadly used for the treatment of ovarian, endometrial, head and neck, lung, stomach and other types of cancer. Platinol treatment was used in the study as an example of chemotherapy-associated toxicity. Platinol injected at toxic doses is known to induce myelosuppression (suppression of bone marrow) and nephrotoxicity (kidney damage). The severity of these injuries in mice can be monitored by the degree of weight loss and, in the case of severe adverse effects, the proportion of fatalities in treated groups.

In the study, Protectan CBLB502 was injected 30 minutes before Platinol was administered at a dose of 1 mcg/mouse (0.04 mg/kg, which is less than 1% of maximal tolerable dose). Platinol was injected either at the maximal tolerable dose or at double maximal tolerable dose. Mice were monitored daily for weight and behavioral abnormalities for 30 days, or until death. Mice losing more than 25% of their weight were sacrificed, per conventional ethical guidelines for animal treatment.

In mice that received the maximal tolerable dose of Platinol, CBLB502-treated animals showed neither weight loss nor behavioral signs of morbidity, both of which were seen in all of the control group mice.

In mice that received twice the maximal tolerable dose of Platinol, the majority of mice in the control group died or were sacrificed due to loss of more than 25% of their weight by day 10, while all of the animals that received Protectan CBLB502 before Platinol survived, never reaching more than 20% weight loss.

Thus in both of these dose groups, a single injection of CBLB502 prior to treatment with Platinol strongly reduced the toxicity of the drug, as indicated by less severe weight loss and lack of behavioral changes in treated mice.

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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 side effects of various treatments, including chemotherapy.

We plan to initiate a Phase I/II study in the second half of 2008 for Protectan CBLB502 in head and neck cancer patients. The endpoint of the study will be the reduction of side effects 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 actually result in better outcomes for patients with cancers of the head and neck.

Protectan CBLB502 has also shown efficacy as a potential adjuvant for radiation therapy in mouse models of sarcoma and 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.

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.

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 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 AMD3100 (a promising clinical-stage 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 this study, a single injection of Protectan CBLB612 was given to mice in combination with the current standard methodology for stem cell donor isolation, which is four daily injections of G-CSF followed by one injection of AMD3100. The addition of Protectan CBLB612 to the protocol yielded eight to ten times higher concentrations of short-term and long-term HSC in peripheral blood compared to the standard protocol. Even a single administration of Protectan CBLB612 in combination with AMD3100 yielded twice as many mobilized HSC compared with that of the standard regimen. Furthermore, Protectan CBLB612 mobilized all major classes of HSC to peripheral blood, suggesting that no HSC classes would be lost in the enrichment process.

A report published by the NIH division of HHS entitled "Regenerative Medicine 2006," notes that hematopoietic stem cells have been used clinically since 1959 and are used increasingly routinely for transplantations, albeit almost exclusively in a non-pure form. Currently, the main indications for bone marrow transplantation are either hematopoietic cancers (leukemias and lymphomas), or the use of high-dose chemotherapy for nonhematopoietic malignancies (cancers in other organs). Other indications include diseases that involve genetic or acquired bone marrow failure, such as aplastic anemia, thalassemia sickle cell anemia, and increasingly, autoimmune diseases. Producing a ready supply of hematopoietic stem cells for an individual, without painful procedures, risk of contamination, or side effects, would be tantamount to enabling the body to repair itself from any damage to its blood-forming system.

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.

Protectan CBLB612 also has been shown to provide protection in a mouse model from lethal hematopoietic-induced ARS when administered between 48 hours prior or up to 24 hours after radiation exposure.

Protectan CBLB612 does not display any significant toxicity at its therapeutic doses in rodents and non-human primates.

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. Its first human trials are projected for 2009. The development of our Protectan CBLB612 has been supported by a grant from the Defense Advanced Research Projects Agency of the Department of Defense.

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.

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. These features make Curaxin CBLC102 our prime IND drug candidate among other curaxins.

We have applied for a patent covering the use of Curaxin CBLC102 as an anticancer agent based on a newly-discovered mechanism of action.

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. On May 26, 2006, we filed our IND application with the FDA to begin clinical trials in patients with androgen-independent, prostate cancer. On June 26, 2006, the FDA advised us that we may initiate clinical Phase II studies after making minor modifications to the protocol for such clinical studies.

A Phase II efficacy clinical trial using Curaxin CBLC102 in patients with advanced hormone-refractory (androgen-independent) prostate cancer started in January 2007 at the University of Chicago, Cleveland Clinic, and Case Western Reserve University Hospitals. We are applying CBLC102 as the monotherapy to patients who have

failed to respond satisfactorily after undergoing established cancer treatments and will use the suppression of tumor growth and prolonged patient survival as major endpoints. Reducing the prostate-specific antigen, or PSA, level is an additional endpoint (elevated PSA levels are indicative of the progression of prostate cancer). We expect to report the results of this trial in mid-2008.

We intend to seek orphan drug status with respect to Curaxin CBLC102. The orphan drug provisions of the Federal Food, Drug, and Cosmetic Act provide incentives to drug and biologic manufacturers to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the U.S. or, for a disease that affects more than 200,000 individuals in the U.S., where the sponsor does not realistically anticipate that its drug will become profitable. We believe that Curaxin CBLC102 may qualify as an orphan drug for purposes of treatment of RCC, soft tissue sarcoma, and multiple myeloma - all diseases that affects fewer than 200,000 individuals in the U.S. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first designated orphan drug approved by the FDA will be granted a seven-year period of marketing exclusivity for that drug. There is no assurance that we will receive orphan drug status for Curaxin CBLC102. Even if we do receive orphan drug status, while the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same compound for the same indication, it would not prevent other types of drugs from being approved for the same indication and therefore may not provide sufficient protection against competitive products.

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. In February 2008, three lead candidates were chosen for preclinical development based on their efficacy, low toxicity profiles, high stability and suitability for human administration.

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. Gudkov and his research team while at the Cleveland Clinic. Pursuant to an Exclusive License 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	$	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 parties are discussing the possibility of entering into an additional project arising from the optimization project. There can be no assurance the parties will agree to proceed with such project on favorable terms, or at all. The library access agreement does not have a specified term or any termination provisions.

We have a strong working relationship with ChemBridge. This relationship has already resulted in the isolation of bioactive small molecules with clinical potential that helped to establish either new therapeutic concepts (p53 inhibitors) or identify molecules for important indications acting through previously unknown mechanisms (novel class of inhibitors of multidrug transporters). Both lines of study have resulted in high visibility publications and are slated for further exploration by us.

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 three 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;

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- 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;
- Activation of p53 and Inhibition of NF-kB for Cancer Treatment;
- Methods of Protecting Against Apoptosis Using Lipopeptides;
- Modulation of Cell Growth; and
- Mitochondrial Cytochrome B.

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

- Quinacrine Isomers;
- Modulation of Androgen Receptor for Treatment of Prostate Cancer; and
- Method of Increasing Hematopoietic Stem Cells.

MANUFACTURING

We do not intend to establish or operate facilities to manufacture our drug candidates, and therefore will be dependent upon third parties to do so. As we develop new products or increase sales of any existing product, we must establish and maintain relationships with manufacturers to produce and package sufficient supplies of our finished pharmaceutical products. We have established a relationship with SynCo Bio Partners B.V., a leading biopharmaceutical manufacturer, to produce Protectan CBLB502 under cGMP specifications, and have completed an agreement to produce sufficient amounts for clinical trials and a commercial launch. For CBLC102, we have contracted with Regis Technologies, Inc. to manufacture sufficient amounts for clinical trials.

Reliance on third party manufacturing presents several risks, 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.

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. 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 to 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. For these reasons, we believe that competition will be driven by the level of development advancement of MRC.

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. Use of G-SCF 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.

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.

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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.

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.

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.

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. Investigational drugs used in clinical studies must be produced in compliance with current GMP rules pursuant to FDA regulations.

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, 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.

The manufacturing and marketing of our proposed products and our R&D activities are and will continue to be subject to regulation by federal, state and local governmental authorities in the U.S. and other countries. In the U.S., pharmaceuticals are subject to rigorous regulation by the FDA, which reviews and approves the marketing of drugs. The Federal Food, Drug and Cosmetic Act, the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing, manufacturing, labeling, storage, record keeping, advertising and promotion of our potential products.

EMPLOYEES

As of March 1, 2008, we had 48 employees, 46 of whom were full-time employees.

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 1, 2008, 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.

PART II

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

From July 21, 2006 (our first day of trading) until August 28, 2007, our common stock was traded on the NASDAQ Capital Market under the symbol "CBLI." Our common stock also traded on the Boston Stock Exchange, first under the symbol "CFB" and then under the symbol "CBLI" until September 2007. On August 28, 2007, trading of our stock moved from the NASDAQ Capital Market to the NASDAQ Global Market.

The following table sets forth the quarterly high and low selling prices for our common stock on the NASDAQ Capital Market or NASDAQ Global Market, as applicable, for the full quarterly periods within the fiscal years ended December 31, 2007 and December 31, 2006.

	Common Stock	
	2007	
	High	Low
4th Quarter	$ 13.07	$ 6.64
3rd Quarter	$ 13.89	$ 9.10
2nd Quarter	$ 11.98	$ 8.00
1st Quarter	$ 13.99	$ 4.49
	2006	
	High	Low
4th Quarter	$ 5.87	$ 4.25
3rd Quarter	$ 5.58	$ 4.17

As of March 1, 2008, there were approximately 44 stockholders of record of our common stock. We have not paid cash dividends on our common stock and do not intend to do so in the foreseeable future.

We made no repurchases of our securities during the year ended December 31, 2007.

Item 6. Selected Financial Data

Not applicable.

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 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. In connection with the initial public offering, we issued warrants to purchase 170,000 shares of common stock to the underwriters and their designees. Those warrants have an exercise price of $8.70 per share. 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 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 1, 2008 the securities issued in the transaction, in the aggregate, were convertible into or exercisable for approximately 6,249,469 shares of common stock (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 to date. 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, 708,743 Series B Preferred were converted and $60,789 in dividends earned were paid as of December 31, 2007.

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 and stock-based compensation expense could be considered critical.

Revenue Recognition

We recognize revenue in accordance with Staff Accounting Bulletin No. 104, "Revenue Recognition." Our revenue sources consist of government grants, government contracts and commercial development contracts.

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

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.

Government contract revenue is recognized periodically upon delivery of an invoice for allowable R&D expenses according to the terms of the contract. Commercial development revenues are recognized when the service or development is delivered.

For the grant from Roswell Park Cancer Institute through the State of New York for collaborative research with the RPCI, we use SFAS 116 to guide the revenue recognition. In accordance with SFAS 116, contributions received are recorded as revenue upon receipt, unless they contain donor-imposed conditions which must be met by the recipient, in which case the contributions are deferred until the conditions are met. Although we currently project the anticipated

use of the funds received, and currently do not expect an event to occur that would result in repayment of the funds, technically we have not earned the funds until the qualifying expenses are incurred. The deferred revenue should be recognized as the approved direct and indirect costs are incurred, inclusive of our general overhead allocation.

R&D 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, 2007, we had made $300,000 in milestone payments. Once a drug receives regulatory approval, we will record any subsequent milestone payments in identifiable intangible assets, less accumulated amortization, and amortize them evenly over the remaining agreement term or the expected drug life cycle, whichever is shorter. We expect our R&D expenses to increase as we continue to develop our drug candidates.

Intellectual Property Related Costs

We capitalize costs associated with the preparation, filing and maintenance of our intellectual property rights. Capitalized intellectual property is reviewed annually for impairment. If a patent application is approved, costs paid by us associated with the preparation, filing and maintenance of the patent will be amortized on a straight line basis over the shorter of 17 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, 2006, we had capitalized $252,978 in expenditures associated with the preparation, filing and maintenance of certain of our patents. For the year ending December 31, 2007, we capitalized an additional $206,124 relating to these costs, totaling $459,102.

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 assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect our experience. We use a risk-free rate based on published rates from the St. Louis Federal Reserve at the time of the option grant; assume a forfeiture rate of zero; assume an expected dividend yield rate of zero based on our intent not to issue a dividend in the foreseeable future; use an expected life based on our best judgment; and compute an expected volatility based on similar high-growth, publicly-traded, biotechnology companies. Compensation expense is recognized using the straight-line amortization method for all stock-based awards.

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.

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 throughout the year for a total of 90,000 options to an outside consultant where Monte Carlo simulation was used to value the issuance.

We recognized a total of $3,401,499, $506,078, and $318,111 in expense for options for the years ended December 31, 2007, 2006, and 2005 respectively.

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

Impact of Recently Issued Accounting Pronouncements

On January 1, 2007, the Financial Accounting Standards Board, or FASB, issued FIN 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109. FIN 48 prescribes a minimum recognition threshold and measurement methodology that a tax position taken or expected to be taken in a tax return is required to meet before being recognized in the financial statements. The minimum recognition threshold is defined in FIN 48 as a tax position that is more likely than not to be sustained upon examination by the applicable taxing authority, including resolution of any related appeals or litigation processes, based on the technical merits of the position. If a tax benefit meets this threshold, it is measured and recognized based on an analysis of the cumulative probability of the tax benefit being ultimately sustained. There was no impact on our financial statements upon adoption of FIN 48.

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 future acquisitions.

In February 2007, the FASB issued Statement No. 159, The Fair Value Option for Financial Assets and Financial Liabilities, Including an amendment of FASB Statement No. 115. The Statement permits entities to choose to measure many financial instruments and certain other items at fair value. The objective of the Statement is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reporting earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The Statement is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. We are currently evaluating the Statement to determine what impact, if any, it will have upon adoption on January 1, 2008.

In September 2006, the FASB issued Statement No. 157, Fair Value Measurements ("SFAS 157). SFAS 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the Statement, fair value measurements would be separately disclosed by level within the fair value hierarchy. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the Statement to determine what impact, if any, it will have on the Company's consolidated financial statements upon adoption on January 1, 2008.

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, 2007, 2006 and 2005, 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, 2007	Year Ended December 31, 2006	Year Ended December 31, 2005
Revenues	$ 2,018,558	$ 1,708,214	$ 1,138,831
Operating expenses	27,960,590	9,126,315	3,626,664
Net interest expense (income)	(1,003,766)	(195,457)	(101,378)
Other expense	2,058,236	-	-
Net income (loss)	$ (26,996,502)	$ (7,222,644)	$ (2,386,455)

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.

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

Agency	Program	Amount	Period of Performance	Revenue 2007	Revenue 2006
NIH	BioShield program	$ 1,500,000	07/2005-01/2007	$ -	$ 1,100,293
NIH	Phase I SBIR program	$ 100,000	08/2005-01/2006	$ -	$ 33,334
NASA	Phase I NASA STTR program	$ 100,000	01/2006-01/2007	$ 33,197	$ 66,393
NIH	Phase II SBIR program	$ 750,000	07/2006-06/2008	$ 459,621	$ 212,713
NIH	NCI Contract	$ 750,000	09/2006-08/2008	$ 440,028	$ 90,481
NY State / RPCI	Sponsored Research Agreement	$ 3,000,000	01/2007-01/2012	$ 329,390	$ -
DTRA	DTRA Contract	$ 1,263,836	03/2007-03/2010	$ 466,322	$ -
				$ 1,728,558	$ 1,503,214

We anticipate our revenue over the next year to be derived mainly from government grants and contracts. In addition, it is common in our industry for companies to enter into licensing agreements with large pharmaceutical companies. To the extent we enter into such licensing arrangements, we will receive additional revenue from licensing fees.

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. 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. We expect these expenses to increase as a result of increased legal and accounting fees anticipated in connection with our compliance with ongoing reporting and accounting requirements of the SEC and also to support the expansion of our business.

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%.

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, 2006 Compared to Year Ended December 31, 2005

Revenue

Revenue increased from $1,138,831 for the year ended December 31, 2005 to $1,708,214 for the year ended December 31, 2006, representing an increase of $569,383 or 50%, resulting primarily from an increase in proceeds from the $1,500,000 BioShield grant. The proceeds from the BioShield grant were $1,100,293 for the year ended December 31, 2006 as compared to $999,556 for all grant proceeds for the year ended December 31, 2005. Also, we realized $205,000 for the year ended December 31, 2006 through a commercial contract with Peprotech Inc. to develop chemical compounds compared to $139,275 for the year ended December 31, 2005.

Operating Expenses

Operating expenses increased from $3,626,664 for the year ended December 31, 2005 to $9,126,315 for the year ended December 31, 2006. This represents an increase of $5,499,651 or 151.6%. This increase resulted primarily from an increase in R&D expenses from $2,640,240 for the year ended December 31, 2005 to $6,989,804 for the year ended December 31, 2006, an increase of $4,349,564 or 164.7%, as we increased the number of research scientists and related projects and started a number of clinical trials. In addition, general and administrative expenses increased from $986,424 for the year ended December 31, 2005 to $2,136,511, for the year ended December 31, 2006. This represents an increase of $1,150,087 or 116.6%. 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.

Liquidity and Capital Resources

We have incurred annual operating losses since our inception, and, as of December 31, 2007, we had an accumulated deficit of $40,641,743. 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 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 $16,607,922 for the year ended December 31, 2007, compared to $6,653,602 used in operating activities for the same period in 2006. Net cash used in operating activities totaled $1,730,513 for the same period in 2005. For all periods, the increase in cash used was primarily attributable to increased R&D activities and creating and maintaining the infrastructure necessary to support these R&D activities.

Net cash used in investing activities was $442,523 for the year ended December 31, 2007 and $14,281 used for the same period in 2006. The increase in cash used for investing activities resulted primarily from the maturing of short-term investments that converted to cash. Net cash used in investing activities was $2,805,113 for the same period in 2005. The decrease from 2005 to 2006 resulted from maturity of investments in long-term certificates of deposit.

Net cash provided by financing activities totaled $28,200,591 for the year ended December 31, 2007, compared to $8,523,414 provided by financing activities for the same period in 2006. The increase in cash provided by financing activities was attributed to the proceeds from the issuance of Series B Preferred in connection with our private placement offering. Net cash provided by financing activities totaled $5,647,347 for the same period in 2005. The

funds provided for the year ended December 31, 2005 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	$	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, 2007, we had accrued and paid $50,000 for the milestone payment relating to the filing of the IND application for Curaxin CBLC102 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 20, 2008. At December 31, 2007, there were no outstanding borrowings under this credit facility.

Although we believe that existing cash resources will be sufficient to finance our currently planned operations for the near-term (approximately 12 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.

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, 2007, we are obligated to make payments under these agreements of 9,715 Euros and 86,412 Australian dollars. We have established means to purchase forward contracts to hedge against this risk. As of December 31, 2007, we had 9,715 Euros and 86,412 Australian dollars in contracts outstanding.

Off-Balance Sheet Arrangements

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

Item 8. Financial Statements and Supplementary Data

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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, 2007 and 2006, 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, 2007. 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, 2007 and 2006, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31 , 2007 in conformity with accounting principles generally accepted in the United States of America.

MEADEN & MOORE, LTD.
Certified Public Accountants

Cleveland, Ohio
March 13, 2008

CLEVELAND BIOLABS, INC.

BALANCE SHEETS

December 31, 2007 and December 31, 2006

	December 31 2007	December 31 2006
ASSETS		
CURRENT ASSETS		
Cash and equivalents	$ 14,212,189	$ 3,061,993
Short-term investments	1,000,000	1,995,836
Accounts receivable:		
Trade	163,402	159,750
Interest	50,042	42,479
Notes receivable - Orbit Brands	-	50,171
Prepaid expenses	325,626	434,675
Total current assets	15,751,259	5,744,904
EQUIPMENT		
Computer equipment	258,089	132,572
Lab equipment	966,517	347,944
Furniture	274,903	65,087
	1,499,509	545,603
Less accumulated depreciation	313,489	142,011
	1,186,020	403,592
OTHER ASSETS		
Intellectual property	459,102	252,978
Deposits	25,445	15,055
	484,547	268,033
TOTAL ASSETS	$ 17,421,826	$ 6,416,529

CLEVELAND BIOLABS, INC.

BALANCE SHEETS

December 31, 2007 and December 31, 2006

	December 31 2007	December 31 2006
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 710,729	$ 644,806
Deferred revenue	1,670,610	-
Dividends payable	396,469	-
Accrued expenses	449,774	128,569
Total current liabilities	3,227,582	773,375
LONG-TERM LIABILITIES		
Milestone payable (long-term)	-	50,000
STOCKHOLDERS' EQUITY		
Series B convertible preferred stock, $.005 par value		
Authorized - 10,000,000 shares at December 31, 2007 and December 31, 2006		
Issued and outstanding 3,870,267 and 0 shares at December 31, 2007 and December 31, 2006, respectively	19,351	-
Additional paid-in capital	24,383,695	-
Common stock, $.005 par value		
Authorized - 40,000,000 shares at December 31, 2007 and December 31, 2006		
Issued and outstanding 12,899,241 and 11,826,389 shares at December 31, 2007 and December 31, 2006, respectively	64,496	59,132
Additional paid-in capital	30,764,914	18,314,097
Accumulated other comprehensive income (loss)	-	(4,165)
Accumulated deficit	(41,038,212)	(12,775,910)
Total stockholders' equity	14,194,244	5,593,154
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 17,421,826	$ 6,416,529

CLEVELAND BIOLABS, INC.

STATEMENT OF OPERATIONS

Years Ended December 31, 2007, 2006, and 2005

	December 31 2007	December 31 2006	December 31 2005
REVENUES			
Grant	$ 1,728,558	$ 1,503,214	$ 999,556
Service	290,000	205,000	139,275
	2,018,558	1,708,214	1,138,831
OPERATING EXPENSES			
Research and development	17,429,652	6,989,804	2,640,240
Selling, general and administrative	10,530,938	2,136,511	986,424
Total operating expenses	27,960,590	9,126,315	3,626,664
LOSS FROM OPERATIONS	(25,942,032)	(7,418,101)	(2,487,833)
OTHER INCOME			
Interest income	1,004,853	206,655	119,371
Sublease revenue	4,427	-	-
OTHER EXPENSE			
Interest expense	1,087	11,198	17,993
Corporate relocation	1,741,609	-	-
Loss on disposal of fixed assets	15,575	-	-
Loss on investment	305,479	-	-
NET LOSS	(26,996,502)	(7,222,644)	(2,386,455)
DIVIDENDS ON CONVERTIBLE PREFERRED STOCK	(1,265,800)	(214,928)	(291,914)
NET LOSS AVAILABLE TO COMMON STOCKHOLDERS	$ (28,262,302)	$ (7,437,572)	$ (2,678,369)
NET LOSS AVAILABLE TO COMMON STOCKHOLDERS PER SHARE OF COMMON STOCK - BASIC AND DILUTED	$ (2.34)	$ (0.84)	$ (0.43)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATING NET LOSS PER SHARE, BASIC AND DILUTED	12,090,430	8,906,266	6,250,447

CLEVELAND BIOLABS, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2005 to December 31, 2007

	Stockholders' Equity			
	Common Stock			
	Shares	Amount	Additional Paid-in Capital	Penalty Shares
Balance at January 1, 2005	5,960,000	29,800	2,255,954	-
Issuance of shares - Series A financing	308,000	1,540	588,122	-
Issuance of shares - stock dividend	69,201	346	138,056	-
Issuance of options (383,840 options issued, 324,240 outstanding)	-	-	318,111	-
Exercise of options (59,600 options exercised)	59,600	298	118,902	-
Accrue unissued shares	-			