

# CLEVELAND BIOLABS, INC.

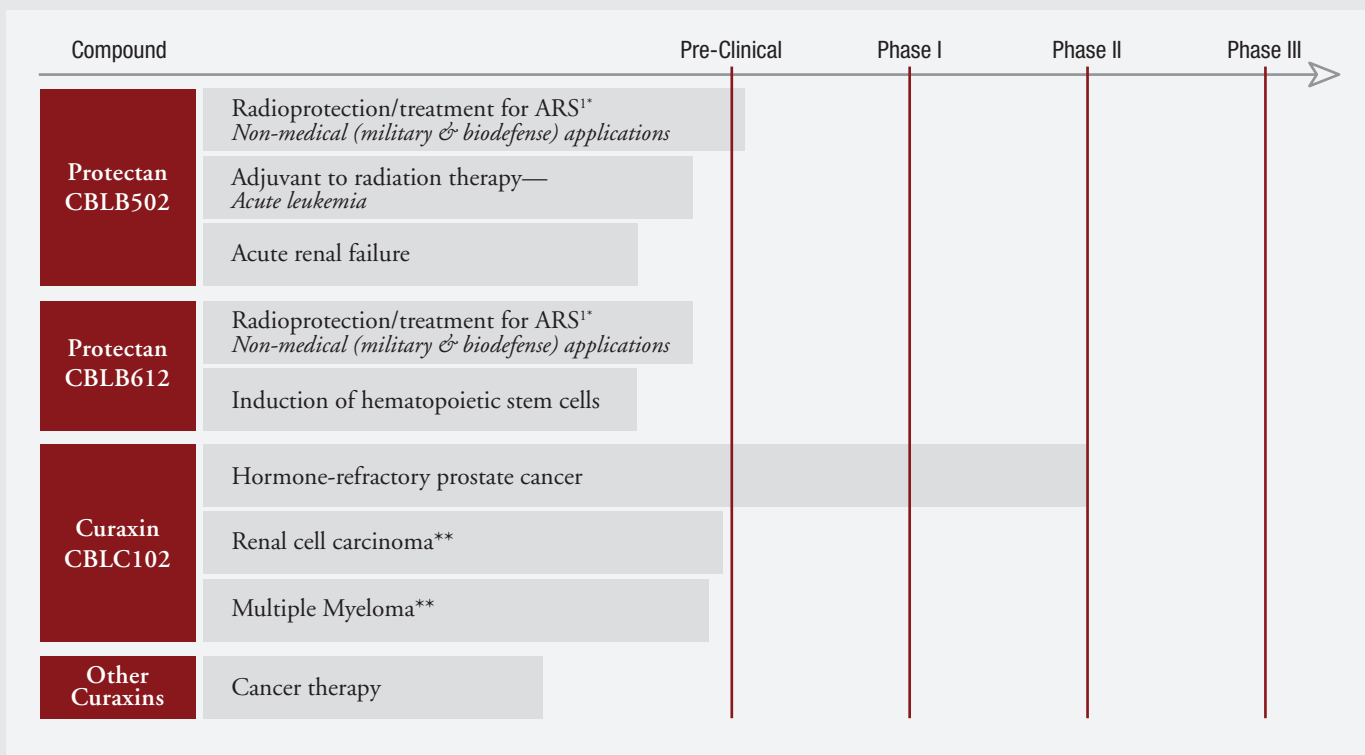
Controlling cell death to protect human life.

| Biodefense |

| Cancer Treatment |

| Tissue Protection |

Cleveland BioLabs, Inc. commenced business operations in June 2003 with a very specific and targeted focus on radiation drug discovery. We have devoted a significant portion of our resources to the identification, development and commercialization of new types of drugs for protection of normal tissues from exposure to radiation and other stresses, such as toxic chemicals and cancer treatments. Our initial target, and most promising near-term opportunity, is to develop a drug to protect humans from the effects of exposure to radiation, whether as a result of military or terrorist acts or as a result of a nuclear accident. Recent acts of terrorism and the proliferation of nuclear weapons programs in rogue states have created a more immediate demand for further research and development, or R&D, in this area. Other potential applications of our drug candidates include destroying tumor cells, reducing the side effects of cancer treatment, generating adult stem cells and protecting against acute organ failure. We have strategic partnerships with the Cleveland Clinic Foundation, Roswell Park Cancer Institute, ChemBridge Corporation and the Armed Forces Research Radiobiology Institute.



<sup>1</sup> ARS is **A**cute **R**adiation **S**yndrome—results from exposure to high levels of radiation that might occur upon a nuclear accident or terrorist detonation.

\* FDA “two-animal rule” applies. Efficacy demonstrated in two animal species and only safety demonstrated in humans. This eliminates the requirement for Phase II and Phase III human clinical trials.

\*\* Phase I study not required due to prior clinical history of compound.

*Dear Stockholders,*

The past year has been an exciting one for Cleveland BioLabs. We became a publicly listed company on Nasdaq in July 2006, and have proceeded to build shareholder value through the achievement of development milestones and new discoveries around our pipeline of drug candidates. I encourage you to read our first annual report thoroughly in order to understand our technology, product candidates, marketplace and the potential value we are creating for our investors.

Cleveland BioLabs is committed to leveraging our discoveries in the area of programmed cell death to develop drug candidates that protect against radiation and fight cancer. Through our research efforts, we are also exploring several additional applications for our drug candidates, including reducing the side effects of cancer treatment, generating adult stem cells and protecting from acute organ failure.

We are actively pursuing development of our two lead product candidates: Protectan CBLB502, a radiation protector, and Curaxin CBLB102, an oral anticancer compound with a demonstrated safety profile.

#### **Protectan CBLB502**

Protectan CBLB502 has demonstrated survival benefits as a radiation protector in animal models when administered up to two hours prior to exposure or up to eight hours after exposure. CBLB502 is the first compound to provide protection of both the gastrointestinal and hematopoietic (bone marrow/blood production) systems against damage caused by the effects of radiation. The compound does not appear to display toxicity at therapeutic doses.

CBLB502 is being developed initially as a radiation antidote for the military, rescue workers, nuclear plant personnel and eventually for all people who may be subject or vulnerable to nuclear attack or accident. This drug is undergoing an accelerated development program under the FDA two-animal rule, which requires us to show efficacy in two animal species and only safety in humans. We are in the process of completing Good Manufacturing Practices compliant (cGMP) manufacturing of the compound and plan to submit an Investigational New Drug (IND) application for a human safety study later this year.

**Cleveland BioLabs is committed to leveraging our discoveries in the area of programmed cell death to develop drug candidates that protect against radiation and fight cancer.**

In February 2007, the Department of Defense (DoD) published a Request For Proposal (RFP) aimed at the acquisition of up to 500,000 doses of radiation antidote. We believe that the two key features outlined in the RFP, protection of the gastrointestinal tract and overall survival benefits, put our lead compound ahead of any known competition. The RFP award would provide funding for development through FDA

approval, as well as a commitment to purchase, thereafter. We expect the RFP to be awarded later in the year.

Recently we received a contract for over \$1 million from the Defense Threat Reduction Agency (DTRA) of the DoD to fund “development leading to the acquisition” of CBLB502, in collaboration with the Armed Forces Radiobiology Research Institute (AFRRI), which has also received significant independent funding for work on our compound. We view this grant as evidence of CBLB502’s importance to the DoD as a potential radiation countermeasure for military personnel.

In March 2007, another significant opportunity for our radiation protector compounds emerged through the Department of Health and Human Services (HHS). HHS declared that it was terminating existing negotiations for a radiation protector with a competing company under the auspices of a RFP published over a year ago, and instead would issue an entirely new RFP pursuant to the new Pandemic and All-Hazards Preparedness Act. This legislation creates the Biomedical Advanced Research and Development Authority (BARDA) agency that enables the HHS to award contracts that grant development funds prior to FDA approval. BARDA enables the HHS to award contracts that grant development funds prior to FDA approval. We believe that we are well positioned to receive part of these grant contracts.

All of these factors give us a high degree of confidence that we are on track for the formal development of CBLB502 as a powerful, FDA approved, radiation protector within the next 12-24 months, and that this product has a promising future.

Our studies of the mechanism of action of our second radiation protector, Protectan CBLB612, led us to discover its ability to generate hematopoietic stem cells (which are responsible for

maintaining our blood and immune systems) and their mobilization into peripheral blood. Although it is still early in our research, it seems that we may have discovered a convenient source of adult stem cells, which can be used without permanent immuno-suppression. The effect of a single injection of CBLB612, as demonstrated in experiments on mice and non-human primates, exceeded the documented results of an existing drug on the market. If borne out by further research, the potential applications for this technology are staggering. 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. We are not planning to enter the development of stem cell therapies, but rather position ourselves as a provider of an economical source of autologous stem cells.

This discovery and others open a huge array of prospects for our Protectan compounds in supportive care of cancer, stem cell medicine, and prevention of acute organ failure.

#### Curaxin CBLC102

In January 2006, we began a Phase II efficacy study of Curaxin CBLC102 in hormone-refractory prostate cancer. CBLC102 is a safe, oral drug used in the past to treat malaria that demonstrates efficacy *in vitro*, in animal models, and in live tumors removed from human patients. We have successfully progressed into the second phase of the trial at our three trial centers at the University of Chicago, the Cleveland Clinic and University Hospitals Case Medical Center. We expect to report anecdotal data from the hormone-refractory prostate trial in late 2007, and it is our intention to initiate additional Phase II trials for CBLC102 in multiple myeloma and renal cell carcinoma this summer.

We are also pleased to share some successes in our corporate development. We signed a strategic agreement with Roswell Park Cancer Institute, establishing a collaborative effort in the area of anti-cancer research and drug trials. In addition to providing us up to \$5 million of non-dilutive funding for our research, this partnership will allow us to run more productive and less expensive drug trials at this distinguished cancer center. This agreement adds a new dimension to

This discovery opens a huge array of prospects for our Protectan compounds in supportive care of cancer, stem cell medicine, and prevention of acute organ failure.

our research and development capabilities and we consider one of our greatest assets to be the support we receive from both the Cleveland Clinic, one of our founders, and Roswell Park.

We recently raised an additional \$30 million in funding through a private placement with accredited investors. These funds, together with the cash remaining from our IPO and

committed grant funds, form a solid capital base for our planned research and development efforts and should be sufficient to support our activities for the next two years.

In summary, we are in the midst of several exciting developments, all of which have the potential to drive tangible value:

- A successful response to the DOD's RFP and further development of Protectan CBLB502, which we forecast to generate significant revenues in 2008;
- The launch of additional Phase II clinical trials for Curaxin CBLC102;
- The progress of our potential stem cell applications from research to clinical development; and
- The movement of our radiation protection compounds into human studies in new therapeutic areas such as supportive care for cancer and acute organ failure.

We look forward to sharing our progress on all of these fronts with you and appreciate your support.

Sincerely,



Michael Fonstein  
*Chief Executive Officer and President*

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**Form 10-KSB**

(Mark one)

**Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Fiscal Year Ended December 31, 2006

or

**Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

**Commission File Number 001-12465**

**CLEVELAND BIOLABS, INC.**

(Exact name of small business issuer as specified in its charter)

**DELAWARE**

(State or other jurisdiction of incorporation or organization)

**20-0077155**

(I.R.S. Employer Identification No.)

**11000 Cedar Ave., Suite 290  
CLEVELAND, OHIO 44106**

(Address of principal executive offices and zip code)

**(216) 229-2251**

(Issuer's telephone number)

Securities registered under Section 12(b) of the Exchange Act:

**Common Stock, \$0.005 par value per share - Nasdaq Capital Market, Boston Stock Exchange**

Securities registered under Section 12(g) of the Exchange Act:

**None**

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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  NO

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Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

YES  NO

Issuer had revenues for its most recent fiscal year of \$1,708,214.

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$62,164,237.73 based on the closing stock price of \$11.23 for the registrant's Common Stock as reported by the Nasdaq Capital Market on March 14, 2007. For purposes of this calculation, the registrant's directors, executive officers and holders of more than 10% of the registrant's common shares have been assumed to be affiliates.

As of March 14, 2007 there were 11,889,099 shares outstanding of registrant's Common Stock, \$0.005 par value.

DOCUMENTS INCORPORATED BY REFERENCE:

**None**

Transitional Small Business Disclosure Format (Check One): YES  NO

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**Cleveland BioLabs, Inc.**

**Form 10-KSB**

**For the Fiscal Year Ended December 31, 2006**

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## FORWARD-LOOKING STATEMENTS

*This Annual Report on Form 10-KSB 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, "CBL," "we," "our" and "us" refers to Cleveland BioLabs, Inc.*

## PART I

### Item 1. Description of Business

#### GENERAL OVERVIEW

CBL commenced business operations in June 2003 as a development-stage company, with a very specific and targeted focus on radiation drug discovery. We have devoted substantially all of our resources to the identification, development and commercialization of new types of drugs for protection of normal tissues from exposure to radiation and other stresses, such as toxic chemicals and cancer treatments. Our initial target, and most promising opportunity, is to develop a drug to protect humans from the effects of exposure to radiation, whether as a result of military or terrorist acts or as a result of a nuclear accident. Recent acts of terrorism and the proliferation of nuclear weapons programs in rogue states have created a more immediate demand for further research and development, or R&D, in this area. Other potential applications of our drug candidates include reducing the side effects of cancer treatment, destroying tumor cells, and generating adult stem cells.

On July 20, 2006, we sold 1,700,000 shares of common stock in our initial public offering at a per share price of \$6.00. Since the date of our initial public offering, our common stock has been listed on the Nasdaq Capital Market under the symbol "CBLI" and on the Boston Stock Exchange as "CFB."

#### TECHNOLOGY

Our development efforts are based on discoveries made in connection with the investigation of the cell-level process known as apoptosis. Apoptosis is a highly specific and tightly regulated form of cell death that can occur in response to external events such as exposure to radiation, toxic chemicals or internal stresses. Apoptosis is a major determinant of tissue damage caused by a variety of medical conditions including cerebral stroke, heart attack and acute renal failure. Conversely, apoptosis is also an important protective mechanism that allows the body to shed itself of defective cells, which otherwise can cause cancerous growth.



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

If the need is to protect healthy tissues against an external event such as exposure to nuclear 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.

## **PRODUCTS IN DEVELOPMENT**

### **Protectans**

Protectans are modified proteins of microbes that protect cells from apoptosis, and have a broad spectrum of potential applications. These potential applications include 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.

#### *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 acts as a natural activator of NF- $\kappa$ B. Protectan CBLB502 is administered through intramuscular injection.

## **Biodefense Applications**

In collaboration with the Cleveland Clinic, our scientists have demonstrated that injecting Protectan CBLB502 into mice 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 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 animals that received whole-body radiation, versus the 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 Acute Radiation Syndrome, including the lethal effects on both the GI and hematopoietic systems.

### *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 Food and Drug Administration, or 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 marketing approval of an investigational new drug, under the new 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 more 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. We plan to apply for Fast Track approval upon the filing of our IND application for Protectan CBLB502. If Protectan CBLB502 is approved for Fast Track status, we intend to market it outside of the U.S., to the extent permitted by U.S. and foreign government authorities.

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

- Manufacture our drug candidate according to current Good Manufacturing Practices, or cGMP, guidelines;
- Repeat our animal studies with the GMP manufactured drug candidate;
- File an IND and receive a response from the FDA;
- Perform a Phase I Human Study (which does not require GMP-manufactured material and can be done concurrently with the rest of the steps); and
- File a Biologic License Application, or BLA.

In our most optimistic business scenario, all of these steps could be accomplished by mid-to-late 2008. 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. We are currently engaged in the process of completing the cGMP-compliant manufacturing, and we plan to hold the pre-IND meeting with the FDA in April 2007 to finalize our developmental program.

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. The principal provisions of this law are to:

- Facilitate R&D efforts of biomedical countermeasures by the National Institutes of Health, or 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.

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.

#### *Market Opportunities*

Protectan CBLB502 is a candidate for procurement by the U.S. Department of Defense, or 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, 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 timeframe (a maximum of eight years).

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.

The DoD, through the U.S. Army Space and Missile Defense Command, recently 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. A range of 50,000 to 500,000 doses has been specified to achieve IOC. The RFP stated that MRC must be safe, efficacious, quick acting, free from performance-decrementing side effects, relatively non-invasive, approved by the FDA, compatible with current military countermeasures, and usable on the battle field. The MRC should not require refrigeration, nor have other significant logistical burdens, and should have a relatively long shelf life.

The solicitation specifically seeks a drug/biologic intended for use after exposure to ionized radiation, or IR, has occurred. It is anticipated that the countermeasure, when administered following exposure to IR, will prolong survival by treating the GI syndrome of Acute Radiation Syndrome. Specifically, when administered following exposure to IR, the countermeasure should either prevent/reduce the extent of incipient radiation injury or promote repair of manifest radiation injury to allow the preservation/restoration of the anatomic integrity and normal physiologic functioning of the GI tract. Responses to this RFP are due in April 2007, with an anticipated contract award on or around July 20, 2007.

We believe Protectan CBLB502's unique ability to protect against and mitigate the damaging effects of gamma irradiation on the GI system, combined with its safety, stability and method of administration, will make it a very strong candidate for this contract. Moreover, we are actively engaged in the process of completing current cGMP-compliant manufacturing, and we plan to submit an IND application for human safety testing by September 2007.

In summary, we believe that Protectan CBLB502 represents a very promising solution as both a radioprotectant and mitigator of radiation exposure. CBLB502 has shown very encouraging results in non-human primates and rodents for being effective as a radioprotectant when administered as little as 15 minutes prior to exposure, and as a mitigator, if administered up to eight hours after exposure. In addition, CBLB502 is stable in solution and powder form, so it can be quickly dissolved and injected using self-injectable devices, which are the preferred delivery system. Moreover, the compound does not display toxicity at therapeutic doses.

The initial development of Protectan CBLB502 was supported by grants from the Department of Health and Human Services through the Project BioShield Act of 2004 and NASA.

## **Anticancer Applications**

In addition to its military or other non-medical applications, we have found that Protectan CBLB502, on a preliminary research basis, 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.

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*

Our Protectans 600 series are modified factors of Mycoplasmas. Much of our initial research in this series has been in the area of radiation protection. Our lead candidate in this series, Protectan CBLB612, has been shown to provide protection in a mouse model from lethal hematopoietic-induced radiation sickness when administered between 48 hours prior or up to eight hours after radiation exposure. Protectan CBLB612 does not display any significant toxicity at its therapeutic doses in rodents and non-human primates.

Moreover, through our research in the area of radiation protection, we have discovered a unique property of the Protectans 600 series, which has led to a breakthrough in the stem cell arena.

A single administration of 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. Our research indicates that CBLB612 and the other compounds in the 600 series are not only potent stimulators of bone marrow stem cells, but also cause their mobilization and proliferation throughout the blood. 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.

Although it is still very early in our research efforts, we believe that we may have discovered a novel method of producing adult stem cells, which can be used without permanent immuno-suppression. The potential applications for this technology are numerous.

A report published by the NIH division of the Department of Health and Human Services entitled "Regenerative Medicine 2006," notes that hematopoietic stem cells have been used clinically since 1959 and are used routinely for transplantations, albeit almost exclusively in a non-pure form. More than 40,000 transplants were performed annually worldwide by 1995. 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.

The development of our Protectans 600 series 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 hormone refractory prostate cancer, renal cell carcinoma, or RCC, (a highly fatal form of kidney cancer), and soft-tissue sarcoma.

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. The drug candidate is currently in Phase II clinical trials for treatment of hormone refractory prostate cancer. We also intend to conduct additional Phase II clinical trials with Curaxin CBLC102 for RCC and multiple myeloma.

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. We believe that Curaxin CBLC102 may qualify as an orphan drug for purposes of treatment of hormone refractory prostate cancer, RCC, and multiple myeloma. 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.



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 additional minor modifications to the protocol.

Clinical trials with Curaxin CBLC102 began in January 2007 at the University of Chicago, Cleveland Clinic and the Case Western Reserve University Hospital in advanced hormone-refractory (androgen-independent) prostate cancer. We apply our therapy 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. An additional endpoint, prostate-specific antigen, or PSA, level reduction, will be used in the prostate trials. Elevated PSA levels are indicative of the progression of prostate cancer.

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

#### *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. These molecules have a chemical structure different from 9-aminoacridine (Curaxin CBLC102) and are more active and appear to be more selective of tumor cells than the representatives of the first generation of curaxins (e.g., Curaxin CBLC102).

Following additional optimization, we are planning to embark upon the formal development of two to three additional second generation curaxins.

### **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. 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, CBLB100 and CBLB500 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, (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.

## **Roswell Park Cancer Institute**

In January 2007, we entered into a strategic research partnership with Roswell Park Cancer Institute (RPCI) to develop our cancer 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 will establish a major research/clinical facility at the RPCI campus in Buffalo, New York, which will become the foundation for several of our advanced research and clinical trials. Andrei Gudkov, our Chief Scientific Officer, has agreed to become Senior Vice President of Research Programming and Development for RPCI effective April 2007.

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 manufacturing 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.

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

- Methods of Inhibiting Apoptosis Using Latent TFG $\beta$ ;
- Methods of Identifying Modulators of Apoptosis From Parasites and Uses Thereof;
- Methods of Inhibiting Apoptosis Using Inducers of NF-kB;
- Methods of Protecting Against Radiation Using Inducers of NF-kB;
- Methods of Protecting Against Radiation Using Flagellin;
- Small Molecules Inhibitors of MRP1 and Other Multidrug Transporters;
- Flagellin Related Polypeptides and Uses Thereof;
- Modulation of Apoptosis Using Aminoacridines;
- Modulation of Immune Responses;

- 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 (filed in January 2007)

## **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 signed an agreement to produce sufficient amounts for clinical trials and the commercial market. For CBLC102, we have contracted Regis Technologies, Inc. and Aptuit, LLC 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 commercial 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 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

### Biodefense Applications

In the area of radiation-protective antidotes, the most visible market participant is Hollis-Eden Pharmaceuticals, Inc., a biopharmaceutical company that is working on the development of a new class of investigational drugs known as Immune Regulating Hormones (IRH). Hollis-Eden's major developmental focus is on HE2100 (also known as NEUMUNE™ and 5-Adrostenediol), which is licensed from Virginia Commonwealth University. In 2002, Hollis-Eden entered into a CRADA with the DoD to jointly develop HE2100 as a radioprotectant. The compound is currently in Phase I clinical trials.

### Anticancer Applications

The arsenal of medical radiation-protectors is limited to ETHYOL™ (amifostine), sold by MedImmune. 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 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 (filgrastim, Amgen) 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-CSF 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 (Berlex, Richmond, CA) 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, now commonly used among cancer patients undergoing chemotherapy to maintain hemoglobin in the near normal range, also has some ability to mobilize CD34+ cells.

### **Other Sources of Competition**

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

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and intense competition. This competition comes both from biotech firms and from major pharmaceutical and chemical companies. Many of these companies have substantially greater financial, marketing and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing and marketing of pharmaceutical products). Our drug candidates' competitive position among other biotech and biopharmaceutical companies may be based on, among other things, patent position, product efficacy, safety, reliability, availability, patient convenience/delivery devices and price, as well as the development and marketing of new competitive products.

We also experience competition in the development of our drug candidates from universities and other research institutions and compete with others in acquiring technology from such universities and institutions. In addition, certain of our drug candidates may be subject to competition from products developed using other technologies, some of which have completed numerous clinical trials. As a result, our actual or proposed drug candidates could become obsolete before we recoup any portion of our related R&D and commercialization expenses. However, we believe our competitive position is enhanced by our commitment to research leading to the discovery and development of new products and manufacturing methods.

Some of our competitors are actively engaged in R&D in areas where we also are developing drug candidates. The competitive marketplace for our drug candidates is significantly dependent upon the timing of entry into the market. Early entrants may have important advantages in gaining product acceptance and market share contributing to the product's eventual success and profitability. Accordingly, in some cases, the relative speed with which we can develop products, complete the testing, receive approval from regulatory agencies, 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 regulatory 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 that has 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 trials differ 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 trials normally involve 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.

## DIRECTORS AND EXECUTIVE OFFICERS

Our directors and executive officers and their ages as of March 1, 2007 are as follows:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Bernard L. Kasten (1)(2)(3)	60	Director, Chairman of the Board
James J. Antal (1)(2)(3)	56	Director
Paul DiCorleto (1) (3)	55	Director
Michael Fonstein, Ph.D. (1)	47	Director, President and Chief Executive Officer
Andrei Gudkov, Ph.D. (1)	50	Director, Chief Scientific Officer
Yakov Kogan, Ph.D. (1)	33	Director, Executive Vice President, Business Development
H. Daniel Perez (1)(2)(3)	57	Director
John A. Marhofer, Jr., CMA, CFM	44	Chief Financial Officer

(1) Each of the directors has been appointed to hold office until the next annual meeting of stockholders or until their successor is duly elected or appointed, unless their office is earlier vacated.

(2) Member of the Audit Committee, Nominating and Corporate Governance Committee and Compensation Committee.

(3) Determined to be independent, in accordance with the rules of the Nasdaq Capital Market.

**Bernard L. Kasten, M.D.** Dr. Kasten became a member of our board on July 20, 2006 and was appointed Chairman of the Board on August 30, 2006. From 1995 to 2004, Dr. Kasten served at Quest Diagnostics Incorporated where he was Chief Laboratory Officer and most recently Vice President of Medical Affairs of the MedPlus Inc. Subsidiary. Dr. Kasten served as a director of SIGA Technologies from May 2003 to December, 2006, and as SIGA's Chief Executive Officer from July 2004 through April 2006. Dr. Kasten is also a director of several privately held companies. Dr. Kasten is a graduate of the Ohio State University College of Medicine. His residency was served at the University of Miami, Florida and he was awarded fellowships at the National Institutes of Health Clinical Center and NCI, Bethesda, Maryland. He is a diplomat of the American Board of Pathology with certification in anatomic and clinical pathology with sub-specialty certification in Medical Microbiology.

**James J. Antal** Mr. Antal became a member of our board on July 20, 2006. Mr. Antal served as Chief Financial Officer of Experian from 1996 to 2001 and as Chief Investment Officer of Experian from 2001 to 2002. Experian is a leading global provider of consumer and business credit information, direct marketing information services, and integrated customer relationship management processes. He also served on the Board of Directors of First American Real Estate Solutions; an Experian joint venture with First American Financial Corp. Mr. Antal earned a Bachelor of Science degree in Business Administration with an Accounting major from The Ohio State University in 1973. He became a Certified Public Accountant (Ohio) in 1975. Starting in 2002, Mr. Antal served as an advisor to the board of directors for Plexus Vaccine, Inc., a biotech company, until it was acquired by SIGA Technologies in 2004. In December 2004, he joined the SIGA board of directors, and also currently serves on its audit and corporate governance committees. From May 2004 to August 2005, he was engaged as the Chief Financial Advisor to the Black Mountain Gold Coffee Co. In July 2005, he joined Pathway Data Inc, a privately held company engaged in consumer credit notification and identity theft assistance services, as its part-time Chief Financial Officer.

**Paul E. DiCorleto, Ph.D.** Dr. DiCorleto has served as one of our directors since 2004. He is the Chairman of the Lerner Research Institute of the Cleveland Clinic and Chairman of the Department of Molecular Medicine at the Case School of Medicine. Dr. DiCorleto received his undergraduate training in chemistry at Rensselaer Polytechnic Institute and his doctorate in biochemistry from Cornell University. Dr. DiCorleto's research focuses on the molecular and cellular basis of atherosclerosis. He has been with the Cleveland Clinic since 1981, having served previously as Chairman of the Department of Cell Biology, as an Associate Chief of Staff, and as a member of the Clinic's Board of Governors and Board of Trustees. Dr. DiCorleto is currently serving, as the most recent past president, on the Executive Committee of the North American Vascular Biology Organization, as chair of the Vascular Biology study section of the national American Heart Association, and as a member of the Association of American Medical Colleges' Advisory Panel on Research.

**Michael Fonstein, Ph.D.** Dr. Fonstein has served as our Chief Executive Officer and President since our inception in June 2003. He served as Director of the DNA Sequencing Center at the University of Chicago from its creation in 1994 to 1998, when he left to found Integrated Genomics, Inc. located in Chicago, Illinois. He served as CEO and President of Integrated Genomics from 1997 to 2003. Dr. Fonstein has won several business awards, including the Incubator of the Year Award from the Association of University Related Research Parks. He was also the winner of a coveted KPMG Illinois High Tech Award.

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

**Yakov Kogan, Ph.D.** Dr. Kogan has served as one of our directors and as our Executive Vice President of Business Development since our inception in June 2003 and as Secretary since March 2006. From 2001 to 2004, as Director for Business Development at Integrated Genomics, he was responsible for commercial sales and expansion of the company's capital base. Prior to his tenure in business development, Dr. Kogan worked as a Group Leader/Senior Scientist at Integrated Genomics and ThermoGen, Inc. and as Research Associate at the University of Chicago. Dr. Kogan holds a Ph.D. degree in Molecular Biology from VNI Genetica, as well as an M.S. degree in Biology from Moscow State University.

**H. Daniel Perez, M.D.** Dr. Perez became a member of our board on July 20, 2006. Dr. Perez is currently a Venture Partner at Bay City Capital, LLC, a venture firm located in San Francisco. From 2001 until 2006, Dr. Perez was the President and CEO of Berlex Biosciences. He joined Berlex Biosciences in 1993. Berlex Biosciences combined biotechnology and pharmaceutical discovery and development technologies to deliver innovative treatments for cardiovascular, cancer and immuno-based disorders. He earned his undergraduate degree at Mariano Moreno School, Argentina and graduated from Buenos Aires University Medical School. After completing an internship and residency in internal medicine at Beth Israel Medical Center in New York, Dr. Perez was a Fellow in Rheumatology at New York University-Bellevue Medical Center. He served on the NYU faculty until he was recruited by the University of California at San Francisco (UCSF) Medical School to start the Rosalind Russell Arthritis Center at San Francisco General Hospital under the direction of Dr. Ira Goldstein. Dr. Perez is currently a Professor of Medicine at UCSF.

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

## **EMPLOYEES**

As of December 31, 2006, we had 35 employees.

## **RECENT DEVELOPMENTS**

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, or Series B Preferred, 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, including, without limitation, preparing our response to the RFP recently issued by the DoD described above.

Sunrise Securities Corp., or SSC, Reedland Capital Partners, an Institutional Division of Financial West Group, and Basic Investors, Inc., served as placement agents for the transaction. In consideration for their services, each agent (and or its designees) received compensation as follows: SSC received an aggregate of 290,298 shares of Series B Preferred, Series B Warrants to purchase an aggregate of 145,149 shares of common stock, and Series C Warrants, bearing an exercise price of \$11.00 per share, to purchase 267,074 shares of common stock; Reedland received Series B Warrants to purchase an aggregate of 63,543 shares of common stock and cash compensation (in lieu of shares of Series B Preferred and additional Series B Warrants) of \$444,800; Basic Investors received Series B Warrants to purchase an aggregate of 12,480 shares of Common Stock and cash compensation (in lieu of shares of Series B Preferred and additional Series B Warrants) of \$87,360.

In the aggregate, the Series B Preferred and the Series B Warrants issued in the transaction are convertible for and exercisable into, as of the date hereof, a maximum of approximately 6,944,538 shares of common stock (subject to adjustments for stock splits, anti-dilution, etc.). Nasdaq Marketplace Rule 4350(i)(1)(D)(ii) requires that, for the sale, issuance or potential issuance by us of common stock (or securities convertible into or exercisable for common stock) equal to 20% or more of the common stock outstanding before the issuance, for less than the greater of book or market value of the common stock, we must obtain stockholder approval for the issuance. Accordingly, the conversion of the Series B Preferred and the exercise of the warrants into common stock by their respective holders are each limited by and subject to obtaining stockholder approval. Our Board of Directors has resolved to seek this approval at our 2007 annual stockholders meeting, and to recommend to our stockholders that such approval be given. In connection therewith, we have scheduled our 2007 annual meeting to be held on June 12, 2007 for stockholders of record as of April 17, 2007.

Notwithstanding the conversion rights of the Series B Preferred holders and us, and the exercise rights of the holders of Series B Warrants and us, we may not issue any shares of common stock in conversion of the Series B Preferred or in exercise of any Series B Warrant if the conversion or exercise would either (1) cause the applicable holder to beneficially own a number of shares of common stock that exceeds 9.99% of the number of shares of common stock outstanding after giving effect to the conversion or exercise, or (2) cause us to issue a number of shares of common stock that would exceed the number of shares of common stock that we can issue under the rules and regulations of the exchange on which those shares are traded (which currently, under the rules of the Nasdaq Capital Market, is 20% of our outstanding shares of common stock) until such time as we receive the approval of our stockholders for the issuances in accordance with the rules of the Nasdaq Capital Market described above. The holders of Series C Warrants may exercise at any time after September 16, 2007 until expiration, provided, however, that the holders of the Series C Warrants may not exercise until stockholder approval, as required by the Nasdaq Capital Market, is obtained.

In connection with obtaining stockholder approval of the foregoing issuances, on March 16, 2007 we entered into a Voting Agreement with Michael Fonstein, Andrei Gudkov, Yakov Kogan, the Cleveland Clinic, ChemBridge, Sunrise Equity Partners L.P., or SEP, and SSC, each of whom agreed to vote in favor of authorizing the issuance of the shares of common stock underlying all of the Series B Preferred and the warrants. In the aggregate, these parties to the Voting Agreement hold approximately 59% of our outstanding common stock.

In connection with the Securities Purchase Agreement, we also entered into a Registration Rights Agreement with the Buyers, dated as of March 16, 2007. Under the Registration Rights Agreement, we granted the Buyers certain registration rights with respect to common stock issuable upon conversion of the Series B Preferred or exercise of the warrants. On or prior to June 14, 2007, we are required to prepare and file with the SEC a registration statement on Form S-3, or on another appropriate form, covering the resale of all of the shares of common stock issuable upon conversion of the Series B Preferred and upon exercise of the warrants, subject to any limitations imposed by the SEC.

SEP, one of the investors, together with its affiliates is a holder of more than 10% of our outstanding common stock. In the transactions, SEP purchased 600,000 shares of Series B Preferred and received Series B Warrants to purchase 300,000 shares of common stock. As mentioned above, we also issued 290,298 shares of Series B Preferred, Series B Warrants to purchase an aggregate of 145,149 shares of Common Stock, and Series C Warrants to purchase 267,074 shares of common stock to SSC, an affiliate of SEP, in consideration for its services as lead placement agent. We also engaged SSC as our exclusive management agent regarding all exercises of the warrants, for which we will pay SSC a fee equal to 3.5% of the aggregate exercise price of each warrant, payable in cash if the exercise is in cash or in shares of common stock if the exercise is cashless.

#### **AVAILABLE INFORMATION**

The following information can be found on our website at [www.cbiolabs.com](http://www.cbiolabs.com):

- All SEC filings including our annual report on Form 10-KSB, quarterly reports on Form 10-QSB, current reports on Form 8-K, and all amendments and exhibits to those reports as soon as reasonably practicable after such material is electronically filed with the SEC;
- Our policies related to corporate governance, including our Corporate Governance Guidelines, Code of Ethics for Senior Executives and Code of Conduct for all employees; and
- The charters of the Audit, Compensation, and Nominating and Corporate Governance Committees of our Board of Directors.

#### **Item 2. Description of Property**

Our corporate headquarters is currently located at 11000 Cedar Ave., Suite 290, Cleveland, Ohio 44106, where we have leased approximately 10,000 square feet of laboratory and office space through April 2007. In addition, we have leased approximately 1,300 square feet of office space located at 9450 W. Bryn Mawr Rd., Rosemont, Illinois, 60018 through June 2007.

On January 12, 2007, we entered into a strategic research partnership with RPCI to develop our cancer and radio-protectant drug candidates. As part of the sponsored research agreement, we have agreed to move our corporate headquarters and a majority of our research staff and efforts to 73 High St., Buffalo, New York 14203 on the site of RPCI. We plan to lease a 28,000 square foot building for five years from July 2007, the expected month of our move. Our present lease in Cleveland, Ohio will continue on a month-to-month basis on substantially similar terms.



**Item 3. Legal Proceedings**

As of December 31, 2006, 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 Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities**

Our common stock is traded on the Nasdaq Capital Market under the symbol CBLI and on the Boston Stock Exchange under the symbol CFB.

The following table sets forth the quarterly high and low selling prices for our common stock from July 21, 2006 (our first day of trading) through December 31, 2006.

	Common Stock	
	2006	
	High	Low
4th Quarter	\$ 5.87	\$ 4.25
3rd Quarter (from July 21, 2006)	\$ 6.00	\$ 4.17

On March 23, 2007, the closing price of our common stock as reported by the Nasdaq Capital Market was \$8.59 per share. There were approximately 137 stockholders of record of our common stock as of such date. We have not paid cash dividends on our common stock and do not intend to do so in the foreseeable future.

The SEC declared our Registration Statement on Form SB-2 (File No. 333-131918) relating to our initial public offering effective on July 20, 2006. Our initial public offering was consummated on July 26, 2006. In the initial public offering, we sold 1,700,000 shares of our common stock at an offering price of \$6.00 per share. Our underwriters were Sunrise Securities Corp. and Roth Capital Partners LLC. The sale of our common stock generated gross proceeds to us, after underwriting discounts and expenses, but before other expenses, of \$9,180,000 and net proceeds of approximately \$8,300,000. We have been using the proceeds to further the development of Protectan CBLB502 and Curaxin CBLC102, to continue research and development related to new generations of drugs, and for working capital and general corporate purposes.

On November 16, 2006, 50,000 warrants were issued to an outside consultant in connection with assistance in capital raising activities that led to the March 16, 2007 private placement. These warrants were exercisable upon issuance at an exercise price of \$6.00. The warrants expire on November 16, 2011.

We made no repurchases of our securities during the year ended December 31, 2006.

## **Item 6. Management's Discussion and Analysis**

*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 commenced business operations in June 2003. We secured a \$6,000,000 investment via a private placement of Series A Preferred Stock in March 2005. On July 20, 2006, we sold 1,700,000 shares of common stock in our initial public offering at \$6.00 per share. The net proceeds from this offering were approximately \$8,300,000. Beginning July 21, 2006, our common stock was listed on the Nasdaq Capital Market and on the Boston Stock Exchange under the symbols "CBLI" and "CFB" respectively. In connection with the initial public offering, we issued warrants to purchase 170,000 shares of common stock to the underwriters and their designees. The warrants have an exercise price of \$8.70 per share.

On July 20, 2006, the effective date of our initial public offering, we issued 92,407 shares of common stock as accumulated dividends to the Series A preferred stockholders. On the same date, all of our Series A Preferred shares automatically converted on a one-for-one basis into 3,351,219 shares of common stock, and notes of ours in the principal amount of \$283,500 plus accrued interest of \$29,503 automatically converted into 124,206 shares of common stock. In connection with their appointment to the Board, we issued to each of our three new independent directors options to purchase 15,000 shares of common stock with an exercise price of \$6.00 per share.

On September 21, 2006, the SEC declared effective a registration statement of ours 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, unless exercised pursuant to the cashless exercise provisions. The registration statement was filed to satisfy registration rights that we had previously granted in connection with our Series A Preferred transaction.

### **Recent Developments**

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, including, without limitation, preparing our response to the RFP recently issued by the DoD and described above. In the aggregate, the Series B Preferred and the Series B Warrants issued in the transaction are convertible for and exercisable into, as of the date hereof, a maximum of approximately 6,944,538 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 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.

### **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 a commercial development contract.

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

### ***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, 2006, no milestone payments have been made, although \$50,000 had been accrued for milestone payments relating to the filing of an IND with the FDA for Curaxin CBLC102. 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, 2005, we had capitalized \$76,357 in expenditures associated with the preparation, filing and maintenance of certain of our patents. For the year ending December 31, 2006, we capitalized an additional \$176,621 relating to these costs, totaling \$252,978. For the periods ending December 31, 2004 and December 31, 2003, these costs were expensed as general and administrative costs and were \$49,275 and \$21,690, respectively.

### *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. The Company values 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. The assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect our experience. We use a risk-free rate based on published rates from the St. Louis Federal Reserve at the time of the option grant; assume a forfeiture rate of zero; assume an expected dividend yield rate of zero based on our intent not to issue a dividend in the foreseeable future; use an expected life based on the best judgment of the Company; 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 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 the Company's 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.

We recognized a total of \$506,077, \$318,111, and \$0 in expense for options for the year-ended December 31, 2006, 2005, and 2004 respectively.

The weighted average, estimated fair values of stock options granted during the years ended December 31, 2006 and 2005 were \$3.18 and \$1.65, respectively.

#### **Impact of Recently Issued Accounting Pronouncements**

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Correction - a Replacement of APB Opinion No. 20 and FASB Statement No. 3" ("SFAS 154"). SFAS 154 changes the requirements for the accounting for, and the reporting of, a change in accounting principle. SFAS 154 requires that a voluntary change in accounting principle be applied retroactively with all prior period financial statements presented under the new accounting principle. SFAS 154 is effective for accounting changes and corrections of errors in fiscal years beginning after December 15, 2005. We have determined that the adoption of the requirements required under SFAS 154 will not have a material impact on the financial statements of the company.

On July 15, 2006 the FASB issued FIN48, *Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109*. We do not expect that the adoption of the recognition and measurement requirements required under FIN48 to have a material impact on the financial statements of the company.

In December 2004, SFAS No. 123(R), "Share-Based Payment," which addresses the accounting for employee stock options, was issued. SFAS 123(R) revises the disclosure provisions of SFAS 123 and supersedes APB Opinion No. 25. SFAS 123(R) requires that the cost of all employee stock options, as well as other equity-based compensation arrangements, be reflected in the financial statements based on the estimated fair value of the awards. This statement is effective for all public entities as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. We expect the adoption of SFAS 123R to increase our reported net loss per share.

In December 2004, the FASB issued SFAS 153, Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29 (SFAS 153). The guidance in APB Opinion No. 29, Accounting for Nonmonetary Transactions, is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in APB Opinion No. 29, however, included certain exceptions to that principle. SFAS 153 amends APB Opinion No. 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS 153 is effective for nonmonetary asset exchanges in fiscal periods beginning after June 15, 2005. We do not believe that the adoption of SFAS 153 will have a material impact on our results of operations or financial position.

## 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 year ended December 31, 2006, December 31, 2005, and December 31, 2004, and should be read in conjunction with our financial statements and the related notes appearing elsewhere in this filing

	<u>Year Ended December 31, 2006</u>	<u>Year Ended December 31, 2005</u>	<u>Year Ended December 31, 2004</u>
Revenues	\$ 1,708,214	\$ 1,138,831	\$ 636,341
Operating expenses	9,126,315	3,626,664	3,155,784
Net interest expense (income)	(195,457)	(101,378)	3,699
Net income (loss)	<u>\$ (7,222,644)</u>	<u>\$ (2,386,455)</u>	<u>\$ (2,523,142)</u>

### 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.

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

<b>Agency</b>	<b>Program</b>	<b>Amount</b>	<b>Period of Performance</b>	<b>Revenue 2006</b>	<b>Revenue 2005</b>
<b>NIH</b>	Phase I NIH SBIR program	\$ 100,000	08/2004-04/2005	— \$	49,998
<b>DARPA</b>	DARPA, program BAA04-12	\$ 475,000	11/2004-08/2005	— \$	283,185
<b>NIH</b>	Phase I NIH SBIR program	\$ 100,000	06/2005-01/2006	— \$	100,000
<b>NIH</b>	BioShield program (NIAID)	\$ 1,500,000	07/2005-01/2007	\$ 1,100,293	\$ 399,707
<b>NIH</b>	Phase I NIH SBIR program	\$ 100,000	08/2005-01/2006	\$ 33,334	\$ 66,666
<b>NIH</b>	Phase I NIH SBIR program	\$ 100,000	09/2005-02/2006	— \$	100,000
<b>NASA</b>	Phase I NASA STTR program	\$ 100,000	01/2006-01/2007	\$ 66,393	\$ —
<b>NIH</b>	Phase II NIH SBIR program	\$ 750,000	07/2006-06/2008	\$ 212,713	\$ —
<b>NIH</b>	NCI Contract	\$ 750,000	09/2006-08/2008	\$ 90,481	
Totals				<u>\$ 1,503,214</u>	<u>\$ 999,556</u>

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, which include fees and expenses associated with patent applications. R&D expenses have consisted mainly of supporting our R&D teams, process development, sponsored research at 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 expansion of our business.



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 152%. 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 \$4,346,564 or 165%, 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 117%. 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.

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, 2005 Compared to Year Ended December 31, 2004**

##### ***Revenue***

Revenue increased from \$636,341 for the year ended December 31, 2004 to \$1,138,831 for the year ended December 31, 2005, representing an increase of \$502,490 or 79.0%. This increase is primarily due to the increase from grants and contracts received through various government agencies including DARPA (Army) and NIH during 2005. Grant and contract revenue increased from \$531,341 for the year ended December 31, 2004 to \$999,556 for the year ended December 31, 2005, representing an increase of \$468,216 or 88.1%.

Revenue from other sources for the years ended December 31, 2005 and 2004 was \$139,275 and \$105,000 respectively. Other revenue in 2005 was earned through our commercial agreement with Peprotech, Inc. Other revenue in 2004 was earned from high throughput screening services for the Cleveland Clinic.

##### ***Operating Expenses***

Operating expenses increased from \$3,155,784 for the year ended December 31, 2004 to \$3,626,664 for the year ended December 31, 2005. This represents an increase of \$470,880 or 14.9%. Of the \$3,155,784 in operating expenses for the year ended December 31, 2004, \$2,250,000 represents a non-cash expense regarding the valuation of 2,250 pre-stock split shares issued to the Cleveland Clinic in exchange for use of their licenses and technologies. Excluding this one-time, non-cash transaction, operating expenses increased from \$905,784 for the year ended December 31, 2004 to \$3,626,664 for the year ended December 31, 2005. This represents an increase of \$2,720,880 or 300.4%. This increase resulted primarily from an increase in R&D expenses from \$642,967 for the year ended December 31, 2004 (excluding the \$2,250,000 one-time, non cash transaction) to \$2,640,240 for the year ended December 31, 2005 incurred to service the above referenced operating revenue as well as for R&D expenses for internal projects. Research expenditures increased over time in 2004 reflecting our growth from two scientists at the beginning of the year to six scientists by year-end as compared to 2005 when there were 16 scientists at year-end. Research costs totaled \$1,782,155 for 2005 and \$471,195 in 2004 excluding the one-time, non-cash transaction with the Cleveland Clinic. Development activities did not begin until July 2005 and totaled \$546,252 in 2005. In addition, general and administrative expenses of \$851,319 were incurred in 2005 versus \$434,450 in 2004 as a result of creating and improving our infrastructure as we moved into larger lab facilities in May 2005. Accounting and auditing fees also increased to \$70,667 in 2005 from \$2,246 in 2004 as we raised equity capital in March 2005 and began plans for our initial public offering.

## Liquidity and Capital Resources

We have incurred annual operating losses since our inception, and, as of December 31, 2006, we had an accumulated deficit of \$12,775,910. Our principal sources of liquidity have been cash provided by government grants and sales of our securities. Our principal uses of cash have been R&D and working capital. We expect our future sources of liquidity to be primarily government grants, 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. We anticipate that the proceeds from our initial public offering, together with the proceeds of our recently completed private placement, should be sufficient to fully develop Protectan CBLB502 for non-medical applications.

Net cash used in operating activities totaled \$6,653,602 for the year ended December 31, 2006, compared to \$1,730,513 used in operating activities for the same period in 2005. Net cash used in operating activities totaled \$1,730,513 for the year ended December 31, 2005, compared to \$207,911 used in operating activities for the same period in 2004. 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 \$14,281 for the year ended December 31, 2006 and \$2,805,113 used for the same period in 2005. The decrease 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 year ended December 31, 2005 and \$27,991 for the same period in 2004. The increase resulted from investments in long-term certificates of deposit and by purchases of lab equipment.

Net cash provided by financing activities totaled \$8,523,414 for the year ended December 31, 2006, compared to \$5,647,347 provided by financing activities for the same period in 2005. The increase in cash provided by financing activities was attributed to the proceeds from the issuance of common stock as a consequence of the initial public offering. Net cash provided by financing activities totaled \$5,647,347 for the year ended December 31, 2005, compared to \$320,517 for the same period in 2004. The funds provided for the year ended December 31, 2005 were attributable primarily to the net proceeds from our private placement of Series A Preferred Stock in March 2005.

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, 2006, we had accrued \$50,000 for the milestone payment relating to the filing of the IND application for Curaxin CBLC102. In January 2007, we started a Phase II hormone-refractory, prostate cancer clinical trial and accrued an additional \$250,000.

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 fully-secured, working capital line of credit has an interest rate of prime minus 1%, a borrowing limit of \$500,000 and expires on July 1, 2007. At December 31, 2006, there were no outstanding borrowings under this credit facility.

We also obtained an additional line of credit to use as a margin account to purchase forward contracts of foreign currency to hedge against foreign exchange risk. This line of credit is fully secured by our short-term investments, has an interest rate of prime minus 1%, a borrowing limit of \$500,000 and expires on October 25, 2007. At December 31, 2006, 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 (12-24 months), such amounts will not be sufficient to meet our longer-term cash requirements, including our cash requirements for the commercialization of certain of our drug candidates currently in development. We may be required to issue equity or debt securities or enter into other financial arrangements, including relationships with corporate and other partners, in order to raise additional capital. Depending upon market conditions, we may not be successful in raising sufficient additional capital for our long-term requirements. In such event, our business, prospects, financial condition and results of operations could be materially adversely affected.

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

#### ***Impact of Inflation***

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

#### ***Off-Balance Sheet Arrangements***

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

**Item 7. Financial Statements**

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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, 2006 and 2005, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2006. These financial statements are the responsibility of the Company's management. 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, 2006 and 2005, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2006 in conformity with accounting principles generally accepted in the United States of America.

MEADEN & MOORE, LTD.  
Certified Public Accountants

Cleveland, Ohio  
March 5, 2007

CLEVELAND BIOLABS, INC.

BALANCE SHEETS

December 31, 2006 and 2005

	<u>2006</u>	<u>2005</u>
<u>ASSETS</u>		
CURRENT ASSETS		
Cash and equivalents	\$ 3,061,993	\$ 1,206,462
Short-term investments	1,995,836	2,382,190
Accounts receivable:		
Trade	159,750	-
Interest	42,479	37,035
Notes Receivable - Orbit Brands	50,171	-
Prepaid expenses - IPO	-	210,987
Other prepaid expenses	434,675	12,249
Deferred compensation	-	5,134
Total current assets	<u>5,744,904</u>	<u>3,854,057</u>
EQUIPMENT		
Computer equipment	132,572	91,788
Lab equipment	347,944	225,997
Furniture	65,087	40,158
	<u>545,603</u>	<u>357,943</u>
Less accumulated depreciation	<u>142,011</u>	<u>47,080</u>
	403,592	310,863
OTHER ASSETS		
Deferred compensation	-	752
Intellectual Property	252,978	76,357
Deposits	15,055	11,304
	<u>268,033</u>	<u>88,413</u>
TOTAL ASSETS	<u>\$ 6,416,529</u>	<u>\$ 4,253,333</u>

CLEVELAND BIOLABS, INC.

BALANCE SHEETS

December 31, 2006 and 2005

	<u>2006</u>	<u>2005</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
CURRENT LIABILITIES		
Accounts payable:		
Trade	\$ 644,806	\$ 264,783
Deferred revenue	-	100,293
Accrued expenses	<u>128,569</u>	<u>28,579</u>
Total current liabilities	773,375	393,655
LONG-TERM LIABILITIES		
Convertible notes payable	-	303,074
Milestone payables	<u>50,000</u>	<u>-</u>
Total long-term liabilities	50,000	303,074
STOCKHOLDERS' EQUITY		
Series A convertible preferred stock, \$.005 par value		
Authorized - 10,000,000 and 4,000,000 shares at December 31, 2006 and December 31, 2005, respectively	-	15,256
Issued and outstanding 0 and 3,051,219 shares at December 31, 2006 and December 31, 2005, respectively		
Additional paid-in capital	-	4,932,885
Unissued shares - preferred stock	-	360,000
Common stock, \$.005 par value		
Authorized - 40,000,000 and 12,000,000 shares at December 31, 2006 and December 31, 2005, respectively		
Issued and outstanding 11,826,389 and 6,396,801 shares at December 31, 2006 and December 31, 2005, respectively	59,132	31,984
Additional paid-in capital	18,314,097	3,338,020
Unissued shares - common stock	-	81,125
Accumulated other comprehensive income (loss)	(4,165)	(17,810)
Accumulated deficit	<u>(12,775,910)</u>	<u>(5,184,856)</u>
Total stockholders' equity	5,593,154	3,556,604
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 6,416,529</u>	<u>\$ 4,253,333</u>



CLEVELAND BIOLABS, INC.

STATEMENT OF OPERATIONS

Years Ended December 31, 2006, 2005 and 2004

	<u>2006</u>	<u>2005</u>	<u>2004</u>
REVENUES			
Grant	\$ 1,503,214	\$ 999,556	\$ 531,341
Service	<u>205,000</u>	<u>139,275</u>	<u>105,000</u>
	1,708,214	1,138,831	636,341
OPERATING EXPENSES			
Research and Development	6,989,804	2,640,240	2,892,967
General and administrative	<u>2,136,511</u>	<u>986,424</u>	<u>262,817</u>
Total operating expenses	<u>9,126,315</u>	<u>3,626,664</u>	<u>3,155,784</u>
LOSS FROM OPERATIONS	<u>(7,418,101)</u>	<u>(2,487,833)</u>	<u>(2,519,443)</u>
OTHER INCOME (EXPENSE)			
Interest Income	206,655	119,371	320
Interest Expense	<u>(11,198)</u>	<u>(17,993)</u>	<u>(4,019)</u>
Total other income (expense), net	195,457	101,378	(3,699)
NET LOSS	<u>\$ (7,222,644)</u>	<u>\$ (2,386,455)</u>	<u>\$ (2,523,142)</u>
DIVIDENDS ON CONVERTIBLE PREFERRED STOCK	<u>(214,928)</u>	<u>(291,914)</u>	<u>-</u>
NET LOSS AVAILABLE TO COMMON SHAREHOLDERS	<u>\$ (7,437,572)</u>	<u>\$ (2,678,369)</u>	<u>\$ (2,523,142)</u>
NET LOSS AVAILABLE TO COMMON SHAREHOLDERS PER SHARE OF COMMON STOCK - BASIC AND DILUTED	<u>\$ (0.84)</u>	<u>\$ (0.43)</u>	<u>\$ (0.55)</u>
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATING NET LOSS PER SHARE, BASIC AND DILUTED	<u>8,906,266</u>	<u>6,250,447</u>	<u>4,615,571</u>

## STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2004 to December 31, 2006

	Stockholders' Equity			
	Common Stock			
	Shares	Amount	Additional Paid-in Capital	Penalty Shares
Balance at January 1, 2004	3,993,200	\$ 19,966	\$ 5,034	\$ -
Issuance of shares	1,966,800	9,834	2,250,920	-
Net loss	-	-	-	-
Balance at December 31, 2004	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	-	-	(81,125)	81,125
Net loss	-	-	-	-
Other comprehensive income				
Unrealized gains (losses) on short term investments				
Unrealized holding gains (losses) arising during period	-	-	-	-
Comprehensive loss	-	-	-	-
Balance at December 31, 2005	6,396,801.00	31,984	3,338,020	81,125
Issuance of shares - previously accrued penalty shares	54,060	270	80,855	(81,125)
Issuance of shares - stock dividend	184,183	922	367,445	-
Issue penalty shares	15,295	76	(76)	-
Issuance of shares - initial public offering	1,700,000	8,500	10,191,500	-
Fees associated with initial public offering	-	-	(1,890,444)	-
Conversion of preferred stock to common stock	3,351,219	16,756	5,291,385	-
Conversion of notes payable to common stock	124,206	621	312,382	-
Issuance of options	-	-	506,078	-
Exercise of options	625	3	2,810	-
Issuance of warrants	-	-	114,032	-
Proceeds from sales of warrants	-	-	110	-
Net loss	-	-	-	-
Other comprehensive income				
Unrealized gains (losses) on short term investments				
Changes in unrealized holding gains (losses) arising during period	-	-	-	-
Less reclassification adjustment for (gains) losses included in net loss	-	-	-	-
Comprehensive loss	-	-	-	-
Balance at December 31, 2006	11,826,389	\$ 59,132	\$ 18,314,097	\$ -

STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2004 to December 31, 2006

	Stockholders' Equity			
	Preferred Stock			
	Shares	Amount	Additional Paid-in Capital	Penalty Shares
Balance at January 1, 2004	\$ -	\$ -	\$ -	\$ -
Issuance of shares	-	-	-	-
Net loss	-	-	-	-
Balance at December 31, 2004	-	-	-	-
Issuance of shares - Series A financing	3,051,219	15,256	5,292,885	-
Issuance of shares - stock dividend	-	-	-	-
Issuance of options (383,840 options issued, 324,240 outstanding)	-	-	-	-
Exercise of options (59,600 options exercised)	-	-	-	-
Accrue unissued shares	-	-	(360,000)	360,000
Net loss	-	-	-	-
Other comprehensive income				
Unrealized gains (losses) on short term investments				
Unrealized holding gains (losses) arising during period	-	-	-	-
Comprehensive loss	-	-	-	-
Balance at December 31, 2005	3,051,219	15,256	4,932,885	360,000
Issuance of shares - previously accrued penalty shares	240,000	1,200	358,800	(360,000)
Issuance of shares - stock dividend	-	-	-	-
Issue penalty shares	60,000	300	(300)	-
Issuance of shares - initial public offering	-	-	-	-
Fees associated with initial public offering	-	-	-	-
Conversion of preferred stock to common stock	(3,351,219)	(16,756)	(5,291,385)	-
Conversion of notes payable to common stock	-	-	-	-
Issuance of options	-	-	-	-
Exercise of options	-	-	-	-
Issuance of warrants	-	-	-	-
Proceeds from sales of warrants	-	-	-	-
Net loss	-	-	-	-
Other comprehensive income				
Unrealized gains (losses) on short term investments				
Changes in unrealized holding gains (losses) arising during period	-	-	-	-
Less reclassification adjustment for (gains) losses included in net loss	-	-	-	-
Comprehensive loss	-	-	-	-
Balance at December 31, 2006	-	\$ -	\$ -	\$ -

## STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2004 to December 31, 2006

	Stockholders' Equity			
	Other	Accumulated	Total	Comprehensive
	Comprehensive	Deficit		Income
Loss			(Loss)	
Balance at January 1, 2004	\$ -	\$ (136,826)	\$ (111,826)	
Issuance of shares	-	-	2,260,754	
Net loss	-	(2,523,142)	(2,523,142)	\$ (2,523,142)
Balance at December 31, 2004	-	(2,659,968)	(374,214)	
Issuance of shares - Series A financing	-	-	5,897,803	
Issuance of shares - stock dividend	-	(138,433)	(31)	
Issuance of options (383,840 options issued, 324,240 outstanding)	-	-	318,111	
Exercise of options (59,600 options exercised)	-	-	119,200	
Accrue unissued shares	-	-	-	
Net loss	-	(2,386,455)	(2,386,455)	(2,386,455)
Other comprehensive income				
Unrealized gains (losses) on short term investments				
Unrealized holding gains (losses) arising during period	(17,810)	-	(17,810)	\$ (17,810)
Comprehensive loss				\$ (2,404,265)
Balance at December 31, 2005	(17,810)	(5,184,856)	3,556,604	
Issuance of shares - previously accrued penalty shares	-	-	-	
Issuance of shares - stock dividend	-	(368,410)	(43)	
Issue penalty shares	-	-	-	
Issuance of shares - initial public offering	-	-	10,200,000	
Fees associated with initial public offering	-	-	(1,890,444)	
Conversion of preferred stock to common stock	-	-	-	
Conversion of notes payable to common stock	-	-	313,003	
Issuance of options	-	-	506,078	
Exercise of options	-	-	2,813	
Issuance of warrants	-	-	114,032	
Proceeds from sales of warrants	-	-	110	
Net loss	-	(7,222,644)	(7,222,644)	(7,222,644)
Other comprehensive income				
Unrealized gains (losses) on short term investments				
Changes in unrealized holding gains (losses)				
arising during period	6,678	-	6,678	\$ 6,678
Less reclassification adjustment for (gains) losses				
included in net loss	6,967	-	6,967	\$ 6,967
Comprehensive loss				\$ (7,208,999)
Balance at December 31, 2006	\$ (4,165)	\$ (12,775,910)	\$ 5,593,154	

CLEVELAND BIOLABS, INC.

STATEMENTS OF CASH FLOWS

Year Ended December 31, 2006, 2005 and 2004

	<u>2006</u>	<u>2005</u>	<u>2004</u>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net loss	\$ (7,222,644)	\$ (2,386,455)	\$ (2,523,142)
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation	94,931	44,762	2,299
Noncash interest expense	9,929	17,993	4,019
Noncash salaries and consulting expense	620,119	437,311	-
Deferred compensation	5,886	9,141	10,449
Research and development	-	-	2,256,067
Changes in operating assets and liabilities:			
Accounts receivable - trade	(159,750)	225,013	(225,013)
Accounts receivable - interest	(5,616)	(37,035)	-
Other prepaid expenses	(422,427)	(12,249)	-
Deposits	(3,750)	(3,734)	(7,570)
Accounts payable	380,023	10,869	169,980
Deferred revenue	(100,293)	100,293	-
Accrued expenses	99,990	(136,421)	105,000
Milestone payments	50,000	-	-
Total adjustments	<u>569,042</u>	<u>655,942</u>	<u>2,315,231</u>
Net cash (used) provided by operating activities	(6,653,602)	(1,730,513)	(207,911)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Sale/(purchase) of short-term investments	400,000	(2,400,000)	-
Issuance of notes receivable	(50,000)	-	-
Purchase of equipment	(187,660)	(328,756)	(27,991)
Costs of patents pending	(176,621)	(76,357)	-
Net cash provided by investing activities	<u>(14,281)</u>	<u>(2,805,113)</u>	<u>(27,991)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Issuance of preferred stock	-	6,000,000	-
Financing costs	(1,679,456)	(402,622)	(13,000)
Dividends	(43)	(31)	-
Issuance of common stock	10,200,000	-	17
Exercise of stock options	2,813	-	-
Issuance of warrants	100	-	-
Proceeds from convertible notes payable	-	50,000	333,500
Net cash provided by financing activities	<u>8,523,414</u>	<u>5,647,347</u>	<u>320,517</u>
<b>NET INCREASE IN CASH AND EQUIVALENTS</b>	1,855,531	1,111,721	84,615
<b>CASH AND EQUIVALENTS AT BEGINNING OF YEAR</b>	<u>1,206,462</u>	<u>94,741</u>	<u>10,126</u>
<b>CASH AND EQUIVALENTS AT END OF YEAR</b>	<u>\$ 3,061,993</u>	<u>\$ 1,206,462</u>	<u>\$ 94,741</u>
	<u>2006</u>	<u>2005</u>	<u>2004</u>
<b>Supplemental disclosures of cash flow information:</b>			
Cash paid during the period for interest	<u>\$ 1,269</u>	<u>\$ -</u>	<u>\$ -</u>
Cash paid during the year for income taxes	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>
	<u>2006</u>	<u>2005</u>	<u>2004</u>
<b>Supplemental schedule of noncash financing activities:</b>			
Common stock issued as financing fees on issuance of preferred shares	\$ -	\$ 589,662	\$ -
Conversion of notes payable and accrued interest to preferred stock	\$ -	\$ 102,438	\$ -
Issuance of stock options to employees, consultants, and independent board members	\$ 506,078	\$ 318,511	\$ -
Issuance of warrants to consultant	\$ 114,042	\$ -	\$ -
Exercise of stock options into 59,600 common shares by consultant	\$ -	\$ 119,200	\$ -
Issuance of common stock dividend to preferred shareholders	\$ 368,367	\$ 138,402	\$ -
Unissued shares to preferred shareholders for penalty per agreement	\$ -	\$ 441,125	\$ -
Conversion of notes payable and accrued interest to common stock	\$ 313,003	\$ -	\$ -
Conversion of preferred stock to common stock	\$ 5,308,141	\$ -	\$ -

**CLEVELAND BIOLABS, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**Note 1. Organization**

Cleveland BioLabs, Inc. ("CBL" or the "Company") is engaged in the discovery, development and commercialization of products for cancer treatment and protection of normal tissues from radiation and toxins. The Company was incorporated under the laws of the State of Delaware on June 5, 2003 and is headquartered in Cleveland, Ohio. The Company's initial technological development efforts are intended to be used as powerful antidotes with a broad spectrum of applications including protection from cancer treatment side effects, radiation and hypoxia. A recent discovery found that one of its compounds increases the number of progenitor (originator) stem cells in mouse bone marrow. To date, the Company has not developed any commercial products, but in 2006 and 2005 the Company developed and produced biological compounds under a single commercial development contract.

**Note 2. Summary of Significant Accounting Policies**

- A. Cash and Equivalents - The Company considers highly liquid debt instruments with original maturities of three months or less to be cash equivalents. In addition, the Company maintains cash and equivalents at financial institutions, which may exceed federally insured amounts at times and which may, at times, significantly exceed balance sheet amounts due to outstanding checks.
- B. Marketable Securities and Short Term Investments - The Company considers investments with a maturity date of more than three months to maturity to be short-term investments and has classified these securities as available-for-sale. Such investments are carried at fair value, with unrealized gains and losses included as accumulated other comprehensive income (loss) in stockholders' equity. The cost of available-for-sale securities sold is determined based on the specific identification method.
- C. Accounts Receivable - The Company extends unsecured credit to customers under normal trade agreements, which generally require payment within 30 days. Management estimates an allowance for doubtful accounts which is based upon management's review of delinquent accounts and an assessment of the Company's historical evidence of collections. There is no allowance for doubtful accounts as of December 31, 2006, and 2005.
- D. Notes Receivable - On December 7, 2006 the Company entered into an agreement with the Orbit Brands Corporation (Borrower) and its subsidiaries whereby the Company would lend up to \$150,000 each on two promissory notes to the Borrower at a rate of 5% per annum with a maturity date of one year. The proceeds of the loans shall be used by the Borrower solely to cover expenses associated with converting the notes into common stock and preparing the lending motions for the bankruptcy case involving the Borrower. The loans are convertible into common stock of the Borrower and its subsidiaries. The Company is under no obligation to fund or loan any additional amount to the Borrower, although in the event the Company terminates, ceases or withholds its funding, any amounts funded prior thereto shall be forfeited, unless such termination is due to a breach by Borrower. As of December 31, 2006 the balance outstanding was \$50,000 plus accrued interest of \$171.

- E. Equipment - Equipment is stated at cost and depreciated over the estimated useful lives of the assets (generally five years) using the straight-line method. Leasehold improvements are depreciated on the straight-line method over the shorter of the lease term or the estimated useful lives of the assets. Expenditures for maintenance and repairs are charged to expense as incurred. Major expenditures for renewals and betterments are capitalized and depreciated. Depreciation expense was \$94,931, \$44,762, and \$2,299 for the years ended December 31, 2006, 2005, and 2004 respectively.
- F. Impairment of Long-Lived Assets - In accordance with Statements of Financial Accounting Standards, or SFAS, No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, long-lived assets to be held and used, including equipment and intangible assets subject to depreciation and amortization, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets or related asset group may not be recoverable. Determination of recoverability is based on an estimate of discounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset or asset group, the carrying amount of the asset is written down to its estimated net realizable value.
- G. Deferred Compensation - The Company realized deferred compensation upon the valuation of restricted stock granted to the founding stockholders. This deferred compensation was expensed over the three-year vesting period from the grant of the stock. Capitalized Deferred Compensation was \$0 and \$5,887 at December 31, 2006, and 2005, respectively. The Company expensed \$5,887, \$9,140, and \$9,164 in compensation expense in 2006, 2005 and 2004, respectively.
- H. Intellectual Property - The Company capitalizes the costs associated with the preparation, filing, and maintenance of certain intellectual property rights. Capitalized intellectual property is reviewed annually for impairment.

A portion of this intellectual property is owned by the Cleveland Clinic Foundation (“CCF”) and granted to the Company through an exclusive licensing agreement as further discussed in Note 3. As part of the licensing agreement, CBL agrees to bear the costs associated with the preparation, filing and maintenance of patent applications relating to this intellectual property. If the patent application is approved, the costs paid by the Company are amortized on a straight-line basis over the shorter of seventeen years or the anticipated useful life of the patent. If the patent application is not approved, the costs associated with the preparation and filing of the patent application by the Company on behalf of CCF will be expensed as part of selling, general and administrative expenses. Gross capitalized patents pending costs are \$222,789 and \$67,991 on behalf of CCF for 13 patent applications as of December 31, 2006 and 2005, respectively. All of the 13 CCF patent applications are still pending approval.

The Company also has submitted two patent applications as a result of intellectual property exclusively developed and owned by the Company. If the patent applications are approved, costs paid by the Company associated with the preparation, filing, and maintenance of the patents will be amortized on a straight-line basis over the shorter of seventeen years or the anticipated useful life of the patent. If the patent applications are not approved, the costs associated with the preparation and filing of the patent application will be expensed as part of selling, general and administrative expenses at that time. Gross capitalized patents pending costs were \$30,189 and \$8,366 for two patent applications as of December 31, 2006 and 2005, respectively. The patent applications are still pending approval.

- I. Lines of Credit - The Company has a working capital line of credit that is fully secured by short-term investments. This fully-secured working capital line of credit carries an interest rate of prime minus 1%, a borrowing limit of \$500,000, and expires on July 1, 2007. At December 31, 2006, there were no outstanding borrowings under this credit facility

The Company also has an additional line of credit for use as a margin account in forward exchange rate transactions as a hedge against foreign exchange rate risk. This line of credit is fully secured by short term investments, carries an interest rate of prime minus 1%, has a borrowing limit of \$500,000, and expires on October 25, 2007. At December 31, 2006, there were no outstanding borrowings under this credit facility.

- J. Fair Value of Financial Instruments - Financial instruments, including cash and equivalents, accounts receivable, notes receivable, accounts payable and accrued liabilities, are carried at net realizable value. The carrying amounts of the convertible notes payable approximate their respective fair values as they bear terms that are comparable to those available under current market conditions.



- K. Stock Split - As a result of a 596 for 1 stock split of the Company's issued and outstanding shares of common stock, which became effective on February 28, 2005, the 10,000 issued and outstanding shares converted into 5,960,000 shares of common stock. Per SAB Topic 4C, all share and per share stock amounts have been retroactively adjusted to reflect the stock split.
- L. Use of Estimates - The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company bases its estimates on historical experience and on various other assumptions that the Company believes to be reasonable under these circumstances. Actual results could differ from those estimates.
- M. Revenue Recognition - The Company recognizes revenue in accordance with Staff Accounting Bulletin No. 104, "Revenue Recognition." Revenue sources consist of government grants, government contracts and commercial development contracts.

Revenues from federal government grants and contracts are for research and development purposes and are recognized in accordance with the terms of the award and the government agency. Grant revenue is recognized in one of two different ways depending on the grant. Cost reimbursement grants require us to submit proof of costs incurred that are invoiced by us to the government agency, which then pays the invoice. In this case, grant revenue is recognized 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 costs grants is recognized using a percentage-of-completion method, which uses assumptions and estimates. These assumptions and estimates are developed in coordination with the principal investigator performing the work under the 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. The Company has recognized grant revenue from the following agencies: the U.S. Army (DARPA), National Aeronautics and Space Administration (NASA), the National Institutes of Health (NIH) and the Department of Health and Human Services (HHS). Commercial development revenues are recognized when the service or development is delivered.

- N. **Deferred Revenue** - Deferred Revenue results when payment is received in advance of revenue being earned. When cash is received, the Company makes a determination as to whether the revenue has been earned by applying a percentage-of-completion analysis to compute the need to recognize deferred revenue. The percentage of completion method is based upon (1) the total income projected for the project at the time of completion and (2) the expenses incurred to date. The percentage-of-completion can be measured using the proportion of costs incurred versus the total estimated cost to complete the contract.
- O. **Research and Development** - Research and development expenses consist primarily of costs associated with the clinical trials of drug candidates, compensation and other expenses for research and development, personnel, supplies and development materials, costs for consultants and related contract research and facility costs. Expenditures relating to research and development are expensed as incurred.
- P. **Employee Benefit Plan** - The Company maintains a 401(k) retirement savings plan that is available to all full-time employees who have reached age 21. The plan is intended to qualify under Section 401(k) of the Internal Revenue Code of 1986, as amended. The plan provides that each participant may contribute up to a statutory limit of their pre-tax compensation, which was \$15,000 for employees under age 50 and \$20,000 for employees 50 and older in calendar year 2006. Employee contributions are held in the employees' name and invested by the plan trustee. The plan currently provides for the Company to make matching contributions, subject to established limits. The Company made matching contributions of \$48,858, \$0, and \$0 for 2006, 2005, and 2004, respectively.
- Q. **2006 Equity Incentive Plan** - On May 26, 2006, the Company's Board of Directors adopted the 2006 Equity Incentive Plan ("Plan") to attract and retain persons eligible to participate in the Plan, motivate Participants to achieve long-term Company goals, and further align Participants' interests with those of the Company's other stockholders. The Plan expires on May 26, 2016 and allows up to 2,000,000 shares of stock to be awarded. For the year ended December 31, 2006, 45,000 options were granted to independent board members. On February 14, 2007, these 2,000,000 shares were registered with the SEC by filing a Form S-8 registration statement.
- R. **Stock-Based Compensation** - The FASB issued SFAS No. 123(R) (revised December 2004), Share Based Payment, which is a revision of SFAS No. 123 Accounting for Stock-Based Compensation. SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. The Company values 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. The assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect the Company's experience. The Company uses a risk-free rate based on published rates from the St. Louis Federal Reserve at the time of the option grant, assumes a forfeiture rate of zero, assumes an expected dividend yield rate of zero based on the Company's intent not to issue a dividend in the foreseeable future, uses an expected life based on the Company's best judgment using facts and circumstances based on its limited experience, and computes an expected volatility based on similar high-growth, publicly-traded, biotechnology companies. The Company does not include the use of its own stock in the volatility calculation at this time because of the brief history of the stock as a publicly traded security on a listed exchange. Compensation expense is recognized using the straight-line amortization method for all stock-based awards.

The fair value of warrants issued to a key consultant in exchange for services is estimated using the Black-Scholes option valuation model with the same assumptions.

On March 1, 2006, the Company granted 116,750 options pursuant to stock award agreements to certain employees and key consultants. On July 20, 2006, the Company granted 45,000 fully-vested, stock options to independent board members pursuant to stock award agreements. On November 16, 2006, the Company granted 50,000 warrants to a key consultant. The assumptions used to value these option and warrant grants using the Black-Scholes option valuation model are as follows:

	<u>March 1, 2006</u>	<u>July 20, 2006</u>	<u>November 16, 2006</u>
Risk-free interest rate	4.66%	5.04%	4.80%
Expected dividend yield	0%	0%	0%
Expected life	5 years	5 years	2.5 Years
Expected volatility	75.11%	71.43%	68.26%

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 the Company's employee stock options and warrants have characteristics significantly different from those of traded derivative securities, 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 the Company's options and warrants.

The Company recognized a total of \$506,078, \$318,511, and \$0 in expense for options and \$114,032, \$0 and \$0 in expense for warrants for the year-ended December 31, 2006, 2005, and 2004, respectively.

The weighted average, estimated fair values of stock options granted during the year-ended December 31, 2006 and 2005 were \$3.14 and \$1.65, respectively.

The following tables summarize the stock option activity for the years ended December 31, 2006 and 2005.

	<u>Shares</u>	<u>Weighted Average Exercise Price per Share</u>	<u>Weighted Average Remaining Contractual Term (in Years)</u>
Outstanding, December 31, 2005	324,240	\$ 0.82	
Granted, March 1, 2006	116,750	4.50	
Granted, July 20, 2006	45,000	6.00	
Exercised	625	4.50	
Forfeited, Canceled	1,875	4.50	
Outstanding, December 31, 2006	<u>483,490</u>	<u>\$ 2.17</u>	8.77
Exercisable, December 31, 2006	243,183	\$ 2.27	8.78

	<u>Options</u>	<u>Weighted Average Exercise Price per Share</u>	<u>Weighted Average Remaining Contractual Term (in Years)</u>
Outstanding, December 31, 2004	-	\$ -	
Granted, March 1, 2005	10,000	3.00	
Granted, July 1, 2005	353,840	0.55	
Granted, December 1, 2005	20,000	2.00	
Exercised, September 30, 2005	59,600	-	
Forfeited, Canceled	-	-	
Outstanding, December 31, 2005	<u>324,240</u>	<u>\$ 0.82</u>	9.52
Exercisable, December 31, 2005	83,560	\$ 0.88	9.50

- S. **Income Taxes** - The Company utilizes Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes," which requires an asset and liability approach to financial accounting and reporting for income taxes. The difference between the financial statement and tax basis of assets and liabilities is determined annually. Deferred income tax assets and liabilities are computed for those temporary differences that have future tax consequences using the current enacted tax laws and rates that apply to the periods in which they are expected to affect taxable income. Valuation allowances are established, if necessary, to reduce the deferred tax asset to the amount that will, more likely than not, be realized. Income tax expense is the current tax payable or refundable for the year plus or minus the net change in the deferred tax assets and liabilities.
- T. **Net Loss Per Share** - Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period.

The following table presents the calculation of basic and diluted net loss per share:

	<u>2006</u>	<u>2005</u>	<u>2004</u>
Net loss available to common stockholders	\$ (7,437,572)	\$ (2,678,369)	\$ (2,523,142)
Net loss per share, basic and diluted	\$ (0.84)	\$ (0.43)	\$ (0.55)
Weighted-average shares used in computing net loss per share, basic and diluted	8,906,266	6,250,447	4,615,571

The Company has included \$214,928 and \$291,914 in the numerator to account for cumulative dividends for Series A preferred stock that were recognized for 2006 and 2005, respectively. As of December 31, 2006 all of these dividends have been paid.

The Company has excluded all outstanding warrants and options from the calculation of diluted net loss per share because all such securities are antidilutive for all applicable periods presented.

The total number of shares excluded from the calculations of diluted net loss per share, prior to application of the treasury stock method for *warrants*, was 814,424, 594,424 and 294,424 for the years ended December 31, 2006, 2005 and 2004, respectively. Such securities, had they been dilutive, would have been included in the computation of diluted earnings per share.

The total number of shares excluded from the calculations of diluted net loss per share, prior to the application of the treasury stock method for *options*, was 483,490, 324,240 and 0 for the years ended December 31, 2006, 2005 and 2004, respectively. Such securities, had they been dilutive, would have been included in the computation of diluted earnings per share.

- U. Concentrations of Risk - Grant revenue was comprised wholly from grants issued by the federal government and accounted for 88.0%, 88.9% and 83.5% of total revenue for the years ended December 31, 2006, 2005 and 2004, respectively. Although the company anticipates ongoing federal grant revenue, there is no guarantee that this revenue stream will continue in the future.

Financial instruments that potentially subject us to a significant concentration of credit risk consist primarily of cash and cash equivalents and securities available-for-sale. The Company maintains deposits in federally insured institutions in excess of federally insured limits. The Company does not believe it is exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, the Company has established guidelines regarding diversification of its investment portfolio and maturities of investments, which are designed to meet safety and liquidity.

- V. Foreign Currency Exchange Rate Risk - The Company has entered into a manufacturing agreement with a foreign third party to produce one of its drug compounds and is required to make payments in the foreign currency. As a result, the Company's financial results could be affected by changes in foreign currency exchange rates. Currently, the Company's exposure primarily exists with the Euro Dollar. As of December 31, 2006, the Company is obligated to make payments under the agreement of 1,295,385 Euros. The Company has established means to purchase forward contracts to hedge against this risk. As of December 31, 2006, no hedging transactions have been consummated.

- W. Comprehensive Income/(Loss) - The Company applies Statement of Financial Accounting Standards (SFAS) No. 130, "Reporting Comprehensive Income." SFAS No. 130 requires disclosure of all components of comprehensive income on an annual and interim basis. Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources.

- X. Segment Reporting - As of December 31, 2006 the Company has determined that it operates in only one segment. Accordingly, no segment disclosures have been included in the notes to the consolidated financial statements.
- Y. Effect of New Accounting Standards - In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Correction - a Replacement of APB Opinion No. 20 and FASB Statement No. 3" ("SFAS 154"). SFAS 154 changes the requirements for the accounting for and the reporting of a change in accounting principle. SFAS 154 requires that a voluntary change in accounting principle be applied retroactively with all prior period financial statements presented under the new accounting principle. SFAS 154 is effective for accounting changes and corrections of errors in fiscal years beginning after December 15, 2005. The Company has determined that the adoption of the requirements required under SFAS 154 will not have a material impact on the financial statements of the Company.

On July 15, 2006 the FASB issued FIN48, *Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109*. The Company does not expect that the adoption of the recognition and measurement requirements required under FIN48 will have a material impact on the financial statements of the Company.

### **Note 3. Significant Alliances and Related Parties**

#### ***The Cleveland Clinic Foundation***

Effective July 2004, the Company entered into a strategic alliance with CCF. Under the agreement, the Company received an exclusive license to use CCF licensed patents and CCF technology for the benefit of the Company for research and drug development. The Company has primary responsibility to fund all newly developed patents; however, CCF retains patent ownership on those contained in the agreement. The Company also has the responsibility to secure applicable regulatory approvals. In partial consideration of this agreement, in December 2004, the Company issued 1,341,000 shares of its common stock to CCF and recognized \$2,250,000 as non-cash research and development expense in exchange for the stock. The calculation of this expense was based in part on an estimate of the Company's value based on discussions in 2004 with potential investors, in which the Company was estimated to have a value of approximately \$12,500,000. This valuation was reflected in an agreement between the Company and an investment bank dated September 30, 2004. This agreement set forth the terms on which the investment bank was to raise equity capital for the Company. In light of the preliminary and subjective nature of that estimate, the Company discounted that estimate to arrive at a valuation of \$10,000,000.

CCF will receive milestone payments for each product developed with CCF technology as development passes through major developmental stages. In addition, the Company will pay CCF royalties and sublicense royalties as a percentage of net sales of all commercial products developed with CCF technology. No milestone payments, royalties or sublicense royalties have been paid through the year ended December 31, 2006, although the Company has accrued \$50,000 in milestone payments as a long term liability.

The Company recognized \$0, \$0 and \$105,000 in service revenues for the years ended December 31, 2006, 2005 and 2004, respectively, from CCF related to a high-throughput screening engagement. The Company also incurred \$1,142,290, \$475,934 and \$51,129 in subcontract expense to CCF related to technology grants for the years ended December 31, 2006, 2005 and 2004, respectively. The balance remaining is \$7,309 in accounts payable at December 31, 2006.

The Company also rented office and laboratory space from an entity related to CCF on a month to month basis through May of 2005. Rent to this entity related to CCF was \$0, \$11,121 and \$32,400 in 2006, 2005 and 2004, respectively.

***ChemBridge Corporation***

In April 2004, ChemBridge Corporation acquired 357,600 shares of the Company's common stock valued at \$6,081 (subject to antidilution provisions for future equity issues) and holds warrants to purchase an additional 264,624 shares of the Company's common stock for \$1.13 per share. The warrants expire in April 2010. Under the agreement, ChemBridge has agreed to provide chemical technology and expertise for the benefit of the Company for research and drug development.

In April 2004, the Company entered into a chemical libraries license agreement with ChemBridge. Under the terms of the agreement, the Company has a non-exclusive worldwide license to use certain chemical compound libraries for drug research conducted on its own or in collaboration with others. In return, ChemBridge will receive royalty payments on any revenue received by the Company for all contracts, excluding CCF, in which the libraries are used. No revenues or royalties have been paid through the year ended December 31, 2006.



The Company has also agreed to collaborate with ChemBridge on two optimization projects, wherein ChemBridge will have the responsibility of providing the chemistry compounds of the project and the Company will have the responsibility of providing the biological expertise. ChemBridge will retain a 50% ownership interest in two selected “confirmed hits” that make up the optimization projects.

The parties will jointly manage the development and commercialization of any compounds arising from an optimization project. No “confirmed hits” have been selected during the year ended December 31, 2006.

In addition, the Company paid ChemBridge \$29,910, \$3,913, and \$395 for the purchase of chemical compounds in the normal course of business in 2006, 2005 and 2004, respectively.

#### *University of New South Wales*

In June 2003, the Company entered into a three year collaborative research agreement with the University of New South Wales (UNSW) to utilize functional genomic technologies in an attempt to identify genes in childhood neuroblastoma as potential candidates for the future development of molecular-targeted gene therapy. Under this agreement, the Company will make monetary and in-kind contributions with the collaborative partner in connection with the project under terms of the agreement. In return, the Company co-owns resulting intellectual property and has a right to use this intellectual property royalty free for internal purposes. The collaborative parties agree to negotiate a license arrangement for commercial projects resulting from co-owned intellectual property. No collaborative intellectual property has been developed during the term of this agreement. The agreement expired in June 2006 and was not renewed.

UNSW and two related parties to UNSW advanced funds of \$109,000 and \$174,500 during the year ended December 31, 2004 to the Company in exchange for convertible promissory notes, which mature on October 18, 2007 and November 23, 2007, respectively. These balances remained on the balance sheet as of December 31, 2005 as long-term notes payable. On July 20, 2006, the effective date of the initial public offering, the outstanding notes payable and accrued interest were converted into 124,206 shares of common stock. During the year ended December 31, 2005 a party related to UNSW advanced \$50,000 in exchange for a convertible promissory note, which was subsequently converted into Series A Preferred Stock and eventually converted into common stock at the effective date of the initial public offering. In addition, the Company paid UNSW \$0, \$25,011 and \$30,303 for subcontracted research during the years ended December 31, 2006, 2005 and 2004, respectively.

#### ***Cooperative Research and Development Agreement***

In August 2004, the Company entered into a five-year cooperative research and development agreement (CRADA) with the Uniformed Service University of the Health Sciences, which includes the Armed Forces Radiobiology Research Institute, the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., and CCF, to evaluate the companies' radioprotective drug candidates and their effects on intracellular and extracellular signaling pathways. Under the terms of the agreement, all parties are financially responsible for their own expenses related to the agreement. The agreement may be unilaterally terminated by any party upon 30 days prior written notice.

#### ***Sunrise Securities Corp.***

The Company engaged Sunrise Securities Corp. to act as the investment banker for the private placement that took place in March 2005 and as a lead underwriter for the initial public offering in 2006. Sunrise Securities Corp. and parties related to Sunrise Securities Corp. are owners of both common stock and warrants of the Company as a result of the private placement and the initial public offering. The Company paid Sunrise Securities Corp. \$75,000 as an initial retainer for underwriting work associated with the initial public offering and \$945,000 from the proceeds of the initial public offering.

#### ***Subcontractors***

Three company stockholders received payments for subcontract/consulting services performed on certain grant awards and internal research and development. Two of these stockholders were subsequently hired by the Company during 2005 and the other continues to receive payments. Total subcontract expense made to the related parties amounted to \$104,168, \$100,250 and \$77,250 for the years ended December 31, 2006, 2005 and 2004, respectively.

#### ***Consultants***

One company stockholder received payment for consulting services performed related to business development. Total consultant expense made to this related party amounted to \$77,300, \$49,000 and \$0 for the years ended December 31, 2006, 2005, and 2004, respectfully.

#### **Note 4. Stock Transactions**

In June 2003, the Company was incorporated in the State of Delaware and the founders entered into restricted stock agreements as the Company commenced business operations.

As of December 31, 2006 all of the restricted stock was fully vested. The founders, their positions and number of shares purchased appear below. The total initial value assigned to these shares was \$25,000 because at the time, without the involvement of ChemBridge or CCF, the probability of becoming a going concern was deemed to be remote.

<b>Name</b>	<b>Position</b>	<b>Number of Shares</b>
Dr. Andrei Gudkov	Chief Scientific Officer	1,579,400
Dr. Michael Fonstein	Chief Executive Officer, President, Chairman of the Board	1,311,200
Dr. Yakov Kogan	Executive Vice President of Business Development, Secretary	715,200
Dr. Elena Feinstein	Executive Vice President of Research and Development	268,200
Dr. Veronika Vonstein	General Manager	119,200

In April 2004, Dr. George Stark entered into a restricted stock agreement for 208,600 shares of common stock, which fully vested at the time of issuance. As the transaction pre-dated ChemBridge's investment, the Company believed that its value remained at \$25,000, and the value assigned to these shares was \$1,287. He continues to serve the Company as the Chairman of the Scientific Advisory Board.

In August 2004, after ChemBridge acquired its shares, the Company entered into restricted stock agreements with Dr. Vadim Krivokrysenko, Dr. Katerina Gurova and Dr. Michael Chernov for 50,660, 107,280, and 50,660 shares of common stock respectively. With ChemBridge's investment, the Company deemed the probability of becoming a going concern to have increased slightly and the Company was valued at a total of \$75,000. The value assigned to these shares was \$3,387. These stockholders continue to provide the Company with molecular and cancer biology expertise and management of laboratory operations and drug discovery projects.

In August 2004, Dr. Veronika Vonstein sold all 119,200 of her shares back to the Company, effectively terminating her relationship with the Company, to pursue outside opportunities. In August 2004, Dr. Andrei Gudkov sold 29,800 shares back to the Company to maintain an appropriate percentage ownership, as determined by the founders as a group.

In September 2004, the Company issued 29,800 warrants to Sunrise Securities Corp. and its designees at an exercise price of \$2.00 per share, which expire in March 2010. The warrants were issued to retain Sunrise Securities Corp. as an investment banker.

In March 2005, the Company issued 3,000,000 shares of Series A Participating Convertible Preferred Stock (Series A) for \$6 million in gross proceeds. These shares were convertible into common stock on a one-for-one basis and earn a dividend of 6% payable biannually on February 1 and August 1 in cash or common stock. In conjunction with the issuance of the Series A shares, \$50,000 of convertible notes held at December 31, 2004 and a \$50,000 note issued February 3, 2005, including accrued interest, were converted into 51,219 shares of Series A preferred stock. The Company also issued 308,000 shares of common stock and 300,000 warrants to purchase 300,000 shares of common stock with an exercise price of \$2.00 per share to Sunrise Securities Corp., the private placement agent, and its designees as partial consideration for their services rendered. 295,850 of these warrants expire on March 15, 2010 and 4,150 expire on March 28, 2010 resulting from two closing dates.

In March 2005, the Company issued 10,000 stock options under a non-qualified stock option agreement to a consultant who works for the company on an ongoing basis. These options allow for the purchase of common stock at a price of \$3.00 per share. These options have a thirteen month vesting schedule and expire on March 1, 2015. The value of the options is being recognized as consulting expense over the vesting period based on the Black-Scholes option pricing model.

In July 2005, the Company issued 294,240 stock options to various employees of the Company under non-qualified stock option agreements. These options allow for the purchase of 190,000 shares of common stock at a price of \$.66 and 104,240 shares of common stock at a price of \$0.67 per share, respectively. These options have a three-year vesting schedule and expire on June 30, 2015. The value of the options is being recognized as compensation expense over the vesting period based on the Black-Scholes option pricing model.

In July 2005, the company issued fully vested options to purchase 59,600 shares of common stock under a non-qualified stock option agreement to an outside consultant who works for the company on an ongoing basis. These stock options were exercised at a price of \$2.00 per share and the company recorded \$119,200 in consulting fees as a result of the issuance of these stock options.

On August 1, 2005, the Company paid a stock dividend of 69,201 shares of common stock to holders of record of the outstanding Series A preferred stock.

In December 2005, the Company issued 20,000 stock options under a non-qualified stock option agreement to a consultant who works for the company on an ongoing basis. These options allow for the purchase of common stock at a price of \$2.00 per share with a two-year vesting schedule and expire on November 30, 2015.

As a condition of the issuance of the Series A preferred stock in March 2005, all holders of Series A preferred stock received an additional 2% of all preferred stock, common stock and warrants that each Series A preferred stockholder owns for each 30 day period that a delay occurs in a required transaction. These penalty shares are not subject to compounding or prorating based on the number of days of delay. They are earned at the end of each 30-day penalty period. For the first quarter of 2006, one penalty period occurred in which 60,000 shares of Series A preferred stock were earned at \$120,000. In addition, 13,515 shares of common stock were earned at \$27,030. The penalty shares were issued in January 2006.

Pursuant to an Amendment to the Series A Rights Agreement, dated as of February 17, 2006, the Company's obligation to issue penalty shares was suspended for a period of 70 days, subject to a one-time 45-day extension, while the Company's registration statement was being reviewed by the SEC.

On February 1, 2006, the Company paid a common stock dividend of 91,776 shares to holders of the Series A preferred stock to satisfy the dividend requirement of the preferred stock issuance.

On March 1, 2006, the Company issued 116,750 stock options to various employees and consultants of the Company under non-qualified stock option agreements. These options allow for the purchase of 116,750 shares of common stock at a price of \$4.50. These options have a three-year vesting schedule and expire on February 29, 2016.

On June 21, 2006, after the expiration of the 115-day extension and an additional 30-day period, the Company incurred one additional penalty period in which 60,000 shares of Series A preferred stock were earned at \$120,000 and 15,295 shares of common stock were earned at \$30,590. The Company has not incurred any further obligation to issue penalty shares since these issuances.

See Note 8 for further details on stock option agreements.

On July 20, 2006, the Company sold 1,700,000 shares of common stock in its initial public offering at \$6.00 per share. The net proceeds to the Company from this offering were approximately \$8,300,000. Beginning July 21, 2006, the Company's shares were quoted on the Nasdaq Capital Market and listed on the Boston Stock Exchange under the symbols "CBLI" and "CFB" respectively. In connection with its initial public offering, the Company sold warrants to purchase 170,000 shares of common stock to the underwriters and their designees at a cost of \$100.00. The warrants have an exercise price of \$8.70 per share.

On July 20, 2006, the effective date of the Company's initial public offering, the Company issued 92,407 shares of common stock as accumulated dividends to the Series A preferred stockholders. On the same date, all of the Company's Series A Preferred shares automatically converted on a one-for-one basis into 3,351,219 shares of common stock and notes of the Company in the principal amount of \$283,500 plus accrued interest of \$29,503 automatically converted into 124,206 shares of common stock. In connection with their appointment to the Board, the Company issued to each of the Company's three new independent directors, options to purchase 15,000 shares of common stock with an exercise price of \$6.00 per share.

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. The Company 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, the Company will receive the exercise price of those warrants. The registration statement was filed to satisfy registration rights that the Company had previously granted.

On November 16, 2006 the Company issued 50,000 warrants to an outside consultant. These warrants are immediately exercisable into common shares of the Company and have an exercise price of \$6.00 per share and an expiration date of November 16, 2011.

**Note 5. Convertible Notes Payable**

	<u>2006</u>		<u>2005</u>		<u>2004</u>
Unsecured note to a research collaborator of the Company, bearing interest at 6% per annum, principal and interest due October 2007. Mandatory conversion into common stock upon an initial public offering of the Company at the fixed conversion price of \$2.52 per share. Optional conversion into common stock or a new debt agreement depending on whether the Company raises additional capital through additional equity or debt. Upon the option conversion, the conversion amount will be converted into common stock at the new issue price per share or into a new debt instrument with a principal amount equal to the conversion amount.	—	\$	109,000	\$	109,000
Unsecured note to stockholder, bearing interest at 5% per annum, principal and interest due May 2007. This note was converted into preferred stock in March 2005.	—		—		50,000
Two unsecured notes to a research collaborator of the Company, bearing interest at 6% per annum, principal and interest due November 2007. Mandatory conversion into common stock upon an initial public offering of the Company at the fixed conversion price of \$2.52 per share. Optional conversion into common stock or a new debt agreement depending on whether the Company raises additional capital through additional equity or debt. Upon the optional conversion, the conversion amount will be converted into common stock at the new issue price per share or into a new debt instrument with a principal amount equal to the conversion amount.	—		174,500		174,500
		\$	283,500	\$	333,500
Current portion	—		—		—
			283,500		333,500
Long-term accrued interest	—		19,574		4,019
	—	\$	303,074	\$	337,519

All the aforementioned convertible notes were converted into common stock on July 20, 2006 at the completion of the initial public offering.

**Note 6. Income Taxes**

The Company accounts for income taxes under SFAS No. 109, "Accounting for Income Taxes." Significant components of the Company's net deferred tax assets are shown below. A valuation allowance of \$4,898,000, \$2,022,000 and \$1,063,000 has been recognized at December 31, 2006, 2005 and 2004, respectively, to offset all deferred tax assets, as realization of such asset is uncertain. The increase in the valuation allowance of \$2,876,000 between 2005 and 2006 results from additional losses.

	<u>2006</u>	<u>2005</u>	<u>2004</u>
Deferred tax asset			
Net operating loss carryforwards	\$ 4,586,000	\$ 1,897,000	\$ 1,003,000
Deferred compensation	345,000	135,000	66,000
Loss on short term investments	2,000	7,000	—
Depreciation	(35,000))	(17,000))	(6,000))
Total	4,898,000	2,022,000	1,063,000
Valuation allowance	\$ (4,898,000))	\$ (2,022,000))	\$ (1,063,000))
Net deferred tax asset	\$ —	\$ —	\$ —

As of December 31, 2006, the Company has Federal net operating loss carryforwards of approximately \$11,480,000. The Federal net operating loss carryforwards will begin to expire in 2023 unless utilized. Net operating loss carryforwards and available credits are subject to review and possible adjustment by the Internal Revenue Service and may be limited in the event of certain changes in the ownership interest of significant stockholders.



**Note 7. Other Balance Sheet Details**

**Available-For-Sale Cash Equivalents and Marketable Securities**

Available-for-sale Marketable Securities consist of the following:

	<u>Cost</u>	<u>Accrued Interest</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
December 31, 2006 - Current Marketable Securities	\$ 2,000,000	\$ 42,479	\$ -	\$ 4,165	\$ 2,038,314

Available-for sale marketable securities consist of certificates of deposits with various commercial banks throughout the country. The unrealized gains and losses on these securities were primarily caused by recent changes in market interest rates. Because the Company has the ability and intent to hold these securities until a recovery of fair value, which may be at maturity, the Company does not consider these securities to be other than temporarily impaired as of December 31, 2006.

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

As a result of changes in market interest rates on investment, the Company recognized unrealized gains/(losses) of \$13,645, (\$17,810), and \$0 for the years ending December 31, 2006, 2005, and 2004, respectively. In 2006, the Company recaptured \$6,967 of the previously recorded other comprehensive loss due to the maturity of the short term investments and recaptured \$6,678 due to market value fluctuations of the outstanding short term investments. The Company purchased short-term investments and incurred unrealized losses of \$17,810. These gains/(losses) were charged directly against Stockholders' Equity as Other Comprehensive Income/(Loss) in the periods incurred. The Company intends on holding these securities to maturity and views these unrealized losses as temporary in nature.

**Equipment**

Equipment consists of the following:

	<u>2006</u>	<u>2005</u>
Laboratory Equipment	\$ 347,944	\$ 225,997
Computer Equipment	132,572	91,788
Furniture	65,087	40,158
	<u>545,603</u>	<u>357,943</u>
Less accumulated depreciation	(142,011)	(47,080)
	<u>\$ 403,592</u>	<u>\$ 310,863</u>

**Note 8. Commitments and Contingencies**

The Company has entered into various agreements with third parties and certain related parties in connection with the research and development activities of its existing product candidates as well as discovery efforts on potential new product candidates. These agreements include costs for research and development and license agreements that represent the Company's fixed obligations payable to sponsor research and minimum royalty payments for licensed patents. These amounts do not include any additional amounts that the Company may be required to pay under its license agreements upon the achievement of scientific, regulatory and commercial milestones that may become payable depending on the progress of scientific development and regulatory approvals, including milestones such as the submission of an investigational new drug application to the FDA, similar submissions to foreign regulatory authorities and the first commercial sale of the Company's products in various countries. These agreements include costs related to manufacturing, clinical trials and preclinical studies performed by third parties.

The Company is also party to three agreements that require it to make milestone payments, royalties on net sales of the Company's products and payments on sublicense income received by the Company. As of December 31, 2006, no milestone payments have been made, although \$50,000 has been accrued under one of these agreements.

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues for liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. For all periods presented, the Company is not a party to any pending material litigation or other material legal proceedings.

The Company currently has operating lease commitments in place for facilities in Cleveland, Ohio and Chicago, Illinois as well as office equipment. The Company recognizes rent expense on a straight-line basis over the term of the related operating leases. The operating lease expenses recognized were \$160,742, \$112,967 and \$18,900 in 2006, 2005 and 2004, respectively.

Annual future minimum lease payments under present lease commitments are as follows. These future minimum payments have not been adjusted to reflect an inflation adjustment included in the lease for the Cleveland facilities based on the Gross Domestic Product Price Deflator.

	<b>Operating Leases</b>
2007	\$ 63,460
2008	4,949
2009	1,935
	<u>\$ 70,344</u>

The Company has entered into stock option agreements with key employees, board members and consultants with exercise prices ranging from \$0.00 to \$6.00. These awards were approved by the Board of Directors. Option grants beginning in 2005 vest ratably over periods ranging from zero to three years. The options expire ten years from the date of grant, subject to the terms applicable in the agreement. A list of the total stock options awarded and exercised appears below:

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>
Outstanding at December 31, 2004	—	N/A
Granted	383,840	\$ 0.69
Exercised	59,600	\$ —
Forfeited	—	N/A
Outstanding at December 31, 2005	<u>324,240</u>	<u>\$ 0.82</u>
Granted	161,750	\$ 4.92
Exercised	625	\$ 4.50
Forfeited	1,875	\$ 4.50
Outstanding at December 31, 2006	<u>483,490</u>	<u>\$ 2.17</u>

The number of options and weighted average exercise price of options fully vested and exercisable for the years ending December 31, 2006, 2005 and 2004 were 243,183, 83,560 and 0 options at \$2.27, \$0.88 and \$0 respectively. A table showing the number of options outstanding and exercisable (fully vested) at December 31, 2006 appears below:

<u>Exercise Price</u>	<u>Outstanding</u>		<u>Exercisable</u>
	<u>Number of Options</u>	<u>Weighted Average Years to Expiration</u>	<u>Number of Options</u>
\$0.66	190,000	8.5	95,000
0.67	104,240	8.5	52,120
2.00	20,000	8.92	12,500
3.00	10,000	8.17	10,000
4.50	114,250	9.17	28,563
6.00	45,000	9.56	45,000
Total	483,490	8.77	243,183

The Company has entered into warrant agreements with strategic partners and consultants with exercise prices ranging from \$1.13 to \$8.70. These awards were approved by the Board of Directors. The warrants expire between five and six years from the date of grant, subject to the terms applicable in the agreement. A list of the total warrants awarded and exercised appears below.

	<u>Number of Warrants</u>	<u>Weighted Average Exercise Price</u>
Outstanding at December 31, 2004	294,424	\$ 1.22
Granted	300,000	\$ 2.00
Exercised	—	N/A
Forfeited	—	N/A
Outstanding at December 31, 2005	594,424	\$ 1.61
Granted	220,000	\$ 8.09
Exercised	—	N/A
Forfeited	—	N/A
Outstanding at December 31, 2006	814,424	\$ 3.36

The Company has entered into employment agreements with three key executives who, if terminated by the Company without cause as described in these agreements, would be entitled to severance pay.

While no legal actions are currently pending, the Company may be party to certain claims brought against it arising from certain contractual matters. It is not possible to state the ultimate liability, if any, in these matters. In management's opinion, the ultimate resolution of any such claim will not have a material adverse effect on the financial position of the Company.

**Note 9. Subsequent Events**

On January 12, 2007 the Company entered into a Sponsored Research Agreement with the Roswell Park Cancer Institute in Buffalo, New York whereby a portion of the research and development activities of the Company will be relocated to Buffalo, New York. The Roswell Park Cancer Institute has awarded the Company \$3,000,000 in research grant funding, \$2,000,000 to be paid on April 1, 2007 and \$1,000,000 to be paid on April 1, 2008.

**Item 8. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure**

There were no disagreements with accountants and financial disclosures for the years ended, December 31, 2006 and 2005.

**Item 8A. Controls and Procedures**

**Effectiveness of Disclosure**

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2006 as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2006, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective to assure that information required to be declared by us in reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

**Changes in Internal Control over Financial Reporting**

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal year ended December 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies

**Item 8B. Other Information**

Not applicable.

## PART III

### **Item 9. Directors, Executive Officers, Promoters, Control Persons and Corporate Governance; Compliance with Section 16(a) of the Exchange Act**

See the section entitled "Directors and Executive Officers" in Part I, Item 1 hereof for information regarding directors and executive officers.

#### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16 of the Exchange Act requires our officers (as defined under Section 16), directors and persons who beneficially own greater than 10% of a registered class of our equity securities to file reports of ownership and changes in ownership with the SEC. Based solely on a review of the forms it has received, we believe that, during 2006, all Section 16 filing requirements applicable to our officers, directors and greater than 10% beneficial owners were complied with by such persons, except that Form 3 filings for each of CBL's officers, directors and greater than 10% beneficial owners other than Dr. Fonstein and Sunrise Equity Partners, L.P. were not timely filed due to technical delays associated with obtaining the appropriate filing codes prior to our initial public offering. Such filings were made promptly after the technical delays were resolved.

#### **Code of Ethics for Senior Executives and Code of Conduct**

In May 2006, our Board of Directors adopted a Code of Ethics for Senior Executives that is specifically applicable to its executive officers and senior financial officers, including its principal executive officer, its principal financial officer, and controller. The Code of Ethics for Senior Executives is posted on our website, [www.cbiolabs.com](http://www.cbiolabs.com), under the caption "Investor Information." We have also adopted a Code of Conduct in order to promote honest and ethical conduct and compliance with the laws and governmental rules and regulations to which we are subject. The Code of Conduct is applicable to all of our employees, officers and directors, and is posted on the Company's website, [www.cbiolabs.com](http://www.cbiolabs.com), under the caption "Investor Information." A copy of the Code of Ethics for Senior Executives or Code of Conduct can be obtained by requesting such documents in writing from our Chief Financial Officer at our corporate headquarters.

#### **Audit Committee**

The Audit Committee of our Board of Directors consists of Messrs. Antal, Kasten and Perez, each of whom has been determined to be independent in accordance with the standards of the Nasdaq Capital Market. The Audit Committee generally has direct responsibility for our accounting policies and internal controls, financial reporting practices, and legal and regulatory compliance. More specifically, the Audit Committee has responsibility to review and discuss the annual audited financial statements and disclosures with management and the independent auditor; review the financial statements and disclosures provided in our quarterly and periodic reports with management, the senior internal auditing executive, and the independent auditor; oversee the external audit coverage, including appointment and replacement of the independent auditor and pre-approval of all audit and non-audit services to be performed by the independent auditor; and oversee internal audit coverage, including the appointment and replacement of the senior internal auditing executive. The Board of Directors has determined that Mr. Antal is an "audit committee financial expert," as that term is defined in the SEC rules adopted pursuant to the Sarbanes-Oxley Act.



**Item 10. Executive Compensation**

The following table provides information concerning the compensation for services in all capacities to us for the year ended December 31, 2006, to Michael Fonstein, who served as our principal executive officer, and our two most highly compensated executive officers (other than the principal executive officer), Messrs. Kogan and Marhofer (collectively, the “Named Officers”).

**SUMMARY COMPENSATION TABLE**

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)(1)</u>	<u>Stock Awards (\$)</u>	<u>Option Awards (\$)(2)</u>	<u>Non- Equity Incentive Plan Compens- ation (\$)</u>	<u>Non- Qualified Deferred Compens- ation Earnings (\$)</u>	<u>All Other Compensation (\$)</u>	<u>Total</u>
Michael Fonstein	2006	191,667	35,375	-	-	-	-	-	227,042(3)
Chief Executive Officer	2005	155,000	-	-	-	-	-	-	155,000
Yakov N. Kogan	2006	166,667	34,500	-	-	-	-	48,855(4)	250,022
Executive Vice President	2005	143,725	-	-	-	-	-	-	143,725
John A. Marhofer, Jr.	2006	90,000	17,750	-	49,559	-	-	-	157,309
Chief Financial Officer	2005	64,460	558	-	18,552	-	-	-	83,571

(1) Bonuses earned in a given year are paid during the current and the next year. For example, the bonuses indicated as earned in respect of 2006 were paid in September of 2006 and January of 2007.

- (2) Option award amounts are calculated using the provisions of Statement of Financial Accounting Standards (“SFAS”) No. 123R, Share-Based Payment. Further details can be found in Item 6 under “Critical Accounting Policies - *Stock Based Compensation*.”
- (3) Total compensation figure does not include amounts for commuting from primary residence in Chicago, Illinois of \$9,083 for 2006 and \$9,922 for 2005.
- (4) Represents tuition reimbursement for masters in business administration program.

CBL entered into employment agreements dated as of August 1, 2004 with each of Michael Fonstein, CBL’s Chief Executive Officer, and Yakov N. Kogan, CBL’s Executive Vice President. For the year ended December 31, 2006, Dr. Fonstein’s annual base salary was \$191,667 and Dr. Kogan’s annual base salary was \$166,667. These agreements have three-year initial terms and are renewed pursuant to their terms for successive one-year periods, unless earlier terminated in accordance with their terms. If either executive is terminated by CBL without cause as described in the agreements, he would be entitled to severance pay equal to nine months of his annual salary. The agreements also contain standard confidentiality, assignment of inventions, non-competition and non-solicitation provisions to help protect the value of CBL’s intellectual property. Mr. Marhofer does not have an employment agreement.

**OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END**

Below is information relating to unexercised options held by John A. Marhofer, Jr., our Chief Financial Officer, as of December 31, 2006. No other named executive officer held any unexercised options or unvested stock as of such date.

<u>Name</u>	<u>Option Awards</u>		<u>Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)</u>	<u>Option Exercise Price (\$)</u>	<u>Option Expiration Date</u>
	<u>Number of Securities Underlying Unexercised Options (#) Exercisable</u>	<u>Number of Securities Underlying Unexercised Options (#) Unexercisable</u>			
John A. Marhofer, Jr.	5,000	15,000	-	4.50	2/28/2016
	11,592	11,592	-	0.67	6/30/2015

The vesting dates for the option awards in the table above are as follows:

20,000 options expiring on 2/28/2016:

5,000 options immediately vest on grant date of 3/1/2006  
 5,000 options vest on 3/1/2007  
 5,000 options vest on 3/1/2008  
 5,000 options vest on 3/1/2009

23,184 options expiring on 6/30/2015:

5,796 options immediately vested on grant date of 7/1/2005  
 5,796 options vest on 7/1/2006  
 5,796 options vest on 7/1/2007  
 5,796 options vest on 7/1/2008

**DIRECTOR COMPENSATION**

Our independent directors, other than Dr. DiCorleto, receive a payment of \$25,000 per year for two meetings scheduled at our headquarters and an additional \$2,500 for all meetings attended throughout the year. For the period from July 20, 2006 (the effective date of our initial public offering) through December 31, 2006, we paid each of these three independent directors a fee of \$12,500 for their services as director. In addition, we also granted to each of these three independent directors options to purchase 15,000 shares of Common Stock at our initial public offering price of \$6.00 per share. All of those options vested immediately upon grant and are exercisable for ten years. Each of our independent directors is also reimbursed for reasonable out-of-pocket expenses incurred in attending Board of Directors or Board committee meetings. The total compensation of our non-employee directors for the year ended December 31, 2006 in their capacity as directors is shown in the table below.

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$)</u>	<u>Stock Awards (\$)</u>	<u>Option Awards (\$) (1)</u>	<u>Non-Equity Incentive Plan Compensation (\$)</u>	<u>Change in Pension Value and Nonqualified Deferred Compensation Earnings (\$)</u>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</u>
Bernard L. Kasten Jr.	12,500	-	56,449	-	-	-	68,949
Daniel Perez	12,500	-	56,449	-	-	-	68,949
James J. Antal	12,500	-	56,449	-	-	-	68,949
Paul E. DiCorleto	-	-	-	-	-	-	0
Andrei V. Gudkov	-	-	-	-	-	-	0

- (1) Messrs. Kasten, Perez, and Antal each held fully vested options to purchase 15,000 shares of common stock outstanding as of December 31, 2006. Award amounts are calculated using the provisions of Statement of Financial Accounting Standards (“SFAS”) No. 123R, Share-Based Payment. Further details can be found in Item 6 under “Critical Accounting Policies - *Stock Based Compensation*.”

**Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

Below is a summary of securities subject to issuance or available for issuance under our equity compensation arrangements as of December 31, 2006.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	45,000	\$ 6.00	1,955,000
Equity compensation plans not approved by security holders	1,252,914	\$ 2.81	-
Total	1,297,914	\$ 2.92	1,955,000

The terms under which securities were issued without security holder approval are described below:

In April 2004, ChemBridge Corporation acquired warrants to purchase 264,624 shares of our common stock for \$1.13 per share in connection with granting us access to their chemical compound library. The warrants expire in April 2010.

In September 2004, we issued 29,800 warrants to Sunrise Securities Corp. and its designees at an exercise price of \$2.00 per share, which expire in March 2010. The warrants were issued to retain Sunrise Securities Corp. as an investment banker.

In conjunction with the issuance of the Series A Participating Convertible Preferred shares in March 2005, we issued warrants to purchase 300,000 shares of common stock with an exercise price of \$2.00 per share to Sunrise Securities Corp., the private placement agent, and its designees as partial consideration for their services rendered. 295,850 of these warrants expire on March 15, 2010 and 4,150 expire on March 28, 2010 resulting from two closing dates.

In March 2005, we issued 10,000 stock options under a non-qualified stock option agreement to a consultant who works for the company on an ongoing basis. These options allow for the purchase of common stock at a price of \$3.00 per share. These options have a thirteen month vesting schedule and expire on March 1, 2015.

In July 2005, we issued 294,240 stock options to various employees of the Company under non-qualified stock option agreements. These options allow for the purchase of 190,000 shares of common stock at a price of \$.66 and 104,240 shares of common stock at a price of \$0.67 per share, respectively. These options have a three-year vesting schedule and expire on June 30, 2015.

In December 2005, we issued 20,000 stock options under a non-qualified stock option agreement to a consultant who works for the company on an ongoing basis. These options allow for the purchase of common stock at a price of \$2.00 per share with a two-year vesting schedule and expire on November 30, 2015.

On March 1, 2006, we issued 114,250 stock options to various employees and consultants under non-qualified stock option agreements. These options allow for the purchase of 114,250 shares of common stock at a price of \$4.50. These options have a three-year vesting schedule and expire on February 29, 2016.

In connection with our initial public offering in July 2006, we issued warrants to purchase 170,000 shares of common stock to the underwriters and their designees at a cost of \$100.00. The warrants have an exercise price of \$8.70 per share.

On November 16, 2006 we issued 50,000 warrants to an outside consultant in connection with assistance in capital raising activities that led to our March 2007 private placement. These warrants are immediately exercisable into common shares of the Company and have an exercise price of \$6.00 per share and an expiration date of November 16, 2011.

#### SECURITY OWNERSHIP OF MANAGEMENT AND PRINCIPAL STOCKHOLDERS

The following table sets forth, as of March 14, 2007, certain information with respect to the beneficial ownership of the Common Stock by (i) each person known by CBL to own beneficially more than 5% of the outstanding shares of Common Stock, (ii) each CBL director, (iii) each CBL executive officer, and (iv) all Company executive officers and directors as a group. The calculation of the percentage of shares beneficially owned before the offering is based on a total of 11,889,099 shares of common stock outstanding as of March 14, 2007.

<u>Name and Address</u>	<u>Number of Shares of Registrant Common Stock Beneficially Owned</u>		<u>Percentage of Class Beneficially Owned</u>
<b>Directors and Executive Officers</b>			
Bernard L. Kasten Jr. Director, Chairman of the Board	15,000	(3)	*
James J. Antal Director	15,000	(2)	*
Paul E. DiCorleto Director	0		0%
Michael Fonstein Director, CEO & President	1,311,200		11.03%
Andrei V. Gudkov Director, Chief Scientific Officer	1,549,600	(1)	13.03%
Yakov N. Kogan Director, Executive Vice President of Business Development, Secretary	715,200		6.02%
H. Daniel Perez Director	15,000	(4)	*
John A. Marhofer, Jr. Chief Financial Officer	21,592	(5)	*
All directors and officers as a group (eight people)	3,642,592		30.47%
<b>5% Stockholders</b>			
The Cleveland Clinic Foundation(6)	1,341,000	(7)	11.28%
ChemBridge Corporation(8)	622,224	(9)	5.23%
Sunrise Equity Partners, LP(10)	1,436,548	(11)	12.08%
Sunrise Securities Corp.(12)	1,436,548	(13)	12.08%

\* Less than 1%.

(1) On November 30, 2004, Dr. Gudkov entered into a voting agreement with the Cleveland Clinic whereby he irrevocably granted the Cleveland Clinic the right to vote all of his shares. On April 18, 2006, the Cleveland Clinic and Dr. Gudkov agreed to rescind that voting agreement effective as of November 30, 2004, such that Dr. Gudkov retains his rights to vote all of his shares.

(2) Includes options to purchase 15,000 shares of common stock, which are currently exercisable.

(3) Includes options to purchase 15,000 shares of common stock, which are currently exercisable.

(4) Includes options to purchase 15,000 shares of common stock, which are currently exercisable.

(5) Includes options to purchase 21,592 shares of common stock, which are currently exercisable.

(6) 9500 Euclid Avenue, Cleveland, Ohio 44195.

(7) The Cleveland Clinic Foundation is an Ohio non-profit corporation. The power to dispose of and vote these shares is controlled by corporate governance procedures pursuant to the Code of Regulations adopted by The Cleveland Clinic Foundation. Pursuant to these Regulations, the power to dispose of these shares is vested with the Board of Trustees and the power to vote these shares is vested in the (i) Chairman of the Board of Trustees, currently A. Malachi Mixon, II, (ii) President of the Board of Trustees, currently Delos M. Cosgrove, M.D., (iii) Vice President of the Board of Trustees, currently Stephen R. Hardis, and (iv) Vice Chairman of the Board of Trustees, which office is currently vacant. Any vote so exercised by these officers is deemed to have been exercised by and on behalf of The Cleveland Clinic Foundation.

(8) 16981 Via Tazon, Suite G, San Diego, California 92127.

(9) Includes 357,600 shares of common stock and 264,624 shares of common stock underlying a warrant, which is currently exercisable. Eugene Vaisberg, the Chairman and CEO of ChemBridge Corporation, is the majority owner of ChemBridge Corporation and has the power to vote and dispose of securities owned by ChemBridge Corporation. Accordingly, he may be deemed to beneficially own the securities owned by ChemBridge Corporation. Mr. Vaisberg disclaims any beneficial ownership of the securities owned by ChemBridge Corporation.

(10) 641 Lexington Ave., 25th Floor, New York, New York 10022.

(11) Information shown is based on amendment to Schedule 13G filed by Sunrise Equity Partners, LP and Sunrise Securities Corp. with the SEC on January 19, 2007. Includes 1,185,962 shares of common stock owned by Sunrise Equity Partners, LP, and 250,586 shares of common stock owned by Sunrise Securities Corp. Level Counter LLC is the general partner of Sunrise Equity Partners, LP. The three managing members of Level Counter LLC are Nathan Low, the sole stockholder of Sunrise Securities Corp. and its president, Amnon Mandelbaum, one of the Managing Directors of Investment Banking at Sunrise Securities Corp., and Marilyn Adler, who is otherwise unaffiliated with Sunrise Securities Corp., and a unanimous vote of all three persons is required to dispose of the securities of Sunrise Equity Partners, LP. Accordingly, each of such persons may be deemed to have shared beneficial ownership of the securities owned by Sunrise Equity Partners, LP. Such persons disclaim such beneficial ownership. As a result of the relationship of Mr. Low and Mr. Mandelbaum to Sunrise Securities Corp., Sunrise Equity Partners, LP may be deemed to beneficially own the securities owned by Sunrise Securities Corp. and/or Sunrise Securities Corp. may be deemed to beneficially own the securities owned by Sunrise Equity Partners, LP. Sunrise Equity Partners, LP disclaims any beneficial ownership of the securities owned by Sunrise Securities Corp. and Sunrise Securities Corp. disclaims any beneficial ownership of the securities owned by Sunrise Equity Partners, LP.

(12) 641 Lexington Ave., 25th Floor, New York, New York 10022.

(13) Information shown is based on amendment to Schedule 13G filed by Sunrise Equity Partners, LP and Sunrise Securities Corp. with the SEC on January 19, 2007. Includes 250,586 shares of common stock owned by Sunrise Securities Corp., and 1,185,962 shares of common stock owned by Sunrise Equity Partners, LP. Level Counter LLC is the general partner of Sunrise Equity Partners, LP. The three managing members of Level Country LLC are Nathan Low, the sole stockholder of Sunrise Securities Corp. and its president, Amnon Mandelbaum, one of the Managing Directors of Investment Banking at Sunrise Securities Corp., and Marilyn Adler who is otherwise unaffiliated with Sunrise Securities Corp., and a unanimous vote of all three persons is required to dispose of the securities of Sunrise Equity Partners, LP. Accordingly, each of such persons may be deemed to have shared beneficial ownership of securities owned by Sunrise Equity Partners, LP. Such persons disclaim such beneficial ownership. As a result of the relationship of Mr. Low and Mr. Mandelbaum to Sunrise Securities Corp., Sunrise Equity Partners, LP may be deemed to beneficially own the securities owned by Sunrise Securities Corp. and/or Sunrise Securities Corp. may be deemed to beneficially own the securities owned by Sunrise Equity Partners, LP. Sunrise Equity Partners, LP disclaims any beneficial ownership of the securities owned by Sunrise Securities Corp., and Sunrise Securities Corp. disclaims any beneficial ownership of the securities owned by Sunrise Equity Partners, LP.

## **Item 12. Certain Relationships and Related Transactions and Director Independence**

### **Transactions with Related Persons**

As of July 20, 2006, the effective date of our initial public offering, the Audit Committee has been required to conduct appropriate reviews of all transactions with related persons for potential conflict of interest situations on an ongoing basis. All such transactions must be approved by our Audit Committee.

On or around May 31, 2006, we entered into a Collaboration Agreement with one of our stockholders, ChemBridge Corporation, whereby the parties agreed to collaborate on efforts to research and develop pharmaceutical compounds targeting RCC and other cancers. The financial commitment from each party depends on the success of each step of the project.



Pursuant to our existing license agreement with CCF, we had accrued as of December 31, 2006 \$50,000 in milestone payments, which amount is payable upon the earlier to occur of CCF's equity ownership falling below 5% of our total outstanding shares (on a fully-diluted basis) or our receiving more than \$30,000,000 in funding or revenues from sources other than CCF. We have subcontracted with the CCF for grants in the approximate amount of \$220,000, and CCF provides lab services and personnel to CBL in the approximate amount of \$725,000.

From July 20, 2006, the effective date of our registration statement, through December 31, 2006, we did not enter into any related party transactions.

### **Director Independence**

In accordance with Nasdaq Marketplace Rule 4350(c), a majority of CBL's seven directors are "independent directors": James J. Antal, Paul E. DiCorleto, Bernard L. Kasten Jr., and H. Daniel Perez. Under Nasdaq Marketplace Rule 4200(a)(15), "independent director" means a person other than an executive officer or employee of the company or any other individual having a relationship which, in the opinion of the issuer's board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The following persons are not considered independent under the Nasdaq Rule:

(A) a director who is, or at any time during the past three years was, employed by the company or by any parent or subsidiary of the company;

(B) a director who accepted or who has a family member who accepted any compensation from the company in excess of \$60,000 during any period of twelve consecutive months within the three years preceding the determination of independence, other than the following:

(i) compensation for board or board committee service;

(ii) compensation paid to a family member who is an employee (other than an executive officer) of the company; or

(iii) benefits under a tax-qualified retirement plan, or non-discretionary compensation,

(C) a director who is a family member of an individual who is, or at any time during the past three years was, employed by the company as an executive officer;

(D) a director who is, or has a family member who is, a partner in, or a controlling shareholder or an executive officer of, any organization to which the company made, or from which the company received, payments for property or services in the current or any of the past three fiscal years that exceed 5% of the recipient's consolidated gross revenues for that year, or \$200,000, whichever is more, other than the following:

(i) payments arising solely from investments in the company's securities; or

(ii) payments under non-discretionary charitable contribution matching programs.

(E) a director of the issuer who is, or has a family member who is, employed as an executive officer of another entity where at any time during the past three years any of the executive officers of the issuer serve on the compensation committee of such other entity; or

(F) a director who is, or has a family member who is, a current partner of the company's outside auditor, or was a partner or employee of the company's outside auditor who worked on the company's audit at any time during any of the past three years.

Messrs. Antal, DiCorleto, Kasten, and Perez satisfy this standard of independence. In making this determination with respect to Dr. DiCorleto, the Nominating and Corporate Governance Committee and the Board has considered Dr. DiCorleto's affiliation with the Cleveland Clinic and satisfied itself that this affiliation does not detract or interfere with Dr. DiCorleto's ability to exercise independent judgment and carrying out his responsibilities as director and serving the best interests of our stockholders. Messrs. Antal, Kasten, and Perez make up our Compensation Committee, Nominating and Corporate Governance Committee, and Audit Committee. As members of our Audit Committee, they meet the additional independence requirements for audit committee members under Nasdaq Marketplace Rule 4350(d). Specifically, Messrs. Antal, Kasten, and Perez satisfy the criteria for independence set forth in Rule 10a-3(b)(1) under the Exchange Act, and have not participated in the preparation of the financial statements of the company or any current subsidiary of the company at any time during the past three years.

### Item 13. Exhibits

<b>Exhibit No.</b>	<b>Description</b>
3.1	Certificate of Incorporation filed with the Secretary of State of Delaware on June 5, 2003***
3.2	Certificate of Amendment of Certificate of Incorporation filed with the Secretary of State of Delaware on February 25, 2005***
3.3	Certificate of Designation of Series A Participating Convertible Preferred Stock filed with the Secretary of State of Delaware on March 8, 2005***
3.4	Second Certificate of Amendment of Certificate of Incorporation filed with Secretary of State of Delaware on June 30, 2006***
3.5	Certificate of Designations, Preferences and Rights of Series B Convertible Preferred Stock, dated March 16, 2007*****
3.6	Amended and Restated By-Laws***
4.1	Form of Specimen Common Stock Certificate*
4.2	Form of Warrants issues to designees of Sunrise Securities Corp., dated March 2005*

- 4.3 Form of Warrants issued to underwriters\*\*\*
- 4.4 Warrant to Purchase Common Stock issued to ChemBridge Corporation, dated April 27, 2004\*
- 4.5 Form of Series B Warrant \*\*\*\*\*
- 4.6 Form of Series C Warrant \*\*\*\*\*
- 10.1 Restricted Stock Agreement between Cleveland BioLabs, Inc. and Michael Fonstein, dated as of July 5, 2003\*
- 10.2 Restricted Stock Agreement between Cleveland BioLabs, Inc. and Yakov Kogan, dated as of July 5, 2003\*
- 10.3 Restricted Stock Agreement between Cleveland BioLabs, Inc. and Andrei Gudkov, dated as of July 5, 2003\*
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- 10.5 Restricted Stock and Investor Rights Agreement between Cleveland BioLabs, Inc. and ChemBridge Corporation, dated as of April 27, 2004\*
- 10.6 Common Stockholders Agreement by and among Cleveland BioLabs, Inc. and the stockholders named therein, dated as of July 1, 2004\*
- 10.7 Exclusive License Agreement by and between The Cleveland Clinic Foundation and Cleveland BioLabs, Inc., effective as of July 1, 2004\*
- 10.8 Employment Agreement by and between Cleveland BioLabs, Inc. and Dr. Michael Fonstein, dated August 1, 2004\*
- 10.9 Employment Agreement by and between Cleveland BioLabs, Inc. and Dr. Yakov Kogan, dated August 1, 2004\*
- 10.10 Consulting Agreement between Cleveland BioLabs, Inc. and Dr. Andrei Gudkov, dated August 1, 2004\*

- 10.11 Cooperative Research and Development Agreement by and between the Uniformed Services University of the Health Sciences, the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., the Cleveland Clinic Foundation, and Cleveland BioLabs, Inc., dated as of August 1, 2004\*\*
- 10.12 Form of Stock Purchase Agreement between Cleveland BioLabs, Inc. and the Purchasers party thereto, dated as of March 15, 2005\*
- 10.13 Form of Series A Rights Agreement by and among Cleveland BioLabs, Inc. and the parties thereto, dated as of March 15, 2005\*
- 10.14 Employment Agreement by and between Cleveland BioLabs, Inc. and Dr. Farrel Fort, dated June 1, 2005\*
- 10.15 Amendment to Employment Agreement by and between Cleveland BioLabs, Inc. and Dr. Farrel Fort, dated September 30, 2005\*
- 10.16 Amendment to Consulting Agreement between Cleveland BioLabs, Inc. and Dr. Andrei Gudkov, dated as of January 23, 2006\*
- 10.17 Amendment to Restricted Stock Agreement between Cleveland BioLabs, Inc. and Michael Fonstein, dated as of January 23, 2006\*
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- 10.20 Amendment to Common Stockholders Agreement by and among Cleveland BioLabs, Inc. and the parties thereto, dated as of January 26, 2006\*
- 10.21 Form of Amendment to Series A Rights Agreement by and among Cleveland BioLabs, Inc. and the parties thereto, dated as of February 17, 2006\*
- 10.22 Cleveland BioLabs, Inc. 2006 Equity Incentive Plan\*\*\*
- 10.23 Process Development and Manufacturing Agreement between Cleveland BioLabs, Inc. and SynCo Bio Partners B.V., effective as of August 31, 2006\*\*\*\*\*

- 10.24 Sponsored Research Agreement between Cleveland BioLabs, Inc. and Roswell Park Cancer Institute Corporation, effective as of January 12, 2007\*\*\*\*\*
- 10.25 Securities Purchase Agreement, dated March 16, 2007\*\*\*\*\*
- 10.26 Registration Rights Agreement, dated March 16, 2007\*\*\*\*\*
- 10.27 Voting Agreement, dated March 16, 2007\*\*\*\*\*
- 23.1 Consent of Meaden & Moore, Ltd.
- 31.1 Rule 13a-14(a)/15d-14(a) Certification of Michael Fonstein
- 31.2 Rule 13a-14(a)/15d-14(a) Certification of John A. Marhofer, Jr.
- 32.1 Section 1350 Certification.

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\* Incorporated by reference to Amendment No. 1 to Registration Statement on Form SB-2 as filed on April 25, 2006 (File No. 333-131918).

\*\* Incorporated by reference to Amendment No. 2 to Registration Statement on Form SB-2 as filed on May 31, 2006 (File No. 333-131918).

\*\*\* Incorporated by reference to Amendment No. 3 to Registration Statement on Form SB-2 as filed on July 10, 2006 (File No. 333-131918).

\*\*\*\* Incorporated by reference to Form 8-K as filed on October 25, 2006.

\*\*\*\*\* Incorporated by reference to Form 8-K as filed on January 12, 2007.

\*\*\*\*\* Incorporated by reference to Form 8-K as filed on March 19, 2007.

#### **Item 14. Principal Accountant Fees and Services**

Meaden & Moore, Ltd. (“Meaden & Moore”) acts as the principal auditor for us and also provides certain audit-related services. We have entered into an engagement agreement with Meaden & Moore that sets forth the terms by which Meaden & Moore will perform audit services for us. That agreement is subject to alternative dispute resolution procedures and an exclusion of punitive damages. RSM McGladery performs tax services for us.

On May 25, 2005, we engaged the accounting firm of Meaden & Moore, Ltd. as our independent accountants. Meaden & Moore replaced our previous accountants Hausser & Taylor, LLC. Hausser & Taylor, which had audited our financial statements for the years ending December 31, 2003 and 2004, had been engaged in late May 2005 to reissue their opinion specifically to remove the going concern clause as a result of our \$6 million Series A Preferred Stock financing. During the course of that engagement, Hausser & Taylor notified us that as a result of their having provided assistance to management in the drafting of notes to the financial statements, they could not satisfy the independence requirement of the SEC. Meaden & Moore has reaudited our financial statements for the years ended December 31, 2003 and 2004.

The Audit Committee pre-approves all services provided by Meaden & Moore to us. In pre-approving services, the Audit Committee considers whether such services are consistent with the SEC's rules on auditor independence. The fees for the services provided by Meaden & Moore to us were as follows:

Audit Fees were \$66,500 for the year ended December 31, 2006 and were \$50,235 (\$21,000 for Meaden & Moore and \$29,235 for Hausser & Taylor) for the year ended December 31, 2005. Audit Fees consisted of audit work performed in the preparation of financial statements, quarterly financial statement reviews, statutory audits, consultation regarding financial accounting and/or reporting standards and filings with the SEC.

Tax Fees were \$8,080 and \$2,810 for the years ended December 31, 2006, and December 31, 2005, respectively. Tax Fees consisted of all services performed by the independent auditor's tax personnel, except those related to the audit of financial statements, and include tax compliance, tax consulting, tax planning and non-recurring projects.

There were no fees billed by Meaden & Moore for Other Fees during the years ended December 31, 2006, and December 31, 2005.

**SIGNATURES**

In accordance with the requirements of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CLEVELAND BIOLABS, INC.

Dated: March 29, 2007

By: /s/ MICHAEL FONSTEIN

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Michael Fonstein  
Chief Executive Officer  
(Principal Executive Officer)

CLEVELAND BIOLABS, INC.

Dated: March 29, 2007

By: /s/ JOHN A. MARHOFER JR.

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John A. Marhofer Jr.  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/S/ Michael Fonstein <hr/> Michael Fonstein	Chief Executive Officer, President, and Director (Principal Executive Officer)	March 29, 2007
/S/ John A. Marhofer Jr. <hr/> John A. Marhofer Jr.	Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2007
/S/ James Antal <hr/> James Antal	Director	March 29, 2007
/S/ Paul DiCorleto <hr/> Paul DiCorleto	Director	March 29, 2007
/S/ Andrei Gudkov <hr/> Andrei Gudkov	Chief Scientific Officer, and Director	March 29, 2007
/S/ Bernard L. Kasten <hr/> Bernard L. Kasten	Director	March 29, 2007
/S/ Yakov Kogan <hr/> Yakov Kogan	Executive Vice President, and Director	March 29, 2007
/S/ H. Daniel Perez <hr/> H. Daniel Perez	Director	March 29, 2007



## EXHIBIT INDEX

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**Consent of Independent Registered Public Accounting Firm**

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

We consent to the use in the Form 10-KSB of Cleveland BioLabs, Inc. (the "Company") for the fiscal year ended December 31, 2006 and the incorporation by reference in the registration statement on Form S-8 (No. 333-140687) of the Company of our report dated March 5, 2007, with respect to the balance sheets of Cleveland BioLabs, Inc. as of December 31, 2006 and 2005, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2006, which report appears in the December 31, 2006 annual report on Form 10-KSB of the Company.

/s/ Meaden & Moore, Ltd.

Cleveland, Ohio  
March 29, 2007

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**Certification**

I, Michael Fonstein, certify that:

1. I have reviewed this annual report on Form 10-KSB of Cleveland Biolabs, Inc.;
  2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;
  4. The small business issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the small business issuer and have:
    - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - b) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - c) Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting.
  5. The small business issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or persons performing the equivalent functions):
    - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
-

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2007

By: /s/ Michael Fonstein

\_\_\_\_\_  
Michael Fonstein  
Chairman and Chief Executive Officer  
(Principal Executive Officer)

---

**Certification**

I, John A. Marhofer, Jr., certify that:

1. I have reviewed this annual report on Form 10-KSB of Cleveland Biolabs, Inc.;
  2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer as of, and for, the periods presented in this report;
  4. The small business issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the small business issuer and have:
    - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the small business issuer, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - b) Evaluated the effectiveness of the small business issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - c) Disclosed in this report any change in the small business issuer's internal control over financial reporting that occurred during the small business issuer's most recent fiscal quarter (the small business issuer's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the small business issuer's internal control over financial reporting.
  5. The small business issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the small business issuer's auditors and the audit committee of the small business issuer's board of directors (or persons performing the equivalent functions):
    - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
-



b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2007

By: /s/ John A. Marhofer, Jr.  
John A. Marhofer, Jr.  
Chief Financial Officer  
(Principal Financial Officer)

---

**Certification\***

In connection with the Annual Report of Cleveland BioLabs, Inc., (the "Company"), on Form 10-KSB for the fiscal year ending December 31, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Annual Report") pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Michael Fonstein, Chief Executive Officer of the Company, and John A. Marhofer, Jr., Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Annual Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the Annual Report.

Dated: March 29, 2007

By: /s/ Michael Fonstein  
Michael Fonstein  
Chairman and Chief Executive Officer  
(Principal Executive Officer)

Dated: March 29, 2007

By: /s/ John A. Marhofer, Jr.  
John A. Marhofer, Jr.  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

\* This certification accompanies the Annual Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Cleveland BioLabs, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Annual Report), irrespective of any general incorporation language contained in such filing.

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## BOARD OF DIRECTORS

**Bernard L. Kasten, M.D.**  
*Chairman of the Board*

**Michael Fonstein, Ph.D.**  
*Chief Executive Officer and President*

**Andrei Gudkov, Ph.D., D. Sci.**  
*Chief Scientific Officer*

**Yakov Kogan, Ph.D.**  
*Executive Vice President*

**Paul E. DiCorleto, Ph.D.**  
*Director*

**H. Daniel Perez, M.D.**  
*Director*

**James J. Antal**  
*Director*

## CORPORATE OFFICERS

**Michael Fonstein, Ph.D.**  
*Chief Executive Officer and President*

**Andrei Gudkov, Ph.D., D. Sci.**  
*Chief Scientific Officer*

**Yakov Kogan, Ph.D.**  
*Executive Vice President*

**John A. Marhofer, Jr., CMA, CFM**  
*Chief Financial Officer*



CLEVELAND BIOLABS, INC.

## SEC FORM 10-KSB

A copy of the Company's Annual Report to the Securities and Exchange Commission of Form 10-K is available without charge upon written request to:

Rachel Levine  
The Global Consulting Group  
22 Cortlandt Street, 14th Floor  
New York, New York 10007

## DIVIDENDS

The Company has not paid or declared any dividends on its Common Stock since its organization and has no present intention of paying cash dividends on its Common Stock. The Company is required to pay dividends on its outstanding Series B Preferred Stock. It is the present policy of the Board of Directors to retain all earnings, to finance the development of the Company's business.

## CORPORATE HEADQUARTERS

11000 Cedar Avenue, Suite 280  
Cleveland, Ohio 44106  
Telephone: 216-229-2251  
Facsimile: 216-229-1764  
[www.cbiolabs.com](http://www.cbiolabs.com)

## TRANSFER AGENT AND REGISTRAR

Continental Stock Transfer  
and Trust Company  
17 Battery Place  
New York, New York 10004

## LEGAL COUNSEL

Katten Muchin Rosenman LLP  
525 West Monroe Street  
Chicago, Illinois 60661

## INDEPENDENT AUDITORS

Meaden & Moore, Ltd.  
1100 Superior Avenue, Suite 1100  
Cleveland, Ohio 44114

## STOCK LISTING

Cleveland BioLabs, Inc.'s common shares are listed on the NASDAQ Capital Market—ticker symbol CBLI and the Boston Stock Exchange—ticker symbol CFB.



CLEVELAND BIOLABS, INC.

11000 Cedar Avenue, Suite 280

Cleveland, Ohio 44106

Telephone: 216-229-2251

Facsimile: 216-229-1764

[www.cbiolabs.com](http://www.cbiolabs.com)