

CLEVELAND BIOLABS INC  
Form POS AM  
April 11, 2007

As filed with the Securities and Exchange Commission on April 11, 2007

Registration Number 333-136904

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**POST-EFFECTIVE AMENDMENT NO.1 TO  
FORM SB-2**

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

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**CLEVELAND BIOLABS, INC.**  
(Name of small business issuer in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

**8731**  
(Primary Standard Industrial  
Classification Code Number)

**20-0077155**  
(I.R.S. Employer  
Identification No.)

11000 Cedar Ave.  
Suite 290  
Cleveland, Ohio 44106  
(216) 229-2251

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

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**Dr. Michael Fonstein  
Chief Executive Officer & President**

Cleveland BioLabs, Inc.  
11000 Cedar Ave.  
Suite 290  
Cleveland, Ohio 44106  
(216) 229-2251

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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*Copies to:*

**Ram Padmanabhan, Esq.  
Katten Muchin Rosenman LLP**

**525 West Monroe Street  
Chicago, Illinois 60661  
(312) 902-5200 / (312) 902-1061 (Telecopy)**

**Approximate date of commencement of proposed sale to the public:**

From time to time after the effective date of this Registration Statement, as determined by the selling stockholders.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.  x

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  o

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  o

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  o

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.  o

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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The information contained in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

## **PROSPECTUS**

**SUBJECT TO COMPLETION, DATED APRIL 11, 2007**

**4,453,601 Shares**

**CLEVELAND BIOLABS, INC.  
Common Stock, \$0.005 Par Value**

This prospectus relates to up to 4,453,601 shares of our common stock that may be offered for sale from time to time by the selling stockholders named in this prospectus. Of these 4,453,601 shares of common stock:

- 3,953,801 shares were acquired pursuant to a private placement between us and the applicable selling stockholders;
- up to 329,800 shares of common stock may be acquired at the price of \$2.00 per share upon the exercise of warrants, which were issued to the selling stockholders pursuant to a private placement between us and those selling stockholders; and
- up to 170,000 shares of common stock may be acquired at the price of \$8.70 per share upon the exercise of warrants issued to designees of the underwriters in our initial public offering.

All of these shares of common stock may be sold by the selling stockholders named in this prospectus, or their respective transferees, pledgees, donees or successors-in-interest. The selling stockholders will receive all proceeds from the sale of the shares of our common stock being offered in this prospectus. We will receive the exercise price of the warrants upon their exercise by the selling stockholders holding warrants. We are registering the offer and sale of the shares of common stock to satisfy registration rights that we have granted.

The shares of common stock to which this prospectus relates may be offered and sold from time to time directly by the selling stockholders or alternatively through ordinary brokerage transactions directly to market makers of our shares or through any other means described in "Plan of Distribution" beginning on page 69. The shares of common stock may be sold in one or more transactions, at fixed prices, at prevailing market prices at the time of sale or at negotiated prices.

Our common stock is quoted on the Nasdaq Capital Market under the symbol "CBLI". Our common stock is also listed on the Boston Stock Exchange under the symbol "CFB". The last reported sales price of our common stock on the Nasdaq Capital Market on April 10, 2007 was \$9.24 per share.

**Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 8.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

The date of this prospectus is \_\_\_\_\_, 2007.

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You should only rely on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. The information contained in, or that can be accessed through, our website is not a part of this prospectus. The selling stockholders will only sell shares of our common stock and seek offers to buy shares of our common stock in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of the prospectus, regardless of the time of delivery of this prospectus or any sale of the common stock.

## PROSPECTUS SUMMARY

*This summary does not contain all of the information you should consider before buying shares of our common stock. We urge you to read the entire prospectus carefully, especially the risks of investing in our common stock discussed under “Risk Factors” and the financial statements and notes to those financial statements included elsewhere in this prospectus, before deciding to invest in shares of our common stock. In this prospectus, unless the context otherwise requires, the terms “CBL”, “company”, “we”, “us”, and “our” refer to Cleveland BioLabs, Inc., a Delaware corporation, and, unless the context otherwise requires, “common stock” refers to the common stock, par value \$0.005 per share, of Cleveland BioLabs, Inc.*

### **Our Company**

Our company is engaged in drug discovery. Our goal is to identify and develop new types of drugs for protection of normal tissues from exposure to radiation and other stresses, such as toxic chemicals and for cancer treatment. 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.

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 or toxic chemicals or to internal stresses. Apoptosis is a major determinant of tissue damage caused by a variety of medical conditions including cerebral stroke, heart attack or acute renal failure. Conversely, however, apoptosis also is 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 attempt to 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 kill 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.

### **Our Products and Technology**

Through our R&D, and our strategic partnerships, we have established a technological foundation for the development of new pharmaceuticals and their rapid preclinical evaluation. We have acquired rights to develop and commercialize the following prospective drugs:

- Protectans are modified proteins of microbes and tumors that protect cells from apoptosis, and which therefore have a broad spectrum of potential applications. These potential applications include both non-medical applications such as protection from exposure to radiation, whether as a result of military or terrorist action or as a result of a nuclear accident, as well as medical applications such as reducing cancer treatment side effects.
- Curaxins are small molecules designed to kill tumor cells by simultaneously targeting two regulators of apoptosis. Initial test results indicate that curaxins can be effective against a number of malignancies, including renal cell carcinoma, or RCC (a highly fatal form of kidney cancer), soft-tissue sarcoma and hormone refractory prostate cancer.

In the area of radiation protection, we have achieved high levels of protection in animal models. With respect to cancer treatment, the biology of cancer is such that there is no single drug that can be successfully used to treat 100% or even 50% of all cancer patients. This means that there likely will be a need for additional anticancer drugs for each type of cancer.

These drug candidates demonstrate the value of our scientific foundation. Based on the expedited approval process currently available for non-medical applications such as protection from exposure to radiation, our most advanced drug candidate, Protectan CBLB502, may be approved for such applications within 24 months. Another drug candidate, Curaxin CBLC102, entered Phase IIa clinical trials earlier this year.

## Our Markets

Protectan CBLB502 is being developed in part to address the unmet need of protection against exposure to nuclear radiation. Recent acts and threats of terrorism and the proliferation of nuclear weapons programs in rogue states have magnified the need for radiation-protecting agents, or radioprotectants, in non-medical applications. The Project BioShield Act, which President Bush signed into law in July 2004, allocated \$5.6 billion over ten years to fund the research, development and procurement of drugs, biological products or devices to treat or prevent injury from exposure to biological, chemical, radiological or nuclear agents as a result of a military, terrorist or nuclear attack. The importance and urgency of developing tissue-protecting agents for these kinds of emergency applications are so great that the FDA approval process is scaled down to preclinical and Phase I trials. Under new FDA rules, costly and time-consuming Phase II and III studies are not required for these non-medical applications. Because Phase II and Phase III testing, which each involve testing a drug candidate on large numbers of participants who suffer from the targeted disease and condition, can last for a total of anywhere from three to six or more years, being permitted to bypass those phases represents a significant time and cost savings towards obtaining FDA approval. Without Phase II and Phase III testing, the FDA approval process is based on efficacy testing in primates and safety testing in humans conducted during preclinical and Phase I trials.

The Department of Defense, or DoD, through the U.S. Army Space and Missile Defense Command, recently issued a Request for Proposal, or 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 gastrointestinal syndrome of Acute Radiation Syndrome. Specifically, when administered following exposure to IR, the countermeasure should either prevent or reduce the extent of incipient radiation injury or promote repair of manifest radiation injury to allow the preservation or restoration of the anatomic integrity and normal physiologic functioning of the gastrointestinal 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 in or around September 2007.

The protection of healthy tissues against side effects of radiation treatment and anticancer drugs provides another application, and, therefore, another market opportunity for Protectan CBLB502. Approximately, 50 to 60% of cancer patients are treated with radiation sometime during the progression of the disease. To obtain optimal results, physicians attempt to strike a judicious balance between the total dose of radiotherapy and the adverse effect on surrounding healthy tissues. If there were a means by which these tissues could be protected from radiotherapy, more aggressive treatment regimens could be possible. In contrast to non-medical applications, use of Protectan CBLB502 to ameliorate the side effects of radiation treatment and anticancer drugs is subject to the full FDA approval process.



CBL's primary targets for curaxins are three treatment-resistant forms of cancer — hormone refractory prostate cancer, RCC, and soft-tissue sarcoma.

Other than skin cancer, prostate cancer is the most common cancer in men in the United States. According to the American Cancer Society, an estimated 234,460 cases were projected to be diagnosed with prostate cancer in 2006. RCC is a niche cancer that accounts for 3% of all cancer cases in the United States, but it is the most common type of kidney cancer in adults. In the United States, approximately 35,000 to 40,000 patients are diagnosed with RCC annually. Soft-tissue sarcomas are rare, representing only about 1% of all cancer cases. According to the American Cancer Society, approximately 9,400 new cases of soft-tissue sarcoma were projected to be diagnosed in the United States in 2006, which were projected to be responsible for approximately 3,500 deaths.

### **Our Industry**

CBL is a biotechnology, or biotech, company focused on developing bio-defense and cancer treatment products. Historically, biotech was defined by newly discovered “genetic engineering” technology, which was first developed in universities and new startup biotech companies in the mid-1970s. Later, other technologies (based on a constant flow of discoveries in the field of biology) started playing a leading role in biotech development. Medicine, and specifically drug development, is a lucrative field for use of these technologies. Large pharmaceutical, or Pharma, companies joined the biotech arena through licensing, sponsored research and corporate agreement relationships. Today biotech is a \$300 billion industry (based on total market capitalization) and includes large companies such as Amgen and Genentech.

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

- During the first stage, biotech companies fund their development through equity or debt financings while conducting R&D, which culminates in phased drug trials.
- During the second stage, when their lead drug candidates enter the drug trials, biotech companies may start licensing their drug candidates to Pharma companies in order to (1) generate revenues, (2) gain access to additional expertise, and (3) establish relations with major players in the market who can eventually take a leading role in distributing successful drugs.
- At the most advanced stage, biotech companies generate revenues by selling drugs or other biotech products to consumers or through alliances of equals.

Today, with the Project BioShield Act, biotech companies now have greater access to grants and contracts with the U.S. government. Several biotech companies have secured grants and contracts from the U.S. government to develop drugs and vaccines as a medical counter-measure against potential terrorist attacks. For biotech companies focused on these types of drugs and vaccines, this type of funding together with the scaled down FDA approval process are major departures from the traditional biotech business model.

CBL is focusing its R&D efforts in the following areas:

- protecting against the effects of radiation;
- reducing cancer treatment side effects; and
- developing anticancer drugs against several specific forms of cancer.

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

### **Our Strategies and Objectives**

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

*Aggressively working towards the commercialization of Protectan CBLB502.* Our most advanced drug candidate, Protectan CBLB502, offers the potential to protect normal tissues against exposure to radiation. Because of the potential military and defense implications of such a drug, the normally lengthy FDA approval process for these non-medical applications is substantially abbreviated resulting in a large cost savings to us, and we anticipate having a developed drug available for these non-medical applications within 18-36 months.

*Leveraging our relationship with leading research and clinical development institutions.* The Cleveland Clinic Foundation, one of the top research medical facilities in the world, is one of our co-founders. In addition to providing us with drug leads and technologies, the Cleveland Clinic will share valuable expertise with us as clinical trials are performed on our drug candidates. Recently, we entered into a strategic research partnership with Roswell Park Cancer Institute, or RPCI, in Buffalo, New York. This partnership will enhance the speed and efficiency of our clinical research and provide us with access to the state-of-the-art clinical development facilities of a globally

recognized cancer research center.

*Utilizing governmental initiatives to target our markets.* Our focus on drug candidates like Protectan CBLB502, which has applications that have been deemed useful for military and defense purposes, provides us with a built-in market for our drug candidates. This enables us to invest less in costly retail and marketing resources. In an effort to improve our responsiveness to military and defense needs, we have established a collaborative relationship with the Armed Forces Radiobiology Research Institute.

*Utilizing other strategic relationships.* We have collaborative relationships with other leading organizations that enhance our drug development and marketing efforts. For example, one of our founders, with whom we maintain a strategic partnership, is ChemBridge Corporation. Known for its medicinal chemistry expertise and synthetic capabilities, ChemBridge provides valuable resources to our drug development research.

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## 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 held approximately 59% of our outstanding common stock prior to the transaction.

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.

## **Risk Factors**

Our business is subject to numerous risks as discussed more fully in the section entitled “Risk Factors” immediately following this prospectus summary. Principal risks of our business include:

- We have a history of operating losses. We expect to continue to incur losses and may exhaust our financial resources before we are able to complete the development of our drug candidates.
- Development of our drug candidates will be an expensive and time-consuming process. We may therefore require substantial additional financing to meet our business objectives.
- Our success depends in large part on the results as well as the cost of our R&D. Failures in our R&D efforts or substantial increases in our R&D costs would adversely affect our results of operations.
- We are subject to significant and complex government regulations, which may delay or prevent the commercialization of any drug candidates.
- Our intellectual property is based primarily upon licensed patents and license agreements with our collaborators. If we lose any of the rights under these agreements, our ability to commercialize our drug candidates would be materially harmed.
- Before obtaining required regulatory approvals for the commercial sale of any of our drug candidates, we must demonstrate through pre-clinical testing and clinical trials that our drug candidates are safe and effective for use in humans. We are subject to numerous risks inherent in conducting clinical trials, any of which could delay or prevent us from developing or commercializing our drug candidates.

## **Our Information**

We were incorporated in Delaware in June 2003. On July 21, 2006, our stock began trading on the Nasdaq Capital Market under the symbol “CBLI” and on the Boston Stock Exchange under the symbol “CFB”. Our principal executive offices are located at 11000 Cedar Avenue, Suite 290, Cleveland, Ohio 44106 and our telephone number is (216) 229-2251. Our website is located at <http://www.cbiolabs.com>. Information contained on our website is not incorporated by reference into this prospectus and you should not consider information on our website as part of this prospectus.

### THE OFFERING

|  |   |
|--|---|
| Common stock offered by the selling stockholders | 4,453,601 shares  |
| Common stock currently outstanding               | 11,889,099 shares   |
| Use of proceeds                                  | We will not receive any of the proceeds from the sale of the shares of common stock by the selling stockholders |
| Nasdaq Capital Market Symbol                     | CBLI  |
| Boston Stock Exchange Symbol                     | CFB   |

The number of shares of common stock currently outstanding is based on the number of shares outstanding as of March 30, 2007 and excludes:

- 4,579,010 shares of common stock issuable upon conversion of outstanding shares of Series B Convertible Preferred Stock, par value \$0.005 per share;
- 562,990 shares of common stock issuable upon exercise of outstanding options with exercise prices ranging from \$0.66 to \$6.00 per share;
- 3,457,821 shares of common stock issuable upon exercise of warrants with exercise prices ranging from \$1.13 to \$11.00 per share; and
- 1,855,500 shares of common stock reserved for issuance under our 2006 Equity Incentive Plan.

**SUMMARY FINANCIAL DATA**

We have derived the following summary financial data for the years ended December 31, 2006, December 31, 2005 and December 31, 2004 from our audited financial statements. In the opinion of our management, this information contains all adjustments necessary for a fair presentation of our results of operations and financial condition for such periods. The information below is not necessarily indicative of the results of future operations and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

**Statement of Operations Data**

|                               | <b>December 31, 2006</b> | <b>December 31, 2005</b> | <b>December 31, 2004</b> |
|-------------------------------|--------------------------|--------------------------|--------------------------|
| Total Revenues                | \$ 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    | \$ 2,136,511             | \$ 986,424               | \$ 262,817               |
| Income (Loss) from Operations | \$ (7,418,101)           | \$ (2,487,833)           | \$ (2,519,443)           |
| Net Income (Loss)             | \$ (7,222,644)           | \$ (2,386,455)           | \$ (2,523,142)           |

**Balance Sheet Data**

|                            | <b>December 31, 2006</b> | <b>December 31, 2005</b> | <b>December 31, 2004</b> |
|----------------------------|--------------------------|--------------------------|--------------------------|
| Cash and Cash Equivalents  | \$ 3,061,993             | \$ 1,206,462             | \$ 94,741                |
| Total Assets               | \$ 6,416,529             | \$ 4,253,333             | \$ 382,219               |
| Total Liabilities          | \$ 823,375               | \$ 696,729               | \$ 756,433               |
| Total Stockholders' Equity | \$ 5,593,154             | \$ 3,556,604             | \$ (374,214)             |



## RISK FACTORS

*An investment in our common stock is highly speculative, involves a high degree of risk, and should be made only by investors who can afford a complete loss. You should carefully consider the following risk factors with all of the other information included in this prospectus before you decide whether to buy our common stock. Any of the following risks could materially adversely affect our business, financial condition or operating results and could result in a partial or complete loss of your investment. The risks and uncertainties described below are not, however, the only ones that we may face. Additional risks and uncertainties not currently known to us, or that we currently believe are not material, could also materially adversely affect our business, financial condition or operating results.*

### Risks Specific to Us

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

We have a history of losses and can provide no assurance as to future operating results. As a result of losses that will continue throughout our development stage, we may exhaust our financial resources and be unable to complete the development of our drug candidates.

We have sustained losses from operations in each fiscal year since our inception in June 2003. In 2006, we had operating losses of approximately \$7,400,000, and in 2005, we had operating losses of approximately \$2,400,000. We had an accumulated deficit of approximately \$12,800,000 as of December 31, 2006 and, approximately \$5,200,000 as of December 31, 2005. To date, we have raised approximately \$44,000,000 in equity financing. We expect losses to continue for the next few years as we spend substantial additional sums on the continued R&D of proprietary drugs and technologies, and there is no certainty that we will ever become profitable as a result of these expenditures.

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

- our ability to obtain approval for, and if approved, to successfully commercialize, Protectan CBLB502;
- our ability to bring to market other proprietary drugs that are progressing through our development process;
- our R&D efforts, including the timing and cost of clinical trials; and
- our ability to enter into favorable alliances with third-parties who can provide substantial capabilities in clinical development, regulatory affairs, sales, marketing and distribution.

Even if we successfully develop and market our drug candidates, we may not generate sufficient or sustainable revenue to achieve or sustain profitability.

***Development of our drug candidates will be an expensive process and we therefore may require substantial additional financing in order to meet our business objectives.***

We anticipate that our existing cash holdings will be sufficient to meet cash requirements for at least the next 24 months. Upon expiration of this 24-month period, or sooner if we experience unanticipated cash requirements, 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 substantial additional capital during the period of drug development

and FDA testing. Depending upon market conditions, we may not be successful in raising sufficient additional capital for our long-term requirements. If we fail to raise sufficient additional financing, we will not be able to develop our drug candidates, and may be required to reduce staff, reduce or eliminate R&D, slow the development of our drug candidates, outsource or eliminate several business functions or shut down operations. Even if we are successful in raising such additional financing, we may not be able to successfully complete planned clinical trials, development, and marketing of all, or of any, of our drug candidates. In such event, our business, prospects, financial condition and results of operations could be materially adversely affected.

***We were formed in 2003 and commenced operations in the latter half of 2003. As a result, we have a limited operating history, which does not afford investors a sufficient history on which to base an investment decision.***

We were formed in June 2003. Accordingly, we have a limited operating history. Investors must consider the risks and difficulties frequently encountered by early stage companies, particularly in the rapidly evolving biopharmaceutical industry. Such risks include the following:

- competition from companies that have substantially greater assets and financial resources than we have;
- need for regulatory approval and commercial acceptance of drugs;

- ability to anticipate and adapt to a competitive market and rapid technological developments;
- amount and timing of operating costs and capital expenditures relating to expansion of our business, operations and infrastructure;
- need to rely on multiple levels of outside funding due to the length of drug development cycles and government approved protocols associated with the biopharmaceutical industry; and
- dependence upon key personnel, including key independent consultants and advisors.

We cannot be certain that our strategies will be successful or that we will successfully address these risks. In the event that we do not successfully address these risks, our business, prospects, financial condition and results of operations could be materially and adversely affected.

***Development of pharmaceutical products is a time-consuming process, subject to a number of factors, many of which are outside of our control. Consequently, we can provide no assurance of the successful and timely development of new drugs.***

Our drug candidates are in their developmental stage. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. Our success will depend on our ability to achieve scientific and technological advances and to translate such advances into reliable, commercially competitive drugs on a timely basis. Drugs that we may develop are not likely to be commercially available for a few years. The proposed development schedules for our drug candidates may be affected by a variety of factors, including technological difficulties, proprietary technology of others, and changes in government regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our drug candidates could result either in such drugs being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects, the unproven technology involved and the other factors described elsewhere in “Risk Factors”, we may not be able to complete successfully the development or marketing of any drugs.

We may fail to successfully develop and commercialize our drug candidates because they:

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

Drug development failure can occur at any stage of clinical trials and as a result of many factors and there can be no assurance that we or our collaborators will reach our anticipated clinical targets. Even if we or our collaborators complete our clinical trials, we do not know what the long-term effects of exposure to our drug candidates will be. Furthermore, our drug candidates may be used in combination with other treatments and there can be no assurance that such use will not lead to unique safety issues. Failure to complete clinical trials or to prove that our drug candidates are safe and effective would have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations.

***We must comply with significant and complex government regulations, compliance with which may delay or prevent the commercialization of our drug candidates.***

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

The process of obtaining FDA approval has historically been costly and time consuming. Current FDA requirements for a new human drug or biological product to be marketed in the United States include:

- the successful conclusion of pre-clinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety;

- filing with the FDA of an IND application to conduct human clinical trials for drugs or biologics;
- the successful completion of adequate and well-controlled human clinical investigations to establish the safety and efficacy of the product for its recommended use; and
- filing by a company and acceptance and approval by the FDA of a New Drug Application, or NDA, for a drug product or a biological license application, or BLA, for a biological product, to allow commercial distribution of the drug or biologic.

A delay in one or more of the procedural steps outlined above could be harmful to us in advancing our drug candidates through clinical testing and to market.

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 good manufacturing practice, or GMP, rules pursuant to FDA regulations.

Sales outside the United States 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 United States, 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 regulatory 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.

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

***We can provide no assurance that our drug candidates will obtain regulatory approval or that the results of clinical studies will be favorable.***

The testing, marketing and manufacturing of any product for use in the United States will require approval from the FDA. We cannot predict with any certainty the amount of time necessary to obtain such FDA approval and whether any such approval will ultimately be granted. For example, the FDA raised concerns in connection with the clinical study regimens for Curaxin CBLC102 because part of our demonstration with respect to safety relies on samples of a previously marketed formulation of a related compound, which is no longer available. Preclinical and clinical trials may reveal that one or more products are ineffective or unsafe, in which event further development of such products could be seriously delayed or terminated. Moreover, obtaining approval for certain products may require testing on human subjects of substances whose effects on humans are not fully understood or documented. Delays in obtaining FDA or any other necessary regulatory approvals of any proposed drug and failure to receive such approvals would have an adverse effect on the drug's potential commercial success and on our business, prospects, financial condition and results of operations. In addition, it is possible that a proposed drug may be found to be ineffective or unsafe due to conditions or facts that arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such proposed drug from the market. To the extent that our success will depend on any regulatory approvals from government authorities outside of the United States that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist.

***Even if we obtain regulatory approvals, our marketed drug candidates will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and foreign regulations, we could lose our approvals to market these drugs and our business would be seriously harmed.***

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 would 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 or 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.

***Development of our drug candidates requires a significant investment in R&D. Our R&D expenses in turn, are subject to variation based on a number of factors, many of which are outside of our control. A sudden or significant increase in our R&D expenses could materially and adversely impact our results of operations.***

Because we expect to expend substantial resources on R&D, our success depends in large part on the results as well as the costs of our R&D. A failure in our R&D efforts or substantial increase in our R&D expenses would adversely affect our results of operations. R&D expenditures are uncertain and subject to much fluctuation. Factors affecting our R&D expenses include, but are not limited to:

- the number and outcome of clinical studies we are planning to conduct; for example, our R&D expenses may increase based on the number of late-stage clinical studies that we may be required to conduct;
- the number of drugs entering into development from late-stage research; for example, there is no guarantee that internal research efforts will succeed in generating sufficient data for us to make a positive development decision or that an external candidate will be available on terms acceptable to us, and some promising candidates may not yield sufficiently positive pre-clinical results to meet our stringent development criteria;
- licensing activities, including the timing and amount of related development funding or milestone payments; for example, we may enter into agreements requiring us to pay a significant up-front fee for the purchase of in-process R&D that we may record as R&D expense; or
- future levels of revenue; R&D as a percentage of future potential revenues can fluctuate with changes in future levels of revenue and lower revenues can lead to less spending on R&D efforts.

***If we lose our funding from R&D grants, we may not be able to fund future R&D and implement technological improvements, which would materially harm our operating results.***

We received \$1,503,214 or 88% of our revenues in 2006 from grant and contract development work in connection with grants from the NIH, NASA and the Defense Advanced Research Projects Agency or DARPA (Department of Defense), as well as from universities and commercial companies related to drug development efforts for our radioprotectants and anticancer development work. We received \$999,556 in grant revenue in 2005, which represented 87.8% of our total revenues in 2005. Through 2006, we have received fundable scores for grants totaling

\$4,245,000. Also, we plan to submit follow-up applications for grants totaling \$1,300,000 and new applications for grants totaling \$5,610,000.

In addition, prior to our initial public offering, we historically received approximately 30% of our grant revenues through the SBIR and Small Business Technology Transfer grant programs. As a result of our growth, we have ceased to be eligible for SBIR grant programs, and therefore no longer qualify to receive these grants. These revenues have funded some of our personnel and other R&D costs and expenses. If other new grants and contracts are not awarded in the future, our ability to fund future R&D and implement technological improvements would be diminished, which would negatively impact our ability to compete in our industry.

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

Before obtaining required regulatory approvals for the commercial sale of any of our drug candidates, we must demonstrate through pre-clinical testing and clinical trials that our drug candidates are safe and effective for use in humans. We must outsource our clinical trials to third parties. Delays in finalizing agreements for the conduct of these trials could delay commencement or completion of the trials.



Agreements with clinical investigators and medical institutions for clinical testing and with other third parties for data management services place substantial responsibilities on these parties, which could result in delays in, or termination of, our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with FDA-approved good clinical practices, we may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for or successfully commercialize Protectan CBLB502, Curaxin CBLC102 or other drug candidates.

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

Our clinical trial operations will be subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we may receive reports of observations or warning letters detailing deficiencies, and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions that we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be precluded from conducting any ongoing or any future clinical trials, the government may refuse to approve our marketing applications or allow us to manufacture or market our drug candidates, or we may be criminally prosecuted.

***Certain of our drug candidates may be subject to the orphan drug provisions of the Federal Food, Drug, and Cosmetic Act, which, even if successfully marketed, may not yield sufficient returns to make us profitable.***

We intend to seek orphan drug status with respect to Curaxin CBLC102. The orphan drug provisions of the Federal Food, Drug, and Cosmetic Act provide incentives to drug and biologic manufacturers to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the U.S. or, for a disease that affects more than 200,000 individuals in the U.S., where the sponsor does not realistically anticipate that its drug will become profitable. We believe that Curaxin CBLC102 may qualify as an orphan drug for purposes of treatment of hormone refractory prostate cancer, RCC and soft-tissue sarcoma. 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.

***Efforts of government and third-party payors to contain or reduce the costs of health care may adversely affect our revenues.***

Our ability to earn sufficient returns on our drug candidates may depend in part on the extent to which government health administration authorities, private health coverage insurers and other organizations will provide reimbursement for the costs of such drugs and related treatments. Significant uncertainty exists as to the reimbursement status of newly approved health care drugs, and we do not know whether adequate third-party coverage will be available for our drug candidates. If our current and proposed drugs are not considered cost-effective, reimbursement to the

consumers may not be available or sufficient to allow us to sell drugs on a competitive basis. The failure of the government and third-party payors to provide adequate coverage and reimbursement rates for our drug candidates could adversely affect the market acceptance of our drug candidates, our competitive position and our financial performance.

If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and criminal prosecutions.

***Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information. Disclosure of our trade secrets or proprietary information could compromise any competitive advantage that we have.***

We depend upon confidentiality agreements with our officers, employees, consultants, and subcontractors to maintain the proprietary nature of the technology. These measures may not afford us sufficient or complete protection, and may not afford an adequate remedy in the event of an unauthorized disclosure of confidential information. In addition, others may independently develop technology similar to ours, otherwise avoiding the confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition, and results of operations.

***We will rely upon licensed patents to protect our technology. We may be unable to obtain or protect such intellectual property rights, and we may be liable for infringing upon the intellectual property rights of others.***

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies and the proprietary technology of others with which we have entered into licensing agreements. We have exclusively licensed 13 patent applications from the Cleveland Clinic and have filed three patent applications on our own. There can be no assurance that any of these patent applications will ultimately result in the issuance of a patent with respect to the technology owned by us or licensed to us. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the United States Patent and Trademark Office use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. Further, we rely on a combination of trade secrets, know-how, technology and nondisclosure, and other contractual agreements and technical measures to protect our rights in the technology. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

We do not believe that any of the drug candidates we are currently developing infringe upon the rights of any third parties nor are they infringed upon by third parties; however, there can be no assurance that our technology will not be found in the future to infringe upon the rights of others or be infringed upon by others. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our drug candidates so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology and the technology exclusively licensed from the Cleveland Clinic. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

Moreover, the cost to us of any litigation or other proceeding relating to our patents and other intellectual property rights, even if resolved in our favor, could be substantial, and the litigation would divert our management's efforts. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

***Other companies or organizations may assert patent rights that prevent us from developing and commercializing our drug candidates.***

We are in a relatively new scientific field that has generated many different patent applications from organizations and individuals seeking to obtain important patents in the field. Because the field is so new, very few of these patent applications have been fully processed by government patent offices around the world, and there is a great deal of uncertainty about which patents will issue, when, to whom, and with what claims. It is likely that there will be significant litigation and other proceedings, such as interference proceedings in various patent offices, relating to patent rights in the field. Others may attempt to invalidate our patents or other intellectual property rights. Even if our rights are not directly challenged, disputes among third parties could lead to the weakening or invalidation of those intellectual property rights.

Thus, it is possible that one or more organizations will hold patent rights to which we will need a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and drug candidates, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

***We are dependent upon our license agreement with the Cleveland Clinic, as well as proprietary technology of others. If we lose the right to utilize any of the proprietary information that is the subject of the Cleveland Clinic license agreement or any of the other third-party proprietary technology on which we depend, we may incur substantial delays and costs in development of our drug candidates.***

The manufacture and sale of any products developed by us may involve the use of processes, products or information, the rights to certain of which are owned by others. Although we have obtained licenses with regard to the use of the Cleveland Clinic's patent applications as described above and certain processes, products and information of others, we cannot assure you that such licenses will not be terminated or expire during critical periods, that we will be able to obtain licenses for other rights that may be important to us, or, if obtained, that such licenses will be obtained on commercially reasonable terms. While we have no reason to believe that our licenses will be terminated and our material licenses have no definitive expiration date, such licenses may be terminated if we breach certain material provisions and fail to cure the breach in a certain period of time. If we are unable to maintain and/or obtain third-party licenses, we may have to develop alternatives to avoid infringing upon the patents of others, potentially causing increased costs and delays in drug development and introduction or preclude the development, manufacture, or sale of planned products. Additionally, we can provide no assurance that the patents underlying any licenses will be valid and enforceable. To the extent any drugs developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from drug sales and may render the sales of such drugs uneconomical.

***If we fail to comply with our obligations under our license agreement with the Cleveland Clinic, we could lose our license rights that are necessary for developing our drug candidates.***

Our current exclusive license with the Cleveland Clinic imposes various development, royalty, diligence, record keeping, insurance and other obligations on us. If we breach any of these obligations and do not cure such breaches within the 90 day period provided, the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. In addition, while we cannot currently determine the dollar amount of the royalty obligations we will be required to pay on sales of future products, if any, the amounts may be significant. The dollar amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

***We will rely upon third-party manufacturers to manufacture our drug candidates. If these third-party manufacturers fail to produce our drug candidates in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical or drug manufacturers, we may face delays in the delivery of, or be unable to meet demand for, our drug candidates.***

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. Reliance on third party manufacturing presents the following risks:

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

***Our collaborative relationships with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return.***

We anticipate substantial reliance upon strategic collaborations for marketing and the commercialization of our drug candidates and we may rely even more on strategic collaborations for R&D of our other drug candidates. Our business depends on our ability to sell drugs to both government agencies and to the general pharmaceutical market. Offering our drug candidates for non-medical applications to government agencies does not require us to develop new sales, marketing or distribution capabilities beyond those already existing in the company. Selling anticancer drugs, however, does require such development. We plan to sell anticancer drugs through strategic partnerships with pharmaceutical companies. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our revenue and drug development may be limited. To date, we have not entered into any strategic collaborations with third parties capable of providing these services. In addition, we have not yet marketed or sold any of our drug candidates or entered into successful collaborations for these services in order to ultimately commercialize

our drug candidates.

If we determine to enter into R&D collaborations during the early phases of drug development, our success will in part depend on the performance of our research collaborators. We will not directly control the amount or timing of resources devoted by our research collaborators to activities related to our drug candidates. Our research collaborators may not commit sufficient resources to our programs. If any research collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to this collaboration could be delayed or terminated. Also, our collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us. Finally, if we fail to make required milestone or royalty payments to our collaborators or to observe other obligations in our agreements with them, our collaborators may have the right to terminate those agreements.

Manufacturers producing our drug candidates must follow current GMP regulations enforced by the FDA and foreign equivalents. If a manufacturer of our drug candidates does not conform to the current GMP regulations and cannot be brought up to such a standard, we will be required to find alternative manufacturers that do conform. This may be a long and difficult process, and may delay our ability to receive FDA or foreign regulatory approval of our drug candidates and cause us to fall behind on our business objectives.

Establishing strategic collaborations is difficult and time-consuming. Our discussion with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our drug candidates or the generation of sales revenue. To the extent that we enter into collaborative arrangements, our drug revenues are likely to be lower than if we directly marketed and sold any drugs that we may develop.

Management of our relationships with our collaborators will require:

- significant time and effort from our management team;
- coordination of our marketing and R&D programs with the marketing and R&D priorities of our collaborators; and
- effective allocation of our resources to multiple projects.

***As a consequence of our business, we are inherently at risk for product liability claims against us. If our insurance coverage for those claims is inadequate, we may incur substantial liabilities.***

We face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials and will face an even greater risk if the drug candidates are sold commercially or otherwise distributed. An individual may bring a liability claim against us if one of the drug candidates causes, or merely appears to have caused, an injury. With respect to non-medical applications of Protectan CBLB502 pursuant to the Project BioShield Act of 2004, we do not believe the absence of certain typical regulatory requirements such as Phase II or Phase III testing will limit or diminish our potential liability exposure. If we cannot successfully defend ourselves against the product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our drug candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- diversion of our management's time and attention;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- the inability to commercialize drug candidates; and
- increased difficulty in raising required additional funds in the private and public capital markets.

We currently have product liability insurance relating to our ongoing clinical trials. We intend to expand such coverage to include the sale of commercial drugs if marketing approval is obtained for any of our drug candidates. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

***We employ the use at our laboratories of certain chemical and biological agents and compounds that may be deemed hazardous and we are therefore subject to various environmental laws and regulations. Compliance with these laws and regulations may result in significant costs, which could materially reduce our ability to become profitable.***

We use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. As appropriate, we safely store these materials and wastes resulting from their use at our laboratory facility pending their ultimate use or disposal. We contract with a third party to properly dispose of these materials and wastes. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. We may incur significant costs complying with environmental laws and regulations adopted in the future.

*If we use biological and hazardous materials in a manner that causes injury, we may be liable for damages.*

Our R&D and manufacturing activities will involve the use of biological and hazardous materials. Although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. We carry limited biological or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies, which include coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources and insurance coverages, and our clinical trials or regulatory approvals could be suspended.



***With our limited resources, we may be unable to effectively manage growth.***

As of the date of this prospectus, we have 36 employees and several consultants and independent contractors. We intend to expand our operations and staff materially. Our new employees will include a number of key managerial, technical, financial, R&D and operations personnel who will not have been fully integrated into our operations. We expect the expansion of our business to place a significant strain on our limited managerial, operational and financial resources. We will be required to expand our operational and financial systems significantly and to expand, train and manage our work force in order to manage the expansion of our operations. Our failure to fully integrate our new employees into our operations could have a material adverse effect on our business, prospects, financial condition and results of operations.

***We may not be able to attract and retain highly skilled personnel.***

Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other pharmaceutical companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than us. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, our business, prospects, financial condition and results of operations will be materially and adversely affected.

***We depend upon our senior management and key consultants and their loss or unavailability could put us at a competitive disadvantage.***

We currently depend upon the efforts and abilities of our management team, as well as the services of several key consultants. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition and results of operations. We have not obtained, do not own, nor are we the beneficiary of, key-person life insurance.

***Political or social factors may delay or impair our ability to market our drug candidates.***

Drugs developed to treat diseases caused by or to combat the threat of bio-terrorism will be subject to changing political and social environments. The political and social responses to bio-terrorism have been highly charged and unpredictable. Political or social pressures may delay or cause resistance to bringing our drug candidates to market or limit pricing of our drug candidates, which would harm our business. Changes to favorable laws, such as the Project BioShield Act, could have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations.

***There may be conflicts of interest among our officers, directors and stockholders.***

Our executive officers and directors and their affiliates may engage in other activities and have interests in other entities on their own behalf or on behalf of other persons. Neither we nor any of our stockholders will have any rights in these ventures or their income or profits. In particular:

- Our executive officers or directors or their affiliates may have an economic interest in, or other business relationship with, partner companies that invest in us.
- Our executive officers or directors or their affiliates may have interests in entities that provide products or services to us. For example, one of our directors also holds a position with the Cleveland Clinic, the licensor of certain of our key product patent applications.

In any of these cases:

- Our executive officers or directors may have a conflict between our current interests and their personal financial and other interests in another business venture.
- Our executive officers or directors may have conflicting fiduciary duties to us and the other entity.
- The terms of transactions with the other entity may not be subject to arm's length negotiations and therefore may be on terms less favorable to us than those that could be procured through arm's length negotiations.

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*We expect to enter into contracts with various U.S. government agencies. U.S. government agencies have special contracting requirements that give the government agency various rights or impose on the other party various obligations that can make the contracts less favorable to the non-government party. Consequently, if a large portion of our revenue is attributable to these contracts, our business may be adversely affected should the governmental parties exercise any of these additional rights or impose any of these additional obligations.*

We intend to enter into contracts with various U.S. government agencies. Substantially all of our revenue may be derived from government contracts and grants. In contracting with government agencies, we will be subject to various federal contract requirements. Future sales to U.S. government agencies will depend, in part, on our ability to meet these requirements, certain of which we may not be able to satisfy.

U.S. government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which subjects us to additional risks. These risks include the ability of the U.S. government to unilaterally:

- suspend or prevent us for a set period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations;
- terminate our existing contracts;
- reduce the scope and value of our existing contracts;
- audit and object to our contract-related costs and fees, including allocated indirect costs;
- control and potentially prohibit the export of our drug candidates; and
- change certain terms and conditions in our contracts.

The U.S. government may terminate any of its contracts with us either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms. Termination for convenience provisions generally enable us to recover only our costs incurred or committed, and settlement expenses and profit on the work completed prior to termination. Termination for default provisions do not permit these recoveries and make us liable for excess costs incurred by the U.S. government in procuring undelivered items from another source.

As a U.S. government contractor, we may become subject to periodic audits and reviews. Based on the results of these audits, the U.S. government may adjust our contract-related costs and fees, including allocated indirect costs. As part of any such audit or review, the U.S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, compensation and/or management information systems. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. In addition, under U.S. government purchasing regulations, some of our costs, including most financing costs, amortization of intangible assets, portions of our R&D costs and some marketing expenses, may not be reimbursable or allowed under our contracts. Further, as a U.S. government contractor, we may become subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities to which purely private sector companies are not.

*We may fail to obtain contracts to supply the U.S. government, and we may be unable to commercialize our drug candidates.*

The U.S. government has undertaken commitments to help secure improved countermeasures against bio-terrorism. The process of obtaining government contracts is lengthy and uncertain, and we must compete for each contract. Moreover, the award of one government contract does not necessarily secure the award of future contracts covering the same drug. If the U.S. government makes significant future contract awards for the supply of its emergency stockpile to our competitors, our business will be harmed and it is unlikely that we will be able to ultimately commercialize our competitive drug candidate.

In addition, the determination of when and whether a drug is ready for large scale purchase and potential use will be made by the government through consultation with a number of government agencies, including the FDA, the NIH, the Centers for Disease Control, and the Department of Homeland Security. Congress has approved measures to accelerate the development of bio-defense drugs through NIH funding, the review process by the FDA and the final government procurement contracting authority. While this may help speed the approval of our drug candidates, it may also encourage competitors to develop their own drug candidates.

***The market for treating exposure to nuclear or radiological events is uncertain.***

We do not believe that any drug has been approved and commercialized for treatment of large-scale radiation injury. Indeed, the incidence of large-scale exposure has been low. Accordingly, even if Protectan CBLB502 is approved by regulatory authorities, we cannot predict with certainty the size of the market, if any.

***The U.S. government's commitment to funding the development of radioprotectant drugs under the Project BioShield Act is uncertain, and if it decides to curtail or limit allocations to radioprotectant drugs, it would materially harm our results of operations.***

The potential market for Protectan CBLB502 is largely dependent on the size of procurement contracts, if any, from the U.S. government. While a number of federal contracts have historically been made by the U.S. government under the Project BioShield Act of 2004 to procure drugs to treat indications such as anthrax exposure and certain long-term effects of radiation exposure, we are unaware of any significant contract for drugs to treat radiation injury due to exposure to radiation. Any decision by the U.S. government to enter into a commitment to purchase Protectan CBLB502 prior to FDA approval could possibly occur if there are serious threats or accidents, but this possibility is remote and beyond our control. Our development plans and timelines may vary substantially depending on whether we receive such a commitment and the size of such commitment prior to FDA approval. In addition, even if Protectan CBLB502 is approved by regulatory authorities, we cannot guarantee that we will receive any procurement contracts or that any such contract would be profitable to us or that Protectan CBLB502 will achieve market acceptance by the general public.

***If the U.S. government fails to continue funding bio-defense drug candidate development efforts or fails to purchase sufficient quantities of any future bio-defense drug candidate, we may be unable to generate sufficient revenues to continue operations.***

We hope to receive funding from the U.S. government for the development of our bio-defense drug candidates. Changes in government budgets and agendas, however, may result in future funding being decreased and de-prioritized, and government contracts typically contain provisions that permit cancellation in the event that funds are unavailable to the government agency. Furthermore, we cannot be certain of the timing of any future funding, and substantial delays or cancellations of funding could result from protests or challenges from third parties. If the U.S. government fails to continue to adequately fund R&D programs, we may be unable to generate sufficient revenues to continue operations. Similarly, if we develop a drug candidate that is approved by the FDA, but the U.S. government does not place sufficient orders for this drug, our future business may be harmed.

**Risks Related to the Biotechnology/Biopharmaceutical Industry**

***The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with enterprises equipped with more substantial resources than us.***

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition based primarily on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain government approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with

other biopharmaceutical companies. These companies, as well as academic institutions, government agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

We are aware of numerous products under development or manufactured by competitors that are used for the prevention or treatment of certain diseases we have targeted for drug development. Various companies, such as Hollis-Eden, are developing biopharmaceutical products that potentially directly compete with our non-medical application drug candidates even though their approach to such treatment is different.

We expect that our drug candidates under development and in clinical trials will address major markets within the cancer sector. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of the market introduction of some of our potential drugs or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop drugs, complete pre-clinical testing, clinical trials, approval processes and supply commercial quantities to market are important competitive factors. We expect that competition among drugs approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price and patent protection.

*The successful development of biopharmaceuticals is highly uncertain. A variety of factors including, pre-clinical study results or regulatory approvals, could cause us to abandon development of our drug candidates.*

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

- pre-clinical study results that may show the product to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or a BLA, preparation, discussions with the FDA, an FDA request for additional pre-clinical or clinical data or unexpected safety or manufacturing issues;
- manufacturing costs, pricing or reimbursement issues, or other factors that make the product not economical; and
- the proprietary rights of others and their competing products and technologies that may prevent the product from being commercialized.

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

### **Risks Related to the Securities Markets and Investments in Our Common Stock**

*The price of our common stock may be subject to extreme price fluctuations that could adversely affect your investment.*

The trading price of our common stock may fluctuate substantially. The price of the common stock that will prevail in the market may be higher or lower than the price you have paid, depending on many factors, some of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose part or all of your investment in our common stock. Factors that could cause fluctuations include, but are not limited to, the following:

- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in our earnings or fluctuations in our operating results or in the expectations of securities analysts;
- general economic conditions and trends;
- major catastrophic events;

- sales of large blocks of our stock;
- departures of key personnel;
- changes in the regulatory status of our drug candidates, including results of our clinical trials;
- events affecting the Cleveland Clinic, Roswell Park Cancer Institute, ChemBridge Corporation or any other collaborators;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;
- regulatory developments in the United States and other countries;
- failure of our common stock to be listed or quoted on the Nasdaq Capital Market, other national market system or any national stock exchange;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.



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

***We may incur increased costs as a result of recently enacted and proposed changes in laws and regulations relating to corporate governance matters.***

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the Securities and Exchange Commission, or SEC, and by the Nasdaq Capital Market, will result in increased costs to us as we evaluate the implications of these laws and regulations and respond to their requirements. These laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We are presently evaluating and monitoring developments with respect to these laws and regulations and cannot predict or estimate the amount or timing of additional costs we may incur to respond to their requirements.

***There is no assurance of an established public trading market for our common stock.***

A regular trading market for our common stock may not be established or sustained in the future. Market prices for our common stock will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering;
- changes in interest rates;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- variations in quarterly operating results;
- change in financial estimates by securities analysts;
- the depth and liquidity of the market for our common stock;
- investor perceptions of our company and the biopharmaceutical and biotech industries in general; and
- general economic and other national conditions.

***A limited public trading market may cause volatility in the price of our common stock that could adversely affect your investment.***

Our common stock has been approved for quotation on the Nasdaq Capital Market and for listing on the Boston Stock Exchange. The quotation of our common stock on the Nasdaq Capital Market and its listing on the Boston Stock Exchange does not assure that a meaningful, consistent and liquid trading market will exist, and in recent years, the market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility. Sales of substantial amounts of

common stock, or the perception that such sales might occur, could adversely affect the prevailing market prices of our common stock. Our stock price may decline substantially in a short time and our stockholders could suffer losses or be unable to liquidate their holdings.

***We may not be able to achieve secondary trading of our stock in certain states because our common stock is not nationally traded.***

Until our common stock is approved for trading on the Nasdaq Global Market or listed for trading on a national securities exchange, trading in or the offer and sale of our common stock will be subject to the securities laws of the various states and jurisdictions of the United States in addition to federal securities law. These laws cover any primary offering and all secondary trading by our stockholders. While we intend to take appropriate steps to register our common stock or qualify for exemptions for our common stock in all of the states and jurisdictions of the United States, if we fail to do so, the investors in those jurisdictions where we have not taken such steps may not be allowed to purchase our stock or those who presently hold our stock may not be able to resell their shares without substantial effort and expense. These restrictions and potential costs could be significant burdens on our stockholders.

***Our executive officers and directors control our business and may make decisions that are not in our stockholders' best interests.***

As of March 30, 2007, our officers and directors, in the aggregate, beneficially owned approximately 17.82% of the outstanding shares of our common stock on a fully diluted basis. As a result, such persons, acting together, have the ability to substantially influence all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets, and to control our management and affairs. Accordingly, such concentration of ownership may have the effect of delaying, deferring or preventing a change in discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would be beneficial to other stockholders. Our founders and executive officers together with two of our stockholders, The Cleveland Clinic Foundation and ChemBridge Corporation, have agreed that in the event of a liquidation, dissolution, bankruptcy or receivership of the Company during the 24 months after July 20, 2006, the effective date of our initial public offering, they will subordinate their right to receive any proceeds until each other holder of our common stock has received an amount equal to the number of shares held multiplied by the public offering price. Such founders, officers and stockholders have also agreed during the same 24-month period not to sell, transfer or otherwise dispose of their shares in a tender offer, merger or other sale transaction unless such transaction is approved by a majority of the other stockholders.

***Sales of additional equity securities may adversely affect the market price of our common stock and your rights in us may be reduced.***

We expect to continue to incur drug development and selling, general and administrative costs, and in order to satisfy our funding requirements, we may need to sell additional equity securities, which may be subject to certain registration rights. The sale or the proposed sale of substantial amounts of our common stock in the public markets may adversely affect the market price of our common stock and our stock price may decline substantially. Our stockholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, any new securities issued may have greater rights, preferences or privileges than our existing common stock.

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

We are authorized to issue 40,000,000 shares of our common stock and 10,000,000 shares of our preferred stock. As of March 30, 2007, we had 11,889,099 shares of our common stock issued and outstanding, excluding shares issuable upon the exercise of our outstanding warrants and options, and 4,579,010 shares of our Series B Convertible Preferred Stock, or Series B Preferred, issued and outstanding. As of March 30, 2007, we had outstanding 562,990 options to purchase shares of our common stock with exercise prices ranging from \$0.66 to \$9.14 per share of which 281,120 options have vested or will vest within 60 days of March 30, 2007, and outstanding warrants to purchase 3,457,821 shares of our common stock with exercise prices ranging from \$1.13 to \$11.00 per share, of which 825,219 are exercisable within 60 days of March 30, 2007. To the extent the shares of common stock are issued or options and warrants are exercised, holders of our common stock will experience dilution. In addition, in the event of any future financing of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution.

***Shares eligible for future sale may adversely affect the market.***

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 promulgated under the Securities Act of 1933, as amended, subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one-year holding period may, under certain

circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitations, by a non-affiliate of our company who has satisfied a two-year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have an adverse effect on the market price of our securities.

An aggregate of 1,700,000 shares of common stock have been registered with the SEC. A total of 4,453,601 shares of common stock are being registered pursuant to the registration statement of which this prospectus forms a part. All of these shares would otherwise be eligible for future sale under Rule 144 after passage of the minimum one-year holding period for holders who are not officers, directors or affiliates of the company. We have also agreed to register with the SEC on or before June 14, 2007, up to an aggregate of approximately 7,211,612 shares of common stock issuable upon conversion of our Series B Preferred or exercise of our Series B Warrants or Series C Warrants.

***Because we will not pay cash dividends, stockholders may have to sell shares in order to realize their investment.***

We have not paid any cash dividends on our common stock and do not intend to pay cash dividends on our common stock in the foreseeable future. We intend to retain future earnings, if any, for reinvestment in the development and expansion of our business. Any credit agreements, which we may enter into with institutional lenders, may restrict our ability to pay dividends. Whether we pay cash dividends in the future will be at the discretion of our board of directors and will be dependent upon our financial condition, results of operations, capital requirements and any other factors that the board of directors decides is relevant.

***We are able to issue shares of preferred stock with rights superior to those of holders of our common stock. Such issuances can dilute the tangible net book value of shares of our common stock.***

Our Certificate of Incorporation provides for the authorization of 10,000,000 shares of “blank check” preferred stock. Of such authorized shares, 3,750,000 of these shares were previously designated as Series A Participating Convertible Preferred Stock, or Series A Preferred Stock and 4,579,010 of these shares have been designated as Series B Preferred. All of the outstanding Series A Preferred Stock converted into common stock in connection with our initial public offering. Pursuant to our Certificate of Incorporation, our board of directors is authorized to issue such “blank check” preferred stock with rights that are superior to the rights of stockholders of our common stock, at a purchase price then approved by our board of directors, which purchase price may be substantially lower than the market price of shares of our common stock, without stockholder approval.

### **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events. These statements include, but are not limited to:

- statements as to the anticipated timing of clinical tests and other business developments;
- statements as to the development of new products and the commercialization of products;
- expectations as to the adequacy of our cash balances to support our operations for specified periods of time and as to the nature and level of cash expenditures; and
- expectations as to the market opportunities for our drug candidates as well as our ability to take advantage of those opportunities.

These statements may be found in the sections of this prospectus entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, and “Business,” as well as in this prospectus generally. Actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including all the risks discussed in “Risk Factors” and elsewhere in this prospectus.

In addition, statements that use the terms “can,” “continue,” “could,” “may,” “potential,” “predicts,” “should,” “will,” “believe,” “plan,” “intend,” “estimate,” “anticipate,” “scheduled” and similar expressions are intended to identify forward-looking statements. All forward-looking statements in this prospectus reflect our current views about future events and are based on assumptions and are subject to risks and uncertainties that could cause our actual results to differ materially from future results expressed or implied by the forward-looking statements. Many of these factors are beyond our ability to control or predict. Forward-looking statements do not guarantee future performance and involve risks and uncertainties. Actual results will differ, and may differ materially, from projected results as a result of certain risks and uncertainties. The risks and uncertainties include, without limitation, those described under “Risk Factors” and elsewhere in this prospectus, and include, among others, the following:

- our limited operating history and ability to continue as a going concern;
- our ability to successfully develop and commercialize products;
- a lengthy approval process and the uncertainty of the FDA and other government regulatory requirements;
- clinical trials that fail to demonstrate the safety and effectiveness of our applications or therapies;
- the degree and nature of our competition;
- our ability to employ and retain qualified employees; and
- the other factors referenced in this prospectus, including, without limitation, under the section entitled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and “Business.”

These risks are not exhaustive. Other sections of this prospectus may include additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or to the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results. These forward-looking statements are made only as of the date of this prospectus. Except for our ongoing obligation to disclose material information as required by federal securities laws, we do not intend to update you concerning any future revisions to any forward-looking statements to reflect events or circumstances occurring after the date of this prospectus.

### **USE OF PROCEEDS**

All proceeds from the sale of the shares offered by this prospectus will be received by the selling stockholders, although we will receive proceeds from the exercise of the warrants if any are exercised.

## DIVIDEND POLICY

We have neither declared nor paid any cash dividend on our common stock, and we currently intend to retain future earnings, if any, to finance the expansion of our business, and therefore do not expect to pay any cash dividends in the foreseeable future. The decision whether to pay cash dividends on our common stock will be made by our board of directors, in their discretion, and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers significant.

Shares of our Series B Preferred entitle their holders to an annual dividend payment at the rate of 5% payable in semi-annual installments until the earlier of conversion into shares of common stock or the maturity date.

## PRICE RANGE OF COMMON STOCK

Since July 21, 2006, our common stock has been quoted on the Nasdaq Capital Market under the symbol "CBLI" and listed on the Boston Stock Exchange under the symbol "CFB." The following table sets forth, for the period indicated, the high and low closing sale prices for our common stock as reported by the Nasdaq Capital Market.

|   | <b>High</b> | <b>Low</b> |
|---|-------------|------------|
| <b><u>2007</u></b>                      |             |            |
| Second Quarter (through April 10, 2007) | \$ 9.24     | \$ 8.28    |
| First Quarter                           | \$ 13.38    | \$ 4.56    |
| <b><u>2006</u></b>                      |             |            |
| Fourth Quarter                          | \$ 5.87     | \$ 4.25    |
| Third Quarter (from July 21, 2006)      | \$ 6.00     | \$ 4.17    |

On April 10, 2007, the last reported sales price of our common stock as reported on the Nasdaq Capital Market was \$9.24 per share. As of March 30, 2007, we had 137 holders of record of our common stock.



**CAPITALIZATION**

The following table sets forth the actual capitalization of the company as of December 31, 2006. This table should be read in conjunction with our Financial Statements and the Notes thereto, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the other financial information included elsewhere in this prospectus.

|  | <b>Actual</b> |
|--|---------------|
| Long-term obligations, net of current portion  | \$ 50,000     |
| Convertible notes payable  | -             |
| Accrued interest notes payable   | -             |
| Series A convertible preferred stock; 10,000,000 shares authorized, 0 shares outstanding     | -             |
| Additional paid-in capital preferred shares  | -             |
| Common stock, \$0.005 par value: 40,000,000 shares authorized, 11,826,389 shares outstanding | 59,132        |
| Additional paid-in capital   | 18,314,097    |
| Accumulated deficit  | (12,775,910)  |
| Other comprehensive loss   | (4,165)       |
| Total stockholders' equity   | 5,593,154     |
| Total capitalization   | \$ 5,643,154  |

The above table excludes as of December 31, 2006:

- 483,490 shares of common stock issuable upon exercise of outstanding options with exercise prices ranging from \$0.66 to \$6.00 per share;
- 814,424 shares of common stock issuable upon exercise of warrants with exercise prices ranging from \$1.13 to \$8.70 per share; and
- 1,955,000 shares of common stock reserved for issuance under our 2006 Equity Incentive Plan.

**SELECTED FINANCIAL DATA**

We have derived the following selected financial data for the years ended December 31, 2006, December 31, 2005 and December 31, 2004 from our audited financial statements. In the opinion of our management, this information contains all adjustments necessary for a fair presentation of our results of operations and financial condition for such periods. The information below is not necessarily indicative of the results of future operations and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

**Statement of Operations Data**

|                                     | <b>December 31,<br/>2006</b> | <b>December 31,<br/>2005</b> | <b>December 31,<br/>2004</b> |
|-------------------------------------|------------------------------|------------------------------|------------------------------|
| Total Revenues                      | \$ 1,708,214                 | \$ 1,138,831                 | \$ 636,341                   |
| Operating Expenses                  |                              |                              |                              |
| Research and Development            | \$ 6,989,804                 | \$ 2,640,240                 | \$ 2,892,967                 |
| Selling, General and Administrative | \$ 2,136,511                 | \$ 986,424                   | \$ 262,817                   |
| Income (Loss) from Operations       | \$ (7,418,101)               | \$ (2,487,833)               | \$ (2,519,443)               |
| Net Income (Loss)                   | \$ (7,222,644)               | \$ (2,386,455)               | \$ (2,523,142)               |

**Balance Sheet Data**

|                            | <b>December 31,<br/>2006</b> | <b>December 31,<br/>2005</b> | <b>December 31,<br/>2004</b> |
|----------------------------|------------------------------|------------------------------|------------------------------|
| Cash and Cash Equivalents  | \$ 3,061,993                 | \$ 1,206,462                 | \$ 94,741                    |
| Total Assets               | \$ 6,416,529                 | \$ 4,253,333                 | \$ 382,219                   |
| Total Liabilities          | \$ 823,375                   | \$ 696,729                   | \$ 756,433                   |
| Total Stockholders' Equity | \$ 5,593,154                 | \$ 3,556,604                 | \$ (374,214)                 |

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*This management's discussion and analysis of financial condition and results of operations and other portions of this prospectus contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking information. Factors that may cause such differences include, but are not limited to, availability and cost of financial resources, results of our R&D efforts and clinical trials, product demand, market acceptance and other factors discussed in this prospectus 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 prospectus.*

### 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, the Company 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 the 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 (including shares of Series B Preferred and Series B Warrants issued to the placement agents) 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 the 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 \$3.14 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 years 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

|                               | <b>Year Ended<br/>December 31,<br/>2006</b> | <b>Year Ended<br/>December 31,<br/>2005</b> | <b>Year Ended<br/>December 31,<br/>2004</b> |
|-------------------------------|---|---|---|
| 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)             | \$ (7,222,644)                              | \$ (2,386,455)                              | \$ (2,523,142)                              |

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**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:

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

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 \$4,349,564 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 \$986,424 were incurred in 2005 versus \$262,817 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 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.

## **BUSINESS**

### **Our Company**

Our company is engaged in drug discovery. Our goal is to identify and develop new types of drugs for protection of normal tissues from exposure to radiation and other stresses, such as toxic chemicals and for cancer treatment. Our initial target 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 in this area. Other potential applications of our drug candidates include reducing the side effects of cancer treatment as well as killing tumor cells.

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 or toxic chemicals or to internal stresses. Apoptosis is a major determinant of tissue damage caused by a variety of medical conditions including cerebral stroke, heart attack or acute renal failure. Conversely, however, apoptosis also is 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.

Our initial drug development is based on drug prototypes discovered at the Cleveland Clinic and exclusively licensed to us. Our core competency, which adds critical value to these prototypes, is our ability to develop and enhance these prototypes through preclinical and clinical development. Our strength in the therapeutic areas of protection from radiation and cancer therapy is another critical component of our core competency.

### **Product Development**

#### *Process*

In general, the process for drug discovery and development includes:

- target discovery — finding what part of the cell is affected by the drug;
- validation — confirmation that hitting the target does what we think and nothing else;

- isolation of prototype drugs using high throughput screening — applying robotics to large collections of chemicals to find the ones that hit the target or effect whole cells in a desirable way;
- hit-to-lead optimization — improving properties of selected chemicals to make drug prototypes by generating chemical derivatives of initial hit and testing properties in an array of assays;
- formal preclinical pharmacological and toxicological drug product characterization — testing safety and efficiency of drugs in primates using highly regulated standard approaches; and
- clinical trials — testing drug safety and actions using humans.



### ***Scientific Foundation***

CBL concentrates on the development of small molecule drugs and biologics focusing on two major therapeutic directions:

- Development of drugs that protect normal tissues from the damaging effects of ionizing radiation and chemotherapy (protectants). This consists more specifically of:
  - development of radioprotectants for non-medical applications, e.g., protection against the military or terrorist use of nuclear weapons; and
  - development of cancer treatment supplements that decrease the side effects of radiation treatment and anticancer drugs and allow for an increased dose of radiation and anticancer drugs to be safely received by a patient.
- Development of anticancer drugs targeting a newly discovered way of regulating cell death (curaxins).

Our drug development strategy is based on several original concepts that view a cell's inherent ability to commit suicide as a target for pharmacological treatment. Depending on the desired outcome, we develop both cell-death inhibiting (for normal tissue protection) and cell-death inducing (for cancer treatment) pharmaceuticals.

*Pharmacological modulation of programmed cell death for protection of normal tissues.* Apoptosis is considered a major determinant of tissue damage associated with a variety of stresses including cerebral stroke, heart attack or acute renal failure. Consequently, pharmacological inhibition of apoptosis is considered a therapeutic strategy for treatment of these conditions. Cancer treatment side effects, resulting from injuries caused by radiation and chemotherapy to normal sensitive tissues, are also associated with apoptosis. This includes injuries to the hematopoietic and immune systems, the epithelium of the digestive tract and hair follicles. We are employing pharmacological inhibition of programmed cell death to combat the side effects of cancer treatment. Indeed, whereas normal sensitive tissues respond to traditional DNA-damaging (genotoxic) anticancer treatment by apoptosis, those tumor cells, which have lost suicidal properties, are killed by these drugs through alternative mechanisms. Therefore, temporary and reversible inhibitors of apoptosis are expected to selectively protect normal tissues having no effect on the tumor's sensitivity to the anticancer drugs. To further assure the selectivity of normal tissue protection, we will embark upon the pharmacological imitation of survival mechanisms that are already active in tumor cells — inhibition of p53 (pro-apoptotic) and/or activation of NF-kB (anti-apoptotic). These concepts are in contrast with conventional views on p53 and NF-kB as cancer treatment targets, which generally hold that p53 should be stimulated and NF-kB should be suppressed.

As the basis for the development of NF-kB-inducing tissue protecting drugs, we will explore a unique source of natural modulators of apoptosis — microbes inhabiting the human body as well as tumors themselves. Both microbial parasites and tumors depend on the viability of the host cells. Therefore, they secrete a variety of factors inhibiting apoptosis of host cells as part of their survival strategy. These natural anti-apoptotic factors, when optimized, form the core of our tissue protecting drugs known as protectants.

*Pharmacological modulation of programmed cell death for cancer treatment.* Apoptosis is an important natural biological mechanism that removes defective cells. Cancer cells, however, frequently acquire defects in their apoptotic machinery as part of their progression strategy, which inhibits the death of these cells. In many tumors, this happens due to the deregulation of two major mechanisms controlling apoptosis — p53 and NF-kB pathways. Thus, in cancer cells, p53 is usually physically or functionally lost, whereas NF-kB becomes constitutively active. As a result, the natural therapeutic procedures that cause death in normal sensitive tissues may not be effectively damaging to cancer

cells. Deciphering mechanisms of apoptosis deactivation in tumors allows for the rational design of new, targeted therapeutic approaches aimed at their restoration, and therefore at the increased killing of cancer cells. Our team has discovered a novel mechanism of tumor resistance to apoptosis that involves functional repression of p53 by constitutively active NF- $\kappa$ B thereby leading to the inhibition of apoptosis. We are developing small molecules, curaxins, capable of killing tumor cells by reversing this mechanism, thereby restoring the ability to undergo apoptosis. Since constitutively active NF- $\kappa$ B is present only in tumor cells, curaxins are harmless to normal tissues.

### **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.

## **Non-Medical 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 radioprotectant known to us is its ability to effectively protect not only the hematopoietic system but also the gastrointestinal 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 gastrointestinal tract may make Protectan CBLB502 uniquely useful as a radioprotective antidote. In addition, Protectan CBLB502 has proved to be a stable compound for storage purposes. It can be stored at temperatures close to freezing and room temperature, and can tolerate extreme heat for a short period of time. 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. In experiments conducted in 2006, 70% of the animals that received whole-body radiation one hour after administration of Protectan CBLB502 survived, as opposed to 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.

In April 2007, we completed an additional study of Protectan CBLB502's efficacy as a mitigator of both gastrointestinal and hematopoietic (bone marrow/blood production) radiation-induced damage in non-human primates. In the study, rhesus monkeys were irradiated with 6.5 Gy of total body irradiation and injected intramuscularly with either a single dose of Protectan CBLB502 or a placebo, one hour after irradiation. No supportive therapy was applied. The animals were observed for 40 days. Protectan CBLB502 enabled survival of 70% of the animals in the protected group, versus the control group, in which 20% of the animals survived. In addition, gross pathology results showed that the majority of control animals displayed severe damage to the GI tract, while the Protectan CBLB502 treated animals did not.

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 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. This drug development strategy complies with recently adopted FDA rules for investigational drugs that address situations such as radiation injury, where it would be unethical to conduct efficacy studies in humans. While Phase II and Phase III human clinical trials are normally required for the 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 24-36 months. Because Phase II and Phase III testing, which each involve testing a drug candidate on large numbers of participants who suffer from the targeted disease and condition, can last for a total of anywhere from three to six or more years, bypassing these phases represents a significant time and savings in getting FDA approval.

As part of this expedited approval process, the FDA has indicated that it intends to engage in a highly interactive review of IND and NDA applications and to provide for accelerated review or approval of certain medical products for counterterrorism applications, including granting eligible applications "Fast Track" approval status.

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 simultaneously with the rest of the steps); and
- file Biologic License Application, or BLA.

In the most optimistic business scenario, these steps could be accomplished by mid-to-late 2008. In a more business conservative scenario, it could take up to 30 months or more to complete the development and approval of Protectan CBLB502 for non-medical applications. We are currently in the process of completing the current GMP-compliant manufacturing, and we plan to hold the pre-IND meeting with the FDA in April 2007.

The Project BioShield Act of 2004, which further expedites approval of drug candidates for certain uses, is aimed to bolster the 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 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.

The law also allows 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 the 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.

Congress recently has enacted the Support Anti-Terrorism by Fostering Effective Technologies (SAFETY) Act and the Public Readiness and Emergency Preparedness (PREP) Act, each of which provide some level of liability protection to companies involved in the production or distribution of anti-terrorism or military and defense related goods. The SAFETY Act provides to certain sellers of anti-terrorism technologies a qualified limitation of liability based on an amount of liability insurance coverage, a limitation on joint and several liability for non-economic damages, and limitations on punitive damages. The PREP Act offers liability protections to companies involved in the development, manufacturing and deployment of pandemic and epidemic products, and security countermeasures. In addition, as a result of the scaled down FDA approval process and the Project BioShield Act, members of Congress have proposed the Project BioShield II Act of 2005, which would provide for additional product liability protection for companies that create vaccines or biological defense drugs that could cause injury to patients. Each of these acts and proposed acts are of recent vintage and have not been subject to much clarification or been subject to much litigation, and therefore, the scope and availability of these protections, as interpreted by courts, have not been fully demonstrated. While we anticipate that our drug candidates developed for these types of uses will be afforded some level of protection under these laws, we cannot predict with any certainty that the enactment of these laws will provide us with a defense to any potential litigation or claim of liability.

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.

### **Medical Applications**

In addition to 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 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 the placebo drug.

A pilot study conducted from December 2005 to July 2006 by Frontier Biotechnologies, Inc. at the National Chengdu Center for Safety Evaluation of Traditional Chinese Medicine in China in which 20 non-human primates received lethal doses of radiation demonstrated a 10-day delay of radiation-associated mortality and a significant reduction in death rates (from 75% to 25%) in the group of animals treated with Protectan CBLB502 without any associated signs of toxicity. An equal degree of protection was achieved in a subgroup of non-human primates that were previously exposed to Protectan CBLB502 demonstrating that Protectan CBLB502 is effective despite multiple administrations, which is not always the case with most protein based drugs. In addition, in the Protectan CBLB502 treated group, half of the non-human primates that survived radiation showed no gross pathologies. In the rest of the survivors from this group, radiation-induced damage to the lymphoid organs and gastrointestinal tract was significantly less pronounced than that suffered by survivors in the control group, which received no radioprotectants. The observed radioprotective efficacy of Protectan CBLB502 may be attributed to a rapid and substantial increase in the blood concentration of a number of tissue protecting growth factors and cytokines following its injection. Although these results are preliminary in nature and results discovered in animal trials are often not indicative of results in humans, they are encouraging because they indicate that Protectan CBLB502 has radioprotective properties.

The use of Protectan CBLB502 to ameliorate the side effects of radiation treatment and anticancer drugs is 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, RCC, 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. But we have discovered new mechanisms of action for quinacrine in the area of apoptosis.

Through assay testing performed in Dr. Gudkov's laboratories 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.

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 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, that has produced sufficient quantities of Curaxin CBLC102 according to the process previously used for production of this drug when it was in common use. In preparation for the IND clinical studies, a stability program for API will be conducted by the producers. For Phase IIb, Phase III and final production, several other vendors will also be reviewed on a competitive basis to select the site for large-scale manufacturing. 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 for such clinical studies.

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

### **Product Development Schedule and Capital Requirements**

Drug development is a slow, expensive, risky and highly volatile process. A survey conducted by the Tufts Center for the Study of Drug Development in 2001 estimated that from the commencement of R&D to FDA approval of a drug, a drug company typically spends approximately \$800 million dollars over a 10 to 15 year period.

We intend to continue R&D of our innovative drug candidates by utilizing technologies and product prototypes licensed from research institutions (e.g., the Cleveland Clinic, which advances our efforts at producing a final product, and adding to them new compounds discovered in-house. Specifically, our efforts are focused on Protectan CBLB502 with potential applications in both non-medical and medical areas and on its newly discovered properties, which allow us to develop this drug candidate as a supportive agent during radiotherapy. We will also continue our work on Curaxin CBLC102 for anticancer therapy. This development will be supplemented with discovery efforts preparing new generations of our drugs. Our development projects are prioritized based on our estimate of the distance from a final product or licensing end-point and the probability of success. Projects will be implemented in parallel or sequential fashion, as resources permit.

We plan to use our existing funds to achieve the following objectives:

- Phase I safety clinical trials for non-medical applications of Protectan CBLB502;
- pivotal study of Protectan CBLB502 using primates for non-medical applications (an equivalent of Phase II/III clinical study);
- filing an IND followed by an NDA to receive all necessary regulatory approvals to manufacture and sell Protectan CBLB502 for non-medical applications;
- preclinical studies, IND filing and Phase I clinical studies for the medical use of Protectan CBLB502;

- clinical studies for Curaxin CBLC102 (Phase IIa in multiple cancers); and
- additional discovery, lead optimization and preclinical studies aimed at developing new generation of curaxins and protectans.

Our selected development projects are unified by a common therapeutic focus and are built upon a common scientific paradigm. We believe that our distinct projects expand the potential value of a common technology. Our seasoned management team will constantly monitor the progress of our projects at the key objectives and compare them with pre-established developmental milestones. By supporting and carefully managing several projects simultaneously, we will attempt to reduce short-term risk and contribute to our long-term potential.

As a result of the outlined development, Protectan CBLB502 may be approved for non-medical applications within 18-36 months. During the same period of time, we also expect to conduct Phase I trials of Protectan CBLB502 with a view to demonstrating its utility for cancer treatment. Additionally, we will continue with Phase II clinical trials of Curaxin CBLC102 for hormone refractory prostate cancer and expect to commence Phase II clinical trials of Curaxin CBLC102 for RCC and soft-tissue sarcoma.

In addition to our existing funds, we will pursue other sources of capital to fund additional development of products.

- *Grants* — Through December 31, 2006, we have received 12 government grant commitments from NIH, DOD and NASA totaling \$4,245,000 including the prestigious \$1,500,000 R01 award from NIH and \$750,000 R02 award from NIH. Each grant awarded is confined to the scope of work described in the grant application and the grant funds cannot be used for any other purpose. The grantee provides the grantor with a final report detailing the results of the work and, depending on the terms of the specific grant, may need to provide status reports on an ongoing basis. The table below lists each of the 12 government grants awarded to us to date.

| Agency | Title   | Amount       | Project    | Status    |
|--------|---|--------------|------------|-----------|
| NASA   | New class of biological radioprotectors   | \$ 70,000    | Protectans | Completed |
| NIH    | N-myc targeted thereapeutics for childhood neuroblastoma                                      | \$ 100,000   | Curaxins   | Completed |
| NIH    | Radioprotectors targeting p53   | \$ 100,000   | Protectans | Completed |
| NIH    | Development of new inhibitors of androgen receptors   | \$ 100,000   | Curaxins   | Completed |
| DARPA  | Tissue protecting antidotes from anti-apoptotic factors of Mycoplasma                         | \$ 475,000   | Protectans | Completed |
| NIH    | Bacterial proteins as cancer drugs and radioprotectors  | \$ 100,000   | Protectans | Completed |
| NIH    | Protecting immune system by modulators of p53 and NF-kB                                       | \$ 1,500,000 | Protectans | Funded    |
| NIH    | New approach to improve abdominopelvic radiotherapy by protecting small intestine             | \$ 100,000   | Protectans | Completed |
| NIH    | Effective Radioprotectants Targeting Toll-like Receptor 5                                     | \$ 100,000   | Protectans | Completed |
| NASA   | Use of CBLB502 against biologically harmful effects of ionizing radiation during space flight | \$ 100,000   | Protectans | Funded    |
| NIH    | N-myc targeted therapeutics for childhood neuroblastoma                                       | \$ 750,000   | Curaxins   | Funded    |

Besides being a source of non-dilutive cash, grants play two very important roles:

- validating our science by passing a rigorous review process; and
- creating awareness by exposure to a professional bio-medical community.

· *License of Early-Stage Leads* — In addition to Protectan CBLB502 and Curaxin CBLC102, we possess certain compound prototypes which we are developing with a view to offering them to a pharmaceutical or biotechnology company for strategic alliance or licensing transactions.

We cannot be certain that we will be successful in attracting additional capital from any of the foregoing sources to fund our development of drugs. In the event that we do not successfully attract additional capital, our business, prospects, financial condition and results of operations could be adversely affected.

### **Research and Development**

Over nearly two years of operations, we have been able to build an R&D team headed by our founder and Chief Scientific Officer, Dr. Andrei Gudkov, a distinguished scientist with numerous publications and patents. Our Vice President of Drug Development, Dr. Farrel Fort, who spent 20 years at Abbott Laboratories and TAP Pharmaceutical where he was the Director of Drug Safety, supervises our drug development efforts. Over the last 10 years, the labs of Drs. Gudkov and George Stark of the Cleveland Clinic have received more than \$20 million of grant funding for the development of the basic science forming our technological foundation. Our fully equipped 6,500 square foot research facilities include a modern high-throughput screening, or HTS, core and versatile molecular biology and cell culture capabilities.

Besides academic grants already received by the labs of our scientific founders, we are also eligible for government support. We have historically received approximately 30% of our grant revenues through the SBIR and Small Business Technology Transfer grant programs. As a result of our growth, however, we have ceased to be eligible for SBIR grant programs, and therefore no longer qualify to receive these grants.

We have submitted 14 grant applications to NIH, DOD and NASA. As of December 31, 2006, 12 of the 14 grant applications have been awarded to us bringing \$4,245,000 in grant commitments to our R&D programs.

### **Licensing Revenues**

Licensing and other payments from large pharmaceutical companies (and other institutions, including the U.S. government) are a major revenue source for biotech companies in the process of developing drugs. Licensing and acquisition transactions with large pharmaceutical companies are struck at all stages of drug development, from early discovery to Phase III clinical trials. For example, large pharmaceutical companies, such as Bristol-Myers Squibb Co., Johnson & Johnson, Amgen Inc., AstraZeneca and Novartis AG, that dominate the anticancer drug market, distribute major anticancer drugs that were initially developed by biotech companies. Over the last decade, there has been a substantial increase in the number of collaborative deals between large pharmaceutical companies and biotech companies with the average deal amount increasing to \$30 million in 2003. Such licensing deals can be an attractive way to realize the value of a potential product of a biotech company early in the R&D process — an approach we intend to strategically employ. Historically, some of the larger biopharmaceutical licensing deals have been in the field of cancer research. In addition to bringing in early revenues, such discussions can also serve as an invaluable opportunity to gauge the true market value of specific drug candidates. However, as of the date of this prospectus, we have not realized any revenue from licensing arrangements.

### **Strategic Partnerships**

CBL's development is supported by its strategic partners and founders, the Cleveland Clinic and ChemBridge. Besides being a source of critical intellectual property, the Cleveland Clinic provides access on favorable economic terms to its multiple research cores and animal care facilities, which allows us to avoid building this type of infrastructure and focus instead on mission-critical research and drug development. Even more importantly, leading physicians of the Cleveland Clinic are involved in the design of our clinical trials, which will take place at the Cleveland Clinic among other locations, providing invaluable expertise in various cancer types and radiological treatment. Additionally, we may license certain future intellectual property developed in a laboratory at the Cleveland Clinic headed by one of our founders through our existing exclusive license for cancer applications and tissue protection with the Cleveland Clinic, which we believe will provide a good supply of new concepts and leads for future development.

ChemBridge provided us with access to 180,000 compounds of its compound library in exchange for 357,600 shares of our common stock and warrants to purchase 264,624 shares of our common stock. ChemBridge also expects to play a key role in hit-to-lead optimization providing necessary chemical expertise and synthetic capabilities. Our agreement with ChemBridge allows us to utilize these capabilities for a 50% share in the ownership of two lead compounds selected by ChemBridge and all derivative compounds thereof in lieu of cash reducing our development exposure.

In January 2007, we entered into a strategic research partnership with 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.

We are seeking new strategic partnerships to support the development of our drug candidates. We have engaged in discussions with several leading pharmaceutical and biotech entities as well as various government institutions. In August 2004, we entered into five-year cooperative research and development agreement, or CRADA, with the Uniformed Services University of the Health Sciences which includes the Armed Forces Radiobiology Research Institute (AFRRI), the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (Henry Foundation) and the Cleveland Clinic to:

- evaluate radioprotectant candidates originating from the Cleveland Clinic;
- obtain information on the effects of the radioprotectant candidates originating from AFRRI on intracellular and extracellular signaling pathways; and
- if promising candidates emerge from the radioprotectant candidates supplied by the Cleveland Clinic, develop a plan and initiate studies of these compounds to the FDA to obtain IND status.



The agreement may be unilaterally terminated by any party upon 30 days prior written notice with or without cause. Under the terms of the agreement, all parties are financially responsible for their own expenses related to the agreement. We also discuss from time to time other collaborations with other potential partners. However, there can be no assurance that any of these discussions will result in collaborations on favorable terms or at all.

### **Our Intellectual Property**

Our intellectual property platform is based primarily on 13 patent applications exclusively licensed to us by the Cleveland Clinic and three patent applications, which we have filed and own, all in the field of regulating cell death that cover new cancer treatment concepts, methods of drug discovery and drug candidates isolated in the laboratory of Dr. Andrei Gudkov. Our license with the Cleveland Clinic is for an indefinite term and we may license additional intellectual property in the same licensed field from the Cleveland Clinic in the future. 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 within 90 days of receipt of such termination notice we cure the breach. As consideration for this license, we issued the Cleveland Clinic 1,341,000 shares of common stock and agreed to make certain milestone, royalty and sublicense royalty payments. No milestone payments, royalties or sublicense royalties were recognized or paid through the year ended December 31, 2005. We have, however, as of December 31, 2006, accrued \$50,000 in connection with milestone payments relating to the filing of an IND for Curaxin CBLC102.

The aforementioned 13 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 Aminoacridenes;;
- Activation of p 53 and Inhibition of NF-kB for Cancer Treatment;
- Modulation of Immune Responses;
- Methods of Protecting Against Apoptosis Using Lipopeptides;
- Modulation of Cell Growth; and
- Mitochondrial Cytochrome B

The aforementioned three patent applications, which we filed and own, 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).

### **Need and Opportunity**

Our portfolio of drug candidates and our technological platform are intended to address a broad array of medical problems. We see utility of our potential drug candidates in the following areas:

- protection from the biological effects of a terrorist attack, military use of nuclear devices and accidents involving radiation (protectans);

- reduction of side effects of anticancer treatment (protectans); and
- new therapies aimed at orphan cancer types such as hormone refractory prostate cancer, RCC and soft-tissue sarcoma using drugs capable of restoring apoptosis in tumors (curaxins).

Upon development of the first generation of drug candidates, we intend to extend our potential market, focusing on one or more major cancer types, such as prostate and colon cancers, and other diseases caused by genotoxic stress.

### ***Non-Medical Applications of Protectans***

Recent acts of terrorism and the proliferation of nuclear weapons programs in rogue states have magnified the importance of radioprotectants in military applications. The potential threat of a terrorist attack using a conventional explosive embedded with radioactive material, or “dirty bomb”, or a nuclear device has caused the U.S. government to appropriate significant dollars in the area of Homeland Security and Emergency Preparedness. In a recent legislative act, the Project BioShield Act of 2004, the U.S. government allocated an extra \$5.6 billion over ten years for countermeasures against these threats. As of March 26, 2006, under the Project BioShield Act of 2004, there have only been three contracts awarded for the treatment of radiation, which accounted for approximately \$38 million of the over approximately \$1 billion awarded.

Should either threat become a reality, emergency responders would have to enter the impact area to rescue survivors, assess damage, make repairs and perform containment, thereby potentially exposing themselves to lethal doses of radiation. An emergency of any magnitude, combined with the limited window after radiation exposure in which a drug is effective, would require a stockpile of any drug used to treat the effects of radiation.

The core meltdown, and resulting explosions, at the Chernobyl nuclear power plant in the Ukraine in April 1986 illustrates the impact such events could have on a surrounding population and the need for stockpiling radioprotectants. Officials estimate that at least 600,000 people were involved in some aspect of cleanup and more than 15 million people were exposed to heightened radiation, resulting in medical costs of more than \$60 billion.

High-risk areas include military installations and theater of operations, any urban or metropolitan areas at risk of radiation attack, and a 10-50 mile radius around nuclear power plants or spent fuel facilities. In the New York City metropolitan area, for example, approximately 20 million people live within 50 miles of the Indian Point nuclear power plant located just 35 miles north of New York City thereby creating a large market for stockpiling radioprotectants. In addition, similar market opportunities may exist in both Europe and Asia to the extent permitted by U.S. and foreign government authorities. Other products in the bio-defense area have been granted licenses to export into specific countries by the U.S. State Department in accordance with export regulations, including International Traffic in Arms Regulations.

Currently, the only drug that is considered appropriate for stockpiling for protection against radiation injury is potassium iodide (KI). While KI is useful in protecting the thyroid from the long-term risk of thyroid cancer, it is not useful in protecting against the acute effects of radiation injury and ensuing infections. In Europe, KI has been stockpiled for years in sufficient quantities to treat all civilians living within a number of miles of any of the 300 nuclear power plants in the event of a nuclear accident. Stockpiling of KI has also recently begun for civilians living within 10-50 miles of the 103 active nuclear power plants in the U.S. For example, California recently announced plans to buy 880,000 doses of KI to protect people living close to either of the state’s two nuclear plants.

### ***Medical Applications of Protectans***

Radiotherapy is the most common modality for treating human cancers. Approximately 50%-60% of cancer patients need radiotherapy at some stage of treatment, either for curative or palliative purposes. To obtain optimal results, a

judicious balance between the total dose of radiotherapy delivered and the threshold of the surrounding normal critical tissues is required. In order to obtain better control with a higher dose, normal tissue must be protected against radiation injury. Thus, the role of radioprotective compounds is very important in clinical radiotherapy.

Currently, the only available radioprotectant for cancer patients on the market is Ethyol® (aminofostine), which is produced by MedImmune Inc. Aminofostine is considered an inadequate radioprotectant because of its severe side effects and sub-optimal efficacy. Consequently, its sales have been limited.

The U.S. market for anticancer therapeutics is large and growing. The American Cancer Society estimates overall annual cancer costs in the United States at \$189.8 billion: \$69.4 billion for direct medical costs, \$16.9 billion for morbidity costs, and \$103.5 billion for mortality costs. Treatment of breast, lung and prostate cancer accounts for over half of the direct medical costs. The market for anticancer drugs, valued at more than \$15 billion in 1998, was projected to nearly double by 2003, and, ultimately, exceeded this projection.

Excessive loss of normal, non-cancerous cells through the mechanism of apoptosis occurs during both drug and radiation cancer treatments. The adverse effects of these therapies include injuries to the hematopoietic and immune systems, the epithelium of the digestive tract and hair follicles. Despite significant efforts in the anticancer drug market, some cancer patients die from complications from the drugs, and a significant number of patients cannot tolerate chemotherapy drug regimens due to their toxic side effects. Some of the side effects are dose limiting in that they do not allow the patient to take higher doses or longer treatment, ultimately reducing the potency of the therapy. Two of the most common side effects, chemo-nausea and fatigue, are likely to be reduced by drugs protecting the hematopoietic and gastrointestinal systems similar to Protectan CBLB502. This creates an opportunity for us to offer our drug candidate to a substantial number of patients in a multibillion dollar anti-cancer drug market .

### ***New therapies aimed at cancer (Curaxins)***

We have prioritized our primary disease targets for Curaxin CBLC102 as hormone refractory prostate cancer, RCC and soft-tissue sarcoma based on several factors, including the results of our preliminary research, readily identifiable partnering opportunities, potential or orphan drug status and alternative treatments in other cancer areas.

Prostate cancer is the most common cancer in men in the United States other than skin cancer. According to the American Cancer Society, an estimated 234,460 cases were projected to be diagnosed with prostate cancer in 2006. The majority of patients who are diagnosed with localized prostate cancer are treated and cured with either radiation or surgery. Patients in whom treatment with curative intent is unsuccessful and those who present with metastasis are candidates for androgen suppression. The majority of men who are deprived of androgens, however, ultimately progress to an androgen-independent phase where the initial androgen suppression regimen no longer controls the tumor. As a result, treatment for the androgen-independent phase of prostate cancer is a clear unmet medical need.

RCC is a niche cancer that accounts for 3% of all cancer cases in the United States, but is the most common type of kidney cancer in adults. In the United States, approximately 35,000 — 40,000 patients are diagnosed with RCC annually. For early-stage cancer, the five-year survival rate is 60% to 70%. If the cancer has spread to the lymph nodes, the five-year survival rate is 5% to 15%. If it has spread to other organs, the five-year survival rate is less than 5%. Although the market for RCC treatment is relatively small and large pharmaceutical companies generally are unlikely to enter into the market with their own products that compete directly with us, we may see competition in the RCC market from Wyeth Research and Aeterna Laboratories which are in the late stage development of second-line therapies to combat RCC. These products are aimed at achieving better toxicity profiles and greater survival benefits than conventional treatments for stage IV RCC. Nevertheless, the high mortality rate and small market size may cause other large pharmaceutical companies to license products from a company such as us instead of developing their own products.

Soft-tissue sarcomas are rare, representing only about 1% of all cancer cases. According to the American Cancer Society, approximately 9,400 new cases of soft-tissue sarcoma were projected to be diagnosed in the United States in 2006, which were projected to be responsible for approximately 3,500 deaths per year. If detected early, before it has had a chance to spread, the five-year survival rate is approximately 90%. Treatment requires surgery and radiation therapy with chemotherapy used as an additional means to deal with distant reoccurrences and metastases.

### **Competition**

#### **Non-Medical 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.

### **Medical 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 regulatory 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.

## **Governmental Regulation**

### ***The Drug Regulation Process***

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.

Clinical testing, also known as clinical trials or clinical studies, is either conducted internally by pharmaceutical or biotech companies or is conducted on behalf of these companies by contract research organizations. The process of conducting clinical studies is highly regulated by the FDA, as well as by other government and professional bodies. Below, we describe the principal framework in which clinical studies are conducted, as well as describe a number of the parties involved in these studies.

### **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.

*Protocols.* Before commencing human clinical studies, the sponsor of a new drug must submit an investigational new drug application, or IND, to the FDA. IND status allows initiation of clinical investigation within 30 days of filing of the NDA if the FDA does not respond with questions during the 30-day period. The IND application contains what is known in the industry as a protocol. A protocol is the blueprint for each drug study. The protocol sets forth, among other things, the following:

- who must be recruited as qualified participants;
- how often to administer the drug;
- what tests to perform on the participants; and
- what dosage of the drug to give to the participants.

*Institutional Review Board.* An institutional review board is an independent committee of professionals and lay persons that reviews clinical research studies involving human beings and is required to adhere to guidelines issued by the FDA. The institutional review board does not report to the FDA, but its records are audited by the FDA. Its members are not appointed by the FDA. An institutional review board must approve all clinical studies. The institutional review board's role is to protect the rights of the participants in the clinical studies. It approves the protocols to be used, the advertisements that the company or contract research organization conducting the study proposes to use to recruit participants, and the form of consent that the participants will be required to sign prior to their participation in the clinical studies.

*Clinical Trials.* Human clinical studies or testing of a potential product are generally done in three stages known as Phase I through Phase III testing. The names of the phases are derived from the regulations of the FDA. Generally, there are multiple studies conducted in each phase.

*Phase I.* Phase I studies involve testing a drug or product on a limited number of healthy participants, typically 24 to 100 people at a time. Phase I studies determine a drug's basic safety and how the drug is absorbed by, and eliminated from, the body. This phase lasts an average of nine months to a year.

*Phase II.* Phase II trials involve testing up to 200 participants at a time who may suffer from the targeted disease or condition. Phase II testing typically lasts an average of one to two years. In Phase II, the drug is tested to determine its safety and effectiveness for treating a specific illness or condition. Phase II testing also involves determining acceptable dosage levels of the drug. If Phase II studies show that a new drug has an acceptable range of safety risks

and probable effectiveness, a company will continue to study the substance in Phase III studies.

Phase II trials are sometimes combined with Phase III trials. These Phase II/III trials differ from Phase II trials 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.* Phase III studies involve testing large numbers of participants who suffer from the targeted disease or condition, typically several hundred to several thousand people. The purpose is to verify the effectiveness and long-term safety on a large scale. These studies generally last two to three years and are conducted at multiple locations or sites. Like the other phases, Phase III requires the site to keep detailed records of data collected and procedures performed.

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 Approval.* The results of the clinical trials are submitted to the FDA as part of a new drug application, or NDA. Following the completion of Phase III studies, assuming the sponsor of a potential product in the United States believes it has sufficient information to support the safety and effectiveness of its product, it submits an NDA to the FDA requesting that the product be approved for marketing. The application is a comprehensive, multi-volume filing that includes the results of all clinical studies, information about the drug's composition, and the sponsor's plans for producing, packaging and labeling the product. The FDA's review of an application can take a few months to several years, with the average review lasting 18 months. Once approved, drugs and other products may be marketed in the United States, subject to any conditions imposed by the FDA.

*Phase IV.* The FDA may require that the sponsor conduct additional clinical trials following new drug approval. The purpose of these trials, known as Phase IV studies, is to monitor long-term risks and benefits, study different dosage levels or evaluate safety and effectiveness. In recent years, the FDA has increased its reliance on these trials. Phase IV studies usually involve thousands of participants. Phase IV studies also may be initiated by the company sponsoring the new drug to gain broader market value for an approved drug. For example, large-scale trials may also be used to prove the effectiveness and safety of new forms of drug delivery for approved drugs. Examples may be using an inhalation spray versus taking tablets or a sustained-release form of medication versus capsules taken multiple times per day.

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.

*Fast Track Approval.* On November 21, 1997, former President Clinton signed into law the Food and Drug Administration Modernization Act. That law codified the FDA's policy of granting "Fast Track" approval for cancer therapies and other therapies intended to treat serious or life threatening diseases and that demonstrate the potential to address unmet medical needs. The Fast Track program emphasizes close, early communications between the FDA and the applicant to improve the efficiency of preclinical and clinical development, and to reach agreement on the design of the major clinical efficacy studies that will be needed to support approval. Under the Fast Track program, a sponsor also has the option to submit and receive review of parts of the NDA or BLA on a rolling schedule approved by the FDA, which expedites the review process.

The FDA's Guidelines for Industry Fast Track Development Programs require that a clinical development program must continue to meet the criteria for Fast Track designation for an application to be reviewed under the Fast Track Program. Previously, the FDA approved cancer therapies primarily based on patient survival rates or data on improved quality of life. While the FDA could consider evidence of partial tumor shrinkage, which is often part of the data relied on for approval, such information alone was usually insufficient to warrant approval of a cancer therapy, except in limited situations. Under these Guidelines, 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 broadened authority to consider evidence of partial tumor shrinkage or other surrogate endpoints of clinical benefit for approval. This new policy is intended to facilitate the study of cancer therapies and shorten the total time for marketing approvals. Under accelerated approval, the manufacturer must continue with the clinical testing of the product after marketing approval to validate that the surrogate endpoint did predict meaningful clinical benefit. To the extent applicable, we intend to take advantage of the Fast Track programs to obtain accelerated approval on our future drugs, however, it is too early to tell what effect, if any, these provisions may have on the approval of our drug candidates.

*Orphan Drug Act.* The Orphan Drug Act provides incentives to develop and market drugs for rare disease conditions in the United States. A drug that receives orphan drug designation and is the first product to receive FDA marketing approval for its product claim is entitled to a seven-year exclusive marketing period in the United States for that product claim. Although we may not obtain it, we plan to seek orphan drug status for marketing protection from the FDA for the use of Curaxin CBLC102 in the treatment of RCC, soft-tissue sarcoma and hormone refractory prostate cancer. However, it should be noted that a drug that is considered by the FDA to be different than such FDA-approved orphan drug, is not barred from sale in the United States during this exclusive marketing period, even if it receives approval for the same claim.

The FDA requires that any drug or formulation to be tested in humans be manufactured in accordance with its current GMP regulations. The current GMP regulations set certain minimum requirements for procedures, record-keeping and the physical characteristics of the laboratories used in the production of these drugs.

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.

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.
- 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.

### ***Other Regulations***

Various federal and state laws, regulations, and recommendations relating to safe working conditions, laboratory practices, the experimental use of primates, and the purchase, storage, movements, import, export, use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, are applicable to our activities. They include, among others, the United States Atomic Energy Act, the Clean Air Act, the

Clean Water Act, the Occupational Safety and Health Act, the National Environmental Policy Act, the Toxic Substances Control Act, the Resources Conservation and Recovery Act, national restrictions on technology transfer, import, export, and customs regulations and other present and possible future local, state, or federal regulation. The extent of government regulation that might result from future legislation or administrative action cannot be accurately predicted.

***Hazardous Materials***

Our R&D processes involve the controlled use of hazardous materials, chemicals and radioactive materials and produce waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We do not expect the cost of complying with these laws and regulations to be material. We have no manufacturing capabilities. We plan to rely on third parties to manufacture bulk compounds and finished investigational medicines for clinical trials. Commercial quantities of any drugs that we may seek to develop will have to be manufactured in facilities and by processes that comply with FDA and other regulations. We plan to rely on third parties to manufacture commercial quantities of any products that we successfully develop.

## **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.

## **Employees**

As of the date of this prospectus, we have 36 employees.

## **Facilities**

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.

## **Litigation**

As of the date of this prospectus, we are not a party to any litigation or other legal proceeding.

## **Independent Accountants**

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 change in accountants was approved by our board of directors.

In connection with our audits for the years ended December 31, 2003 and 2004, and during the period from the date of its audit of our financial statements for the year ended December 31, 2003 through May 25, 2005, there were no disagreements with Hausser & Taylor on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements if not resolved to the satisfaction of Hausser & Taylor would have caused them to make reference to the disagreement in their report on our financial statements for those years. During the two most recent fiscal years, there have been no reportable events, as described in Regulation S-B Item 304(a)(1)(v) promulgated under the Securities Act of 1933, as amended.



## 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 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.

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, 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 held approximately 59% of our outstanding common stock prior to the transaction.

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.

## MANAGEMENT

### Executive Officers and Directors

The following are our executive officers and directors and their respective ages as of March 1, 2007.

| Name                 | Age | Position   |
|----------------------|-----|--|
| Bernard L. Kasten    | 60  | Director, Chairman of the Board  |
| James Antal          | 56  | Director   |
| Paul DiCorleto       | 55  | Director   |
| Michael Fonstein     | 47  | Director, President and Chief Executive Officer                          |
| Andrei Gudkov        | 50  | Director, Chief Scientific Officer                                       |
| Yakov Kogan          | 34  | Director, Executive Vice President of Business Development,<br>Secretary |
| H. Daniel Perez      | 57  | Director   |
| John A. Marhofer Jr. | 44  | Chief Financial Officer  |

**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 VNIIGenetica, 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.

### **Audit Committee**

The audit committee consists of three directors elected by a majority of the board. The members of our audit committee comply with the independence requirements of the Nasdaq Capital Market and the rules of the SEC under the Securities Exchange Act of 1934, as amended, or Exchange Act, and include at least one audit committee financial expert. The current members of this committee are Messrs. Antal, Kasten and Perez, with Mr. Antal serving as chairperson and as the audit committee financial expert.

The audit committee is responsible for the following:

- reviewing the results of the audit engagement with the independent registered public accounting firm;
- identifying irregularities in the management of our business in consultation with our independent accountants, and suggesting an appropriate course of action;
- reviewing the adequacy, scope, and results of the internal accounting controls and procedures;
- reviewing the degree of independence of the auditors, as well as the nature and scope of our relationship with our independent registered public accounting firm; and
- reviewing the auditors' fees.

### **Compensation Committee**

The compensation committee consists of three directors elected by a majority of the board. The members of our compensation committee comply with the independence requirements of the Nasdaq Capital Market and the rules of the SEC under the Exchange Act. The current members of this committee are Messrs. Kasten, Antal and Perez, with Mr. Kasten serving as chairperson.

The compensation committee determines the salaries and incentive compensation of our officers and will provide recommendations for the incentive compensation of our other employees and consultants. When determining the long-term incentive component of executive compensation, the compensation committee considers our performance and relative shareholder return, the value of similar incentive awards to executive officers in comparable positions at comparable companies, and awards given to our executive officers in past years.

From time to time, the compensation committee may utilize the services of independent consultants to perform analyses and to make recommendations to the committee relative to executive compensation matters. No compensation consultant has so far been retained by us.

### **Nominating and Corporate Governance Committee**

The nominating and corporate governance committee consists of three directors elected by a majority of the board. The members of our nominating and corporate governance committee comply with the independence requirements of the Nasdaq Capital Market and the rules of the SEC under the Exchange Act. The current members of this committee are Messrs. Kasten, Antal and Perez, with Mr. Kasten serving as chairperson.

The functions of the nominating and corporate governance include the following:

- identifying and recommending to the board of directors individuals qualified to serve as directors of the company and on the committees of the board;
- advising the board with respect to matters of board composition, procedures and committees;
- developing and recommending to the board a set of corporate governance principles applicable to us and overseeing corporate governance matters generally; and
- overseeing the annual evaluation of the board and our management.

### **Codes of Conduct and Ethics**

We have adopted a code of conduct that applies to our officers, employees and directors, including our principal executive officers, principal financial officers and principal accounting officers and a code of ethics applicable to our senior executives. Copies of each of these codes are available on our website. Among their provisions, these codes set forth written standards that are designated to deter wrongdoing and to promote:

- honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- full, fair, accurate, timely and understandable disclosure in reports and documents that we file with, or submit to, the SEC and in other public communications made by us; and
- compliance with applicable governmental laws, rules and regulations.

We have also adopted a whistleblower policy setting forth procedures for the prompt internal reporting of violations of company policies or law to an appropriate person or persons identified therein.

### **Compensation and Term of Directors**

We pay each of our independent directors, other than Dr. DiCorleto, \$25,000 per year and \$2,500 per each meeting of the board or any committee of the board in excess of two meetings, plus expenses incurred. We also have granted each independent director, other than Dr. DiCorleto, 15,000 stock options. We also may, in the future, pay a fee for acting as a committee chair. Each of our directors is elected annually at our annual meeting.

**Executive Compensation**

The following table sets forth the amount of compensation during the years ended December 31, 2006 by our chief executive officer and our two most highly compensated executive officers (other than our chief executive officer):

**Summary Compensation Table**

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

On April 6, 2007, the Compensation Committee of the Board of Directors of CBL approved the payment of cash bonuses and the issuance of stock options to Messrs. Fonstein, Gudkov, Kogan, and Marhofer. The cash bonuses,



consisting of \$40,000 to each individual, are payable in April 2007. The stock options vest immediately and provide the right to purchase the Company's common stock, \$0.005 par value per share, at an exercise price of \$8.36 per share. Messrs. Fonstein, Gudkov, and Kogan each received 37,500 options, and Mr. Marhofer received 25,000 options.

**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.

| Name                  | Option Awards   |   | Equity Incentive Plan Awards:                           | Option Exercise Price (\$) | Option Expiration Date |
|-----------------------|---|---|---|----------------------------|------------------------|
|                       | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Number of Securities Underlying Unexercised Options (#) |                            |                        |
| 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.

| Name                  | Fees<br>Earned<br>or<br>Paid in<br>Cash<br>(\$) | Stock<br>Awards<br>(\$) | Option<br>Awards<br>(\$) <sup>(1)</sup> | Non-Equity<br>Incentive<br>Plan<br>Compensation<br>(\$) | Change in<br>Pension<br>Value and<br>Nonqualified<br>Deferred<br>Compensation |   | All Other<br>Compensation<br>(\$) | Total<br>(\$) |
|-----------------------|---|-------------------------|---|---|---|---|-----------------------------------|---------------|
|                       |   |                         |   |   |   |   |                                   |               |
| Bernard L. Kasten Jr. | 12,500  | -                       | 56,449                                  | -   | -   | - | -                                 | 68,949        |
| H. 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* .”

## 2006 Equity Incentive Plan

The 2006 Equity Incentive Plan provides for the grant of stock options, restricted stock, stock appreciation rights or other equity-based awards to our employees, officers, directors and consultants and was approved by our stockholders prior to our initial public offering. Options may be either “incentive stock options” or non-qualified options under the federal tax laws and will have an exercise price equal to at least fair market value as of the grant date. A total of 2,000,000 shares of common stock have been reserved for issuance under the Plan, subject to adjustments for certain corporate transactions or events.

## Scientific Advisory Board

We have established a Scientific Advisory Board to advise us on our scientific and research path, with each member representing his respective areas of expertise. None of the members of our Scientific Advisory Board is involved in the management of CBL and, other than 208,600 restricted shares of common stock granted to Dr. George R. Stark on April 26, 2004, none of the members of our Scientific Advisory Board receives any compensation from us.

- George R. Stark, Ph.D. Cancer biology, chemistry, technology development
- Inder Verma, Ph.D. Cancer biology, technology development
- Bruce Blazar, MD Pre-clinical aspects of drug development
- Ernest Borden, MD Drug trials

*Dr. George R. Stark, Ph.D.* Dr. Stark, a member of the National Academy of Sciences, Distinguished Scientist of the Lerner Research Institute and Professor of Genetics at the Case Western Reserve University, is an expert in various fields of biochemistry, signal transduction and cancer biology and has pioneered many key technologies in the fields of molecular biology and genetics. He became a professor at Stanford in 1971. In 1983, he moved to the Imperial Cancer Research Fund in London. In 1992, he became the Chair of the Lerner Research Institute of the Cleveland Clinic, which he chaired until 2001.

*Dr. Inder Verma, Ph.D.* Dr. Verma is a member of the National Academy of Sciences, Professor of Salk Institute for Biology Research. He is a member of the board of directors of Cell Genesys and a member of the scientific advisory boards of Cenegen and Zenogen. Dr. Verma is an internationally recognized leader in cancer biology and inflammation.

*Dr. Bruce R. Blazar* Dr. Blazar has served in various academic positions at the University of Minnesota since 1978. Presently, he is a Professor in the Division of Pediatric Bone Marrow Transplantation, Director of the Cytokine Reference Laboratory, Associate Director of the Division of Pediatric Bone Marrow Transplantation and Andersen Chair in Transplantation Immunology. Dr. Blazar has received numerous professional honors and awards, including the American Cancer Society Clinical Fellowship Award, the NIH-NCI National Research Service Award and the MERIT Award. In addition to his past and present work on numerous editorial boards, he is a member of the FDA Advisory Committee on Biological Response Modifiers and the Leukemia and Lymphoma Society Translational Research Grant Committee. He has multiple active grants supporting a substantial research effort and has published over 230 manuscripts.

*Dr. Ernest C. Borden* Dr. Borden is a director of the Center for Drug Discovery and Development of Taussig Cancer Center at the Cleveland Clinic. Dr. Borden uses his expertise to bring new cancer-fighting drugs from laboratory to clinical evaluation. His special interests involve the treatment of melanoma and new cancer therapies including

interferons, vaccines and antibodies.

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**SECURITY OWNERSHIP OF MANAGEMENT AND PRINCIPAL STOCKHOLDERS**

The following table sets forth, as of March 30, 2007, certain information with respect to the beneficial ownership of our 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 30, 2007, and is determined in accordance with Rule 13d-3 under the Exchange Act.

| Name and Address   | Number of<br>Shares<br>of Registrant<br>Common Stock<br>Beneficially<br>Owned | Percentage of<br>Class Beneficially<br>Owned |
|--|---|--|
| <b>Directors and Executive Officers</b>  |   |  |
| Bernard L. Kasten Jr.<br>Director, Chairman of the Board                                   | 15,000  | (3) *  |
| James J. Antal<br>Director   | 15,000  | (2) *  |
| Paul E. DiCorleto<br>Director  | 0   | 0%   |
| Michael Fonstein<br>Director, CEO & President  | 1,311,200   | 11.03%                                       |
| Andrei V. Gudkov<br>Director, Chief Scientific Officer                                     | 1,549,600   | (1) 13.03%                                   |
| Yakov N. Kogan<br>Director, Executive Vice President of Business Development,<br>Secretary | 715,200   | 6.02%  |
| H. Daniel Perez<br>Director  | 15,000  | (4) *  |
| John A. Marhofer, Jr.<br>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) 5.12%                                    |
| 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 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 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.



## SELLING STOCKHOLDERS

This prospectus covers (i) shares of Series A preferred stock sold and shares of common stock underlying warrants sold in connection with our Series A preferred stock private placement, which Series A preferred stock upon consummation of our initial public offering converted to common stock, and (ii) shares of common stock underlying warrants issued to underwriters (or their designees) in our initial public offering. We are registering the shares being offered under this prospectus to satisfy registration rights that we have granted the selling stockholders. The selling stockholders and their transferees, pledgees, donees, assignees or successors, may from time to time offer and sell under this prospectus any or all of the shares listed opposite each of their names below.

The following table sets forth information about the number of shares owned by each selling stockholder that may be offered from time to time under this prospectus. Certain selling stockholders may be deemed to be “underwriters” as defined in the Securities Act. Any profits realized by the selling stockholder may be deemed to be underwriting commissions.

The table below has been prepared based upon information furnished to us regarding the selling stockholders, and we have not sought to verify this information. The selling stockholders identified below may have sold, transferred or otherwise disposed of some or all of their shares since the date on which the information in the following table is presented in transactions exempt from or not subject to the registration requirements of the Securities Act. Information concerning the selling stockholders may change from time to time and, if necessary, we will supplement this prospectus accordingly. Beneficial ownership is determined in accordance with Rule 13d-3 under the Exchange Act. Accordingly, a person is deemed to be the beneficial owner of shares of common stock (or securities convertible into, or exercisable for, common stock) that can be acquired by that person within 60 days of March 30, 2007. The total amount of shares that may be sold hereunder will not exceed the number of shares offered hereby. Please read “Plan of Distribution.”

Except as noted below, to our knowledge, none of the selling stockholders has, or has had within the past three years, any position, office or other material relationship with us or any of our predecessors or affiliates, other than their ownership of shares described below.

Each selling stockholder identified below as an affiliate of a broker-dealer makes the following representations: (1) the seller purchased in the ordinary course of business and (2) at the time of the purchase of the securities to be resold, the seller had no agreements or understandings, directly or indirectly, with any person to distribute the securities.

| Name and Address of Selling Stockholder  | Number of<br>Shares of<br>Common Stock<br>Owned and<br>Offered Hereby | Percentage of<br>Common Stock<br>Outstanding<br>Prior to<br>Offering (1) | Percentage of<br>Common Stock<br>Outstanding<br>After the<br>Offering |
|--|---|--|---|
| Smithfield Fiduciary LLC (2)<br>c/o Highbridge Capital Management, LLC<br>9 West 57 <sup>th</sup> Street, 27 <sup>th</sup> Floor<br>New York, New York 10019 | 296,489   | 2.49%  | -   |
| Helen Goodfriend<br>44 Coconut Row<br>Palm Beach, Florida 33480  | 59,296  | *  | -   |
| JGB Capital L.P. (3)<br>c/o Brett Cohen  | 296,489   | 2.49%  | -   |

660 Madison Ave., 21st Floor  
New York, New York 10021

|   |        |   |   |
|---|--------|---|---|
| FCC Ltd. (4)<br>Levinstein Tower, 21st Floor<br>23 Menachem Begin Rd.<br>Tel Aviv, Israel 66182 | 77,084 | * | - |
|---|--------|---|---|

|  |        |   |   |
|--|--------|---|---|
| Leon Recanati<br>Levinstein Tower, 21st Floor<br>23 Menachem Begin Rd.<br>Tel Aviv, Israel 66182 | 83,016 | * | - |
|--|--------|---|---|

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|--|-----------|-------|---|
| Crestview Capital Master, LLC (5)<br>95 Revere Drive, Suite A<br>Northbrook, Illinois 60062                                | 296,489   | 2.49% | - |
| CAMOFI Master LDC (6)<br>c/o Centrecourt Asset Management LLC<br>350 Madison Avenue, 8th Floor<br>New York, New York 10017 | 151,545   | 1.27% | * |
| Marcia Kucher (7)<br>641 Lexington, 25th Floor<br>New York, New York 10022   | 7,782     | *     | - |
| Yael Lustmann<br>101 California Avenue, #204<br>Santa Monica, California 90403   | 23,717    | *     | - |
| Robert Cohen<br>2 Hickory Lane<br>Scarsdale, New York 10583  | 88,946    | *     | - |
| Bear Stearns Securities Corp.<br>Custodian for Stuart Schapiro IRA (8)<br>41 Winged Foot<br>Lynchmont, New York 10538      | 14,822    | *     | - |
| Sunrise Equity Partners, LP (9)<br>641 Lexington Ave., 25th Floor<br>New York, New York 10022                              | 1,185,962 | 9.98% | - |
| Marilyn S. Adler<br>641 Lexington Ave., 25th Floor<br>New York, New York 10022   | 14,822    | *     | - |
| F. Berdon Co. LP (10)<br>717 Post Rd., Suite 105<br>Scarsdale, New York 10583  | 130,946   | 1.10% | * |
| John L. Gallagher (11)<br>Kariba Capital<br>530 5th Avenue, 26th Floor<br>New York, New York 10036                         | 22,164    | *     | - |
| Derek L. Caldwell (12)<br>400 East 58th, Apt. PHA<br>New York, New York 10022  | 121,625   | 1.02% | - |
| Danny Gabay<br>c/o Shaul Eyal<br>10 Hagalim Street   | 88,946    | *     | - |

Raanana, Israel 43596

|  |         |       |   |
|--|---------|-------|---|
| Bear Stearns as Custodian for Nathan A. Low Roth IRA (13)<br>5 West 86 Street, apt. 5A<br>New York, New York 10024 | 148,243 | 1.25% | - |
|--|---------|-------|---|

|  |        |   |   |
|--|--------|---|---|
| Philip and Maxine Patt<br>938 Stoney Run Drive<br>West Chester, Pennsylvania 19382 | 29,648 | * | - |
|--|--------|---|---|

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|---|---------|-------|---|
| Jay Lefkowitz<br>2211 Broadway #10L<br>New York, New York 10024   | 29,648  | *     | - |
| Yossi Shasha<br>Ahi Meir 24<br>Ramat Gan, Israel  | 14,822  | *     | - |
| Amnon Mandelbaum (14)<br>641 Lexington Ave., 25th Floor<br>New York, New York 10022                                   | 349,443 | 2.94% | - |
| Amnon Mandelbaum IRA NFS as Custodian (15)<br>641 Lexington Ave., 25th Floor<br>New York, New York 10022              | 7,705   | *     | - |
| David Goodfriend (16)<br>641 Lexington Ave., 25th Floor<br>New York, New York 10022                                   | 37,570  | *     | - |
| Yehuda Harats<br>45 Hashayarot St.,<br>Jerusalem, Israel 92544  | 71,155  | *     | - |
| Richard B. Stone (17)<br>122 E. 42nd St., Suite 2606<br>New York, New York 10168                                      | 128,473 | 1.08% | - |
| Judith Green Berger<br>Museum Towers<br>15 W.53rd St., Apt. 28D.<br>New York, New York 10019                          | 14,822  | *     | - |
| IRA Bear Stearns as Custodian 1625421 Ontario, Inc. (18)<br>532 Spring Gate Blvd.<br>Thornhill, Ontario L4JSB7 Canada | 41,505  | *     | - |
| Sem-Tov Yosef<br>Chaim BenEsraim 5<br>Rishon Letzion, Israel 75514  | 14,822  | *     | - |
| Jonathon Andrew Stewart Harris<br>No. 1 Martin Place<br>GPO Box 4294<br>Sydney NSW 1164, Australia                    | 27,193  | *     | - |
| Serge Moyal (19)<br>641 Lexington Ave., 25th Floor<br>New York, New York 10022  | 4,109   | *     | - |

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|--|---------|-------|---|
| David Filer (20)<br>165 East 32nd St., #2F<br>New York, New York 10016                 | 51,380  | *     | - |
| Nathan Low (21)<br>641 Lexington, 25th Floor<br>New York, New York 10022               | 251,701 | 2.12% | - |
| Sunrise Securities Corp. (22)<br>641 Lexington, 25th Floor<br>New York, New York 10022 | 231,000 | 1.94% | - |

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|---|--------|---|---|
| Sunrise Foundation Trust (23)<br>641 Lexington, 25th Floor<br>New York, New York 10022              | 1,192  | * | - |
| Roth Capital Partners, LLC (24)<br>11100 Santa Monica Boulevard, Suite 550<br>Los Angeles, CA 90025 | 82,250 | * | - |
| Eric Abitbol (25)<br>201 East 69th Street, Apt. 15E<br>New York, New York 10022                     | 282    | * | - |
| Samuel Berger (26)<br>1355 East 8th Street<br>Brooklyn, New York 11230                              | 51     | * | - |
| Jeffrey Meyerson (27)<br>641 Lexington, 25th Floor<br>New York, New York 10022                      | 649    | * | - |
| National Securities (28)<br>120 Broadway, 27th Floor<br>New York, New York 10271                    | 1,100  | * | - |

\* Less than 1%.

- (1) Except as otherwise required by Rule 13d-3 under the Exchange Act, this percentage ownership is based on 11,889,099 shares of common stock outstanding as of March 30, 2007.
- (2) Highbridge Capital Management, LLC is the trading manager of Smithfield Fiduciary LLC and has voting control and investment discretion over securities held by Smithfield Fiduciary LLC. Glenn Dubin and Henry Swieca control Highbridge Capital Management, LLC. Each of Highbridge Capital Management, LLC, Glen Dubin and Henry Swieca disclaim beneficial ownership of the securities held by Smithfield Fiduciary LLC.
- (3) The general partner of JGB Capital L.P. is JGB Management Inc. JGB Management Inc. has voting control and investment discretion over securities held by JGB Capital L.P. The President of JGB Management Inc. is Brett Cohen. Brett Cohen disclaims beneficial ownership of the securities held by JGB Capital L.P.
- (4) Yacov Reizman is the President of FCC Ltd. and has voting control and investment discretion over securities held by FCC Ltd. Yacov Reizman disclaims beneficial ownership of the securities held by FCC Ltd.
- (5) Crestview Capital Partners, LLC is the sole manager of Crestview Capital Master, LLC. The managers of Crestview Capital Partners, LLC are Robert Hoyt, Stewart Flink and Daniel Warsh, each of whom has voting control and investment discretion over securities held by Crestview Capital Master, LLC. Such persons disclaim beneficial ownership of the securities held by Crestview Capital Master, LLC.
- (6)

Richard Smithline, Director of CAMOFI Master LDC, exercises voting and dispositive control over these shares. Includes 3,302 shares of Series B Preferred acquired in our March 16, 2007 private placement, which are currently convertible into common stock.

- (7) Includes 6,244 shares of common stock, 1,053 shares of common stock underlying a warrant, which is currently exercisable, and 485 shares of common stock underlying a warrant, which is exercisable on or after July 26, 2007 and before July 25, 2011.
- (8) Stuart Schapiro exercises voting and dispositive control over these shares.
- (9) Level Counter LLC is the general partner of Sunrise Equity Partners, LP. The three managing members of Level Counter LLC are Nathan Low, 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.
- (10) Frederick Berdon, Managing Partner of F. Berdon Co. LP, exercises voting and dispositive control over these shares. Includes 42,000 shares of Series B Preferred acquired in our March 16, 2007 private placement, which are currently convertible into common stock.



- (11) Includes 21,551 shares of common stock and 613 shares of common stock underlying a warrant, which is currently exercisable.
- (12) Includes 118,265 shares of common stock and 3,360 shares of common stock underlying a warrant, which is currently exercisable.
- (13) Nathan A. Low exercises voting and dispositive control over these shares.
- (14) Includes 240,102 shares of common stock, 70,146 shares of common stock underlying a warrant, which is currently exercisable, 12,516 shares of common stock underlying a second warrant, which is currently exercisable, and 26,679 shares of common stock underlying a third warrant, which is exercisable on or after July 26, 2007 and before July 25, 2011.
- (15) Amnon Mandelbaum exercises voting and dispositive control over these shares.
- (16) Includes 25,025 shares of common stock, 7,792 shares of common stock underlying a warrant, which is currently exercisable, 1,788 shares of common stock underlying a second warrant, which is currently exercisable, and 2,965 shares of common stock underlying a third warrant, which is exercisable on or after July 26, 2007 and before July 25, 2011.
- (17) Includes 123,179 shares of common stock, 3,500 shares of common stock underlying a warrant, which is currently exercisable, and 1,794 shares of common stock underlying a second warrant, which is exercisable on or after July 26, 2007 and before July 25, 2011.
- (18) Serge Moyal exercises voting and dispositive control over these shares. Does not include 6,700 shares of Series B Preferred acquired by 1625421 Ontario, Inc. in our March 16, 2007 private placement, which are currently convertible into common stock.
- (19) Includes 2,828 shares of common stock and 1,281 shares of common stock underlying a warrant, which is exercisable on or after July 26, 2007 and before July 25, 2011. Does not include 6,700 shares of Series B Preferred acquired by 1625421 Ontario, Inc. in our March 16, 2007 private placement, which are currently convertible into common stock.
- (20) Includes 46,980 shares of common stock and 4,400 shares of common stock underlying a warrant, which is exercisable on or after July 26, 2007 and before July 25, 2011.
- (21) Includes 120,002 shares of common stock, 72,311 shares of common stock underlying a warrant, which is currently exercisable, 11,324 shares of common stock underlying a second warrant, which is currently exercisable, and 48,064 shares of common stock underlying a third warrant, which is exercisable on or after July 26, 2007 and before July 25, 2011.
- (22) Includes 131,000 shares of common stock, and 100,000 shares of common stock underlying a warrant, which is currently exercisable. Nathan Low is the president and sole stockholder of Sunrise Securities Corp. and exercises voting and dispositive control over these shares.
- (23) Nathan Low and Lisa Low are the two trustees of Sunrise Foundation Trust and exercise voting and dispositive control over these shares.
- (24) Includes 82,250 shares of common stock underlying a warrant, which is exercisable on or after July 26, 2007 and before July 25, 2011. Byron Roth, Chief Executive Officer of Roth Capital Partners, LLC, owns

72.6% of CR Financial Holdings Inc., which owns 72.05% of Roth Capital Partners, LLC. Byron Roth also directly owns 3% of Roth Capital Partners, LLC. Accordingly, Byron Roth exercises voting and dispositive control over these shares. Byron Roth disclaims beneficial ownership of the securities held by Roth Capital Partners, LLC. Gordon Roth, Chief Financial Officer of Roth Capital Partners, LLC, owns 4.7% of CR Financial Holdings Inc. Gordon Roth also directly owns 0.15% of Roth Capital Partners, LLC.

- (25) Includes 282 shares of common stock underlying a warrant, which is exercisable on or after July 26, 2007 and before July 25, 2011.
- (26) Includes 51 shares of common stock underlying a warrant, which is exercisable on or after July 26, 2007 and before July 25, 2011.
- (27) Includes 649 shares of common stock underlying a warrant, which is exercisable on or after July 26, 2007 and before July 25, 2011.
- (28) Includes 1,100 shares of common stock underlying a warrant, which is exercisable on or after July 26, 2007 and before July 25, 2011. Mark Goldwasser is the Chief Executive Officer and President of National Securities and exercises voting and dispositive control over these shares. Mark Goldwasser disclaims beneficial ownership of the securities held by National Securities.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

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.

### The 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 team, originally at the Cleveland Clinic. Pursuant to an Exclusive License Agreement we entered into with the Cleveland Clinic effective as of July 1, 2004, the Cleveland Clinic granted to us 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 of CBL;
- 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) to the Cleveland Clinic;
- make royalty payments (calculated as a percentage of the net sales of the drugs ranging from 1-2%) to the Cleveland Clinic; and
- make sublicense royalty payments (calculated as a percentage of the royalties received from the sublicenses ranging from 5-35%) to the Cleveland Clinic.

The milestone payments for products limited to biodefense uses are as follows: (i) for any IND application, \$50,000; (ii) for the successful completion of Phase I studies, \$100,000; (iii) for any NDA application or product license application, \$350,000; and (iv) for regulatory approval permitting commercial sales, \$1,000,000. The milestone payments for other product applications are: (i) for any IND application, \$50,000; (ii) for Phase II clinical trials, \$250,000; (iii) for Phase III clinical trials, \$700,000; (iv) for any NDA application or product license application, \$150,000; and (v) for regulatory approval permitting commercial sales, \$4,000,000; in each case, such amounts are credited against any future royalty and sublicense royalty payments.

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 within 90 days of receipt of such termination notice we cure the breach.

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.

Additionally, for as long as the Cleveland Clinic owns at least 3% of the company on a fully diluted basis, the Cleveland Clinic will be entitled to have one representative elected to our board of directors, as agreed to among the stockholders who were a party to the common stockholders agreement.

Pursuant to our existing license agreement with the Cleveland Clinic, we had accrued as of December 31, 2006, \$50,000 in milestone payments, which amount is payable upon the earlier to occur of the Cleveland Clinic'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 the Cleveland Clinic. We have subcontracted with the Cleveland Clinic for grants in the approximate amount of \$220,000, and the Cleveland Clinic provides lab services and personnel to CBL in the approximate amount of \$725,000.

## **ChemBridge Corporation**

Another vital component of our drug development capabilities is our strategic partnership with ChemBridge, 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 which, in exchange for 357,600 shares of our common stock and warrants to purchase 264,624 shares of our common stock pursuant to a separate restricted stock agreement, provides us with continual access to a chemical library of 180,000 compounds (100,000 “historical” and 80,000 combinatorial). 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 fifty percent 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.

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.

Dr. Gudkov’s group has 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 PGP modulators). Both lines of study have resulted in high visibility publications and are slated for further exploration by us.

## **Sunrise Securities Corp.**

Upon the consummation of our initial public offering, we sold to SSC and Roth Capital Partners, LLC or their respective designees (including officers) at an aggregate purchase price of \$100, warrants to purchase up to 170,000 shares of common stock. Each warrant represents the right to purchase one share of common stock for a period of four years commencing on the first anniversary of the effective date of our initial public offering. The exercise price of the warrants is \$8.70. The common shares underlying these warrants are being registered pursuant to the registration statement of which this prospectus forms a part. The warrants are noncallable and have a cashless exercise option. No holder of these warrants will possess any rights as a stockholder unless the warrant is exercised.

SSC served as lead placement agent for our March 16, 2007 private placement. 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.

**Founders**

On June 5, 2003, in connection with our formation, we issued an aggregate of 3,993,200 shares of common stock to our five founders in consideration of their knowledge, experience, expertise and services rendered in lieu of a salary in the formation and initial operations of the Company. The founders did not make any cash investments in the Company upon our formation. The stock issuances were as follows:

| <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,<br>Chairman of the Board   | 1,311,200               |
| Dr. Yakov Kogan       | Executive Vice President of Business<br>Development; Secretary | 715,200                 |
| Dr. Elena Feinstein   | Executive Vice President of Research<br>and Development        | 268,200                 |
| Dr. Veronika Vonstein | General Manager  | 119,200                 |

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

A summary of the material terms of any employment and consulting agreements among the founders may be found in the section of this prospectus titled "Management".

## **DESCRIPTION OF OUR COMMON STOCK**

The following summary describes the material terms of our common stock. It summarizes material provisions of our certificate of incorporation and by-laws. You may obtain copies of these organizational documents by contacting us, as described under "Prospectus Summary — Our Information."

### **Common Stock**

Our Certificate of Incorporation authorizes us to issue 40,000,000 shares of common stock, par value \$.005 per share. On February 28, 2005, we completed a 596-for-1 stock split of our common stock in anticipation of the Series A Preferred Stock private placement in order to avoid issuance of fractional shares. As of March 30, 2007, 11,889,099 shares of common stock were issued and outstanding with 562,990 shares of common stock reserved for issuance upon exercise of options and 3,457,821 shares of common stock reserved for issuance upon exercise of warrants.

### **Voting**

Holders of our common stock are entitled to one vote per share. All actions submitted to a vote of stockholders will be voted on by holders of our common stock.

### **Conversion**

The common stock has no conversion rights.

### **Dividends**

Holders of common stock are entitled to receive cash dividends equally on a per share basis, as if and when the dividends are declared by the board of directors from legally available funds.

### **Liquidation**

After satisfaction of the liquidation preferences of all securities ranking senior to the common stock, the holders of common stock will share with each other on an equal basis in any net assets available for distribution to holders of shares of capital stock upon liquidation.

### **Other Terms**

The rights, preferences and privileges of holders of common stock will be subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock which we may designate and issue in the future.

### **Common Stockholders Agreement**

We have entered into a common stockholders agreement with all of our common stockholders who acquired their shares prior to March 1, 2005. Under the common stockholders agreement, as long as the Cleveland Clinic owns at least 3% of the company on a fully diluted basis, the Cleveland Clinic will be entitled to have one representative elected to our board of directors.

### **Registration Rights**

We and all of our stockholders prior to our initial public offering entered into a Series A Rights Agreement, pursuant to which we agreed to file a registration statement with the SEC, which was to include the Registrable Securities (as defined in the Series A Rights Agreement) that were not already registered in connection with our initial public offering by the 30<sup>th</sup> day following the closing of our initial public offering, which occurred on July 26, 2006. The registration statement of which this prospectus forms a part is being filed to satisfy these obligations under the Series A Rights Agreement. We have also agreed to grant certain registration rights to Sunrise Securities Corp. and Roth Capital Partners, LLC and their designees. Pursuant to the underwriting agreement for our initial public offering, such entities and their designees were issued warrants and are entitled to certain demand and “piggyback” registration rights to register the resale of the shares of common stock underlying such warrants. The common shares underlying the warrants are being registered pursuant to the registration statement of which this prospectus forms a part.



### **Lock Up of Certain Shares**

We, each member of our board, each of our executive officers and holders of our common stock prior to March 1, 2005, or the founding holders, have agreed to sign lock-up agreements under which they agree they will not offer, sell, contract to sell, pledge or otherwise dispose of any shares of our capital stock, which amounts to 5,988,157 shares, for a period of 24 months after July 20, 2006, the effective date of our initial public offering. Each of our founders and executive officers together with two of our stockholders, The Cleveland Clinic Foundation and ChemBridge Corporation, have likewise agreed not to sell, pledge, hypothecate, assign or otherwise transfer or dispose of any shares of our capital stock for the same 24 month period, provided that this restriction shall terminate in the event of a merger, sale or other “change of control” transaction that is approved by a majority of the stockholders other than our directors, executive officers and such stockholders.

### **Restricted Securities**

As of March 30, 2007, 11,889,099 shares of common stock were issued and outstanding. Of these shares, 1,700,000 shares sold in our initial public offering are freely tradable without restrictions or further registration under the Securities Act, unless those shares are purchased by affiliates as that term is defined in Rule 144 under the Securities Act.

The remaining 10,189,099 shares of common stock held by stockholders as of March 30, 2007, including the 4,453,601 shares that are subject to the registration statement of which this prospectus forms a part, are currently restricted securities as that term is defined in Rule 144 under the Securities Act. Upon effectiveness of this registration statement, 5,988,157 shares will continue to be subject to the 24 month lock-up described above. In addition, 264,624 warrants issued to ChemBridge Corporation, which are exercisable at any time, will, upon their exercise, be subject to the 24 month lock-up.

### **Common Stockholders**

CBL had 137 stockholders of record as of March 30, 2007.

### **Listing of Stock**

Our common stock is quoted on the Nasdaq Capital Market under the trading symbol “CBLI”. Our common stock is also listed on the Boston Stock Exchange under the symbol “CFB”.

### **Transfer Agent and Registrar**

The transfer agent and registrar for the common stock is Continental Stock Transfer & Trust Company.

### **Directors’ Limitation of Liability**

Our certificate of incorporation and by-laws include provisions to indemnify the directors and officers to the fullest extent permitted by the Delaware General Corporation Law, including circumstances under which indemnification is otherwise discretionary. We believe that these provisions are necessary to attract and retain qualified persons as directors and officers.

We expect to enter into an indemnification agreement with each of our directors, which provides that we will indemnify our directors and advance expenses to our directors to the extent permitted by the laws of the State of Delaware. We have also obtained directors and officers liability insurance in amounts commensurate with those of

similarly situated companies.

Insofar as indemnification for liability arising under the Securities Act of 1933 may be permitted to our directors, officers and controlling persons as stated in the foregoing provisions or otherwise, we have been advised that, in the opinion of the SEC, this indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

#### **DESCRIPTION OF OUR SERIES B CONVERTIBLE PREFERRED STOCK**

We may, by resolution of our board of directors but subject to limitations prescribed by law, designate up to an aggregate of 10,000,000 shares of preferred stock. The preferred stock may be issued in one or more series. With respect to any series, our board of directors may determine the designation and the number of shares, preferences, limitations and special rights, including dividend rights, conversion rights, voting rights, redemption rights and liquidation preferences, which rights may adversely affect the rights of our common stockholders. Because of the rights that may be granted, the issuance of the preferred stock may delay, defer or prevent a change of control.

On March 16, 2007, we entered into a securities purchase agreement with various accredited investors pursuant to which we agreed to sell to the investors, in a private placement, an aggregate of 4,288,712 shares of Series B Convertible Preferred Stock, par value \$0.005 per share, or Series B Preferred. In connection with this sale, we also issued to SSC, in consideration for SSC's services as placement agent in the transaction, an aggregate of 290,298 shares of Series B Preferred. The following summary describes the material terms of our Series B Preferred. It summarizes material provisions of the Certificate of Designations, Preferences and Rights of Series B Convertible Preferred Stock of Cleveland BioLabs, Inc., filed by us on March 16, 2007 with the Secretary of State of the State of Delaware, which is attached as an exhibit to the registration statement of which this prospectus forms a part.

## **Dividends**

The holders of Series B Preferred are entitled to a cash dividend of 5% of the outstanding Series B Preferred amount payable in semi-annual installments in September and March. Dividends cease to accrue upon any share of Series B Preferred that is converted into common stock.

## **Conversion**

Shares of the Series B Preferred are convertible at the holder's election into shares of Common Stock at the conversion rate, which is the quotient of (1) the amount subject to conversion, divided by (2) the conversion price; provided, however, that 2,203,010 of the 4,579,010 shares of Series B Preferred issued in the transaction are not convertible in any event until stockholder approval, as required by the NASDAQ Capital Market, is obtained. The Series B Preferred has an initial conversion price of \$7.00 per share, but it is subject to adjustment in the event of certain corporate transactions, including certain issuances of common stock at a price below the conversion price of the Series B Preferred.

Shares of the Series B Preferred are convertible at our election into shares of common stock at the conversion rate at any time after the six month anniversary of the effectiveness of a registration statement filed pursuant to the Registration Rights Agreement described below if, among other things, the closing sale price of the our common stock exceeds \$20.00 per share for 30 consecutive trading days and the average daily trading volume of our common stock during that 30-trading day period exceeds 100,000 shares.

The Series B Preferred mature on September 16, 2009; upon maturity, we have the option, if certain conditions are satisfied, to elect either to redeem any outstanding Series B Preferred (plus accrued dividends) in cash or to convert any outstanding Series B Preferred into shares of common stock at the existing conversion rate.

If we do not deliver shares of common stock that are issuable upon conversion in a timely manner, we may be required to pay cash penalties to the holder of the Series B Preferred submitted for conversion.

## **Redemption**

Any holder of the Series B Preferred may require us to redeem all or a portion of its Series B Preferred shares if we:

- fail to convert shares of Series B Preferred within 10 business days of the request for conversion or provides written notice to a Series B Preferred holder of our refusal to comply with a request for conversion;
- fail to pay any Series B Preferred holder any amounts payable in connection with the transaction within 10 business days of the due date for payment;
- declare or file for bankruptcy or similar event;
- incur a final judgment in excess of \$250,000, which is not bonded, discharged or stayed pending appeal within 90 days after entry; or
- breach any representation, warranty or covenant in any of the documents entered into in connection with the transaction unless the breach or the event or condition giving rise to the breach would not have a material adverse effect or if the breach is cured within 20 days after notice of the breach.

A holder who elects redemption in this situation is entitled to receive the greater of (a) up to 110% of the stated amount of the shares to be redeemed plus accrued dividends and (b) (i) the closing sale price of the Common Stock on

(x) the day before the event giving rise to the redemption right, (y) the day after the event giving rise to the redemption or (z) the day the holder gives notice of redemption (whichever of the three is greatest) multiplied by (ii) the number of shares to be converted.

A holder of the Series B Preferred may also require us to redeem all or a portion of its shares if we enter into a change of control transaction. A holder who elects redemption in this situation is entitled to receive the greater of (a) up to 110% of the stated amount of the shares to be redeemed plus accrued dividends and (b) (i) the quotient of (x) the closing sale price of our common stock on (A) the day before announcement of the proposed change of control, (B) the day after announcement of the proposed change of control or (C) the day immediately prior to consummation of the change of control (whichever of the three is greatest) divided by (y) the conversion price, multiplied by (ii) the dollar amount to be converted.

## **Voting Rights**

Subject to the rules and regulations of the Nasdaq Capital Market and the limitations set forth below, each holder of Series B Preferred is entitled to the number of votes that the holder would have if it converted its Series B Preferred into shares of common stock.

## **Limitations on Beneficial Ownership**

Notwithstanding the conversion rights of the Series B Preferred holders and us, we may not issue any shares of common stock in conversion of the Series B Preferred if the conversion 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 our common stock that we could 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.

## **Purchase Rights**

If at any time while the Series B Preferred are outstanding, we issue to our holders of common stock securities, rights to purchase securities or property on a pro rata basis, the holders of our Series B Preferred will be entitled to acquire securities, rights or property as if such Series B Preferred holder had held the number of shares of common stock upon conversion of the Series B Preferred.

## **PLAN OF DISTRIBUTION**

The selling stockholders and any of their pledgees, donees, assignees and successors-in interest may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits investors;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
  - purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
  - an exchange distribution in accordance with the rules of the applicable exchange;
  - privately negotiated transactions;
- short sales (other than short sales established prior to the effectiveness of the registration statement to which this prospectus is a part)
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
  - a combination of any such methods of sale; and

any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the securities owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell shares of common stock from time to time under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

Upon our being notified in writing by a selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In addition, our being notified in writing by a selling stockholder that a donee or pledge intends to sell more than 500 shares of common stock, a supplement to this prospectus will be filed if then required in accordance with applicable securities law.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. There can be no assurance that the selling stockholders will sell any or all of the shares of common stock registered pursuant to the registration statement of which this prospectus forms a part.

We are required to pay all fees and expenses incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act. The selling stockholders have also agreed to indemnify us against certain losses, claims, damages and liabilities.

In addition, pursuant to NASD Conduct Rule 2710(g)(1), Sunrise Securities Corp. and Roth Capital Partners, LLC and related persons have agreed that any unregistered equity securities acquired or received from us during the 180-day period immediately preceding the initial filing of our initial public offering, which occurred on February 17, 2006, including dividends and penalty shares on the previously outstanding Series A Preferred Stock, will not be sold, transferred, assigned, pledged or hypothecated or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities for a period of 180 days immediately following July 20, 2006, the effective date of our initial public offering, except as permitted by NASD Conduct Rule 2710(g)(2).

The selling stockholders should be aware that the anti-manipulation provisions of Regulation M under the Exchange Act will apply to purchases and sales of shares of common stock by the selling stockholders, and that there are restrictions on market-making activities by persons engaged in the distribution of the shares. Under Registration M, the selling stockholders or their agents may not bid for, purchase, or attempt to induce any person to bid for or purchase, shares of our common stock while such selling stockholders are distributing shares covered by this Prospectus. The selling stockholders are advised that if a particular offer of common stock is to be made on terms constituting a material change from the information set forth above with respect to the Plan of Distribution, then, to the extent required, a post-effective amendment to the accompanying Registration Statement must be filed with the Commission.

Under the National Securities Markets Improvement Act of 1996, the resale of the common stock, from and after the effective date, may be exempt from state registration requirements as a result of the exemption provided for ordinary brokerage transactions where the parties have not been solicited by the broker-dealer or in some circumstances because we will file periodic and annual reports under the Exchange Act. However, states are permitted to require notice filings and collect fees with regard to these transactions and a state may suspend the offer and sale of common stock within such state if any such required filing is not made or fee is not paid. As of the date of this prospectus, we believe that the following states do not presently require any notice filings or fee payments and permit the resale by stockholders of the common stock:

· Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Dakota, Utah, Virginia, Washington, West Virginia, Wisconsin and Wyoming.

Moreover, as a result of the listing of our securities on the Boston Stock Exchange, we also receive an automatic state securities law, or blue sky law, exemption regarding the registration of our securities in Colorado, Delaware, Hawaii,

Massachusetts, New Hampshire, Rhode Island, Texas and West Virginia.

Additionally, the following states permit the resale of the common stock if the proper NSMIA notice filings have been made and fees paid:

·the District of Columbia, Illinois, Maryland, Michigan, Montana, New Hampshire, North Dakota, Oregon, Rhode Island, South Carolina, Tennessee, Texas and Vermont.

With respect to these states, as of the date of this prospectus, we have determined to make the relevant filings in the states of Illinois, Maryland and in the District of Columbia. Texas, New Hampshire and Rhode Island are included with those states which categorize these securities as exempt securities because the company is listed on the Boston Stock Exchange. The holder of the shares may be required to make the appropriate filings in order to effectuate a lawful offer and sale in the remaining states.



Additionally, if any of these states that has not yet adopted a statute, rule or regulation relating to NSMIA adopts such a statute, rule or regulation in the future requiring a filing or fee or if any state amends its existing statutes with respect to its requirements, compliance with those new requirements would be necessary in order for the common stock to continue to be eligible for resale in those jurisdictions.

Institutional investors in every state may purchase common stock in this offering pursuant to exemptions provided to such entities under the laws of various states. The definition of an “institutional investor” varies from state to state but generally includes financial institutions, broker-dealers, banks, insurance companies and other qualified entities. Some states may require the institutional investors to be Qualified Institutional Buyers, as that term is defined in Rule 144A, promulgated under the Securities Act of 1933, as amended.

In certain limited instances, federal law does not fully preclude state regulation in connection with offers and sales of these securities. The NSMIA preemption indicated above extends to resales by anyone other than issuers, underwriters and dealers. Therefore, the states may regulate or place conditions on offers and sales made by issuers, underwriters, or dealers or with respect to transactions that otherwise do not meet the exemptions set forth above. The definitions of the terms “issuer,” “underwriter” and “dealer” are set forth in the Securities Act of 1933 and the SEC Rules promulgated thereunder. In our initial public offering of common stock, the states of California, Ohio, and Kentucky placed investor suitability conditions on transfers and sales. If they are not preempted by NSMIA from doing so (either because the resale is by an issuer, underwriter or dealer or otherwise does not meet any applicable exemption), the states may condition transfers and resales of the securities offered under this prospectus. The California, Ohio and Kentucky conditions on transfers and sales are set forth below.

Investors in California may be required to have a:

- minimum net worth of at least \$75,000 and a minimum gross income of not less than \$50,000, or
- liquid net worth of at least \$150,000.

In both of the instances above, the calculation shall be exclusive of the investors’ home, home furnishings and automobile. Any investment in an offering shall not exceed ten percent (10%) of the net worth of each such investor.

Notwithstanding the foregoing, up to \$2,500 of our common stock may be purchased by a California resident in an offering so long as they are a “small investor” who, including such offering, shall not have purchased more than \$2,500 worth of our common stock in the past twelve (12) months. For purposes herein, the term “small investor” shall mean either an individual (which shall include both a husband and wife counted as a single individual), or a self-employed individual retirement plan of an individual or an individual retirement account of an individual.

Investors in Kentucky may be required to have a:

- a minimum net worth of \$65,000 and a minimum annual gross income of \$65,000, exclusive of automobile, home and home furnishings, or
- a minimum net worth of \$150,000, exclusive of automobile, home and home furnishings.

Investors in Ohio may be required to have a:

- a minimum annual gross income of \$65,000, and
- a minimum net worth of \$250,000, exclusive of automobile, home and home furnishings.

**LEGAL MATTERS**

The validity of the common stock offered by this prospectus will be passed upon for us by Katten Muchin Rosenman LLP, Chicago, Illinois.

**EXPERTS**

The financial statements appearing in this prospectus and registration statement have been audited by Meaden & Moore, Ltd., independent registered accountants, to the extent and for the periods indicated in their report appearing elsewhere herein, and are included in reliance upon such report and upon the authority of such firms as experts in accounting and auditing.

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### **ADDITIONAL INFORMATION**

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You are able to inspect and copy these reports, proxy statements and other information without charge at the Public Reference Room maintained by the SEC at 100 F Street, N.E., Washington, DC 20549, and copies of all or any part of these materials may be obtained from the SEC upon payment of the prescribed fee. Information regarding the operation of the Public Reference Room may be obtained by calling the SEC at 800-SEC-0330. The SEC maintains a web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the site is <http://www.sec.gov/>.

We have filed with the SEC a registration statement on Form SB-2 under the Securities Act of 1933 for the shares of common stock being offered by the selling stockholders. This prospectus does not contain all of the information in the registration statement and the exhibits and schedules that were filed with the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and the exhibits that were filed with the registration statement. Statements contained in this prospectus about the contents or any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and we refer you to the full text of the contract or other document filed as an exhibit to the registration statement. Anyone may obtain the registration statement and its exhibits and schedules from the SEC.

**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

|                                 | 2006                | 2005                |
|---------------------------------|---------------------|---------------------|
| <b><u>ASSETS</u></b>            |                     |                     |
| <b>CURRENT ASSETS</b>           |                     |                     |
| 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            | 5,744,904           | 3,854,057           |
| <b>EQUIPMENT</b>                |                     |                     |
| Computer equipment              | 132,572             | 91,788              |
| Lab equipment                   | 347,944             | 225,997             |
| Furniture                       | 65,087              | 40,158              |
|                                 | 545,603             | 357,943             |
| Less accumulated depreciation   | 142,011             | 47,080              |
|                                 | 403,592             | 310,863             |
| <b>OTHER ASSETS</b>             |                     |                     |
| Deferred compensation           | -                   | 752                 |
| Intellectual Property           | 252,978             | 76,357              |
| Deposits                        | 15,055              | 11,304              |
|                                 | 268,033             | 88,413              |
| <b>TOTAL ASSETS</b>             | <b>\$ 6,416,529</b> | <b>\$ 4,253,333</b> |

## CLEVELAND BIOLABS, INC.

## BALANCE SHEETS

December 31, 2006 and 2005

|   | 2006                | 2005                |
|---|---------------------|---------------------|
| <b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>  |                     |                     |
| <b>CURRENT LIABILITIES</b>  |                     |                     |
| Accounts payable:   |                     |                     |
| Trade   | \$ 644,806          | \$ 264,783          |
| Deferred revenue  | -                   | 100,293             |
| Accrued expenses  | 128,569             | 28,579              |
| Total current liabilities   | 773,375             | 393,655             |
| <b>LONG-TERM LIABILITIES</b>  |                     |                     |
| Convertible notes payable   | -                   | 303,074             |
| Milestone payables  | 50,000              | -                   |
| Total long-term liabilities   | 50,000              | 303,074             |
| <b>STOCKHOLDERS' EQUITY</b>   |                     |                     |
| 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   | (12,775,910)        | (5,184,856)         |
| Total stockholders' equity  | 5,593,154           | 3,556,604           |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>   | <b>\$ 6,416,529</b> | <b>\$ 4,253,333</b> |

## CLEVELAND BIOLABS, INC.

## STATEMENT OF OPERATIONS

Years Ended December 31, 2006, 2005 and 2004

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



CLEVELAND BIOLABS, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2004 to December 31, 2006

|   | Shares       | Amount    | Stockholders' Equity<br>Common Stock<br>Additional<br>Paid-in<br>Capital | Penalty<br>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)   | -                 |

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|  |            |           |               |      |
|--|------------|-----------|---------------|------|
| 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 | \$ - |

CLEVELAND BIOLABS, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2004 to December 31, 2006

|   | Shares    | Amount | Stockholders' Equity<br>Preferred Stock<br>Additional<br>Paid-in<br>Capital | Penalty<br>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   | - \$        | - \$     | - \$        | - |

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CLEVELAND BIOLABS, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2004 to December 31, 2006

|   | Other<br>Comprehensive<br>Loss | Stockholders' Equity<br>Accumulated<br>Deficit | Total        | Comprehensive<br>Income<br>(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<br>financing                              | -                              | -  | 5,897,803    |                                   |
| Issuance of shares - stock dividend                                     | -                              | (138,433)                                      | (31)         |                                   |
| Issuance of options (383,840 options<br>issued,<br>324,240 outstanding) | -                              | -  | 318,111      |                                   |
| Exercise of options (59,600 options<br>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<br>term investments                  |                                |  |              |                                   |
| Unrealized holding gains (losses)<br>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<br>accrued penalty shares               | -                              | -  | -            |                                   |
| Issuance of shares - stock dividend                                     | -                              | (368,410)                                      | (43)         |                                   |
| Issue penalty shares  | -                              | -  | -            |                                   |

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|   |            |                 |              |                |
|---|------------|-----------------|--------------|----------------|
| 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 |                |

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## CLEVELAND BIOLABS, INC.

## STATEMENTS OF CASH FLOWS

Year Ended December 31, 2006, 2005 and 2004

|   | 2006             | 2005             | 2004           |
|---|------------------|------------------|----------------|
| <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   | 569,042          | 655,942          | 2,315,231      |
| 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                                   | (14,281)         | (2,805,113)      | (27,991)       |
| <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                                   | 8,523,414        | 5,647,347        | 320,517        |
| <b>NET INCREASE IN CASH AND EQUIVALENTS</b>                                 | <b>1,855,531</b> | <b>1,111,721</b> | <b>84,615</b>  |
| <b>CASH AND EQUIVALENTS AT BEGINNING OF YEAR</b>                            | <b>1,206,462</b> | <b>94,741</b>    | <b>10,126</b>  |

|                                     |    |           |    |           |    |        |
|-------------------------------------|----|-----------|----|-----------|----|--------|
| CASH AND EQUIVALENTS AT END OF YEAR | \$ | 3,061,993 | \$ | 1,206,462 | \$ | 94,741 |
|-------------------------------------|----|-----------|----|-----------|----|--------|

|  |  |      |  |      |  |      |
|--|--|------|--|------|--|------|
|  |  | 2006 |  | 2005 |  | 2004 |
|--|--|------|--|------|--|------|

Supplemental disclosures of cash flow information:

|  |    |       |    |   |    |   |
|--|----|-------|----|---|----|---|
| Cash paid during the period for interest   | \$ | 1,269 | \$ | - | \$ | - |
| Cash paid during the year for income taxes | \$ | -     | \$ | - | \$ | - |

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|  | 2006         | 2005       | 2004 |
|--|--------------|------------|------|
| Supplemental schedule of noncash financing activities:                             |              |            |      |
| 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 | \$ -       | \$ - |

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**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:

|                         | <b>March 1, 2006</b> | <b>July 20, 2006</b> | <b>November 16, 2006</b> |
|-------------------------|----------------------|----------------------|--------------------------|
| 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.

|                                | Options | Weighted<br>Average<br>Exercise Price<br>per Share | Weighted<br>Average<br>Remaining<br>Contractual<br>Term (in<br>Years) |
|--------------------------------|---------|--|---|
| 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 | 483,490 | \$ 2.17  | 8.77  |
| Exercisable, December 31, 2006 | 243,183 | \$ 2.27  | 8.78  |

|                                | Options | Weighted<br>Average<br>Exercise<br>Price per<br>Share | Weighted<br>Average<br>Remaining<br>Contractual<br>Term<br>(in Years) |
|--------------------------------|---------|---|---|
| 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 | 324,240 | \$ 0.82   | 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:

|   | 2006           | 2005           | 2004           |
|---|----------------|----------------|----------------|
| 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      |

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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.

UNWS 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

|  | 2006 | 2005    | 2004       |
|--|------|---------|------------|
| 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   | —    | 174,500 | 174,500    |

share or into a new debt instrument with a principal amount equal to the conversion amount.

|                            |     |         |    |         |
|----------------------------|-----|---------|----|---------|
|                            | \$  | 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.

|                                  | 2006            | 2005            | 2004            |
|----------------------------------|-----------------|-----------------|-----------------|
| 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:

|  | Cost         | Accrued Interest | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value   |
|--|--------------|------------------|------------------------|-------------------------|--------------|
| December 31, 2006 - Current<br>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:

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

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**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<br/>Leases</b> |
|------|-----------------------------|
| 2007 | \$ 63,460                   |
| 2008 | 4,949                       |
| 2009 | 1,935                       |
|      | \$ 70,344                   |

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<br/>Options</b> | <b>Weighted Average<br/>Exercise Price</b> |
|----------------------------------|------------------------------|--|
| Outstanding at December 31, 2004 | —                            | N/A  |
| Granted                          | 383,840                      | \$ 0.69                                    |
| Exercised                        | 59,600                       | \$ —                                       |

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|                                  |         |    |      |
|----------------------------------|---------|----|------|
| Forfeited                        |         | —  | N/A  |
| Outstanding at December 31, 2005 | 324,240 | \$ | 0.82 |
| Granted                          | 161,750 | \$ | 4.92 |
| Exercised                        | 625     | \$ | 4.50 |
| Forfeited                        | 1,875   | \$ | 4.50 |
| Outstanding at December 31, 2006 | 483,490 | \$ | 2.17 |

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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:

| <b>Exercise Price</b> | <b>Outstanding<br/>Number of<br/>Options</b> | <b>Weighted<br/>Average<br/>Years to<br/>Expiration</b> | <b>Exercisable<br/>Number of<br/>Options</b> |
|-----------------------|--|---|--|
| \$ 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                                       |
| <b>Total</b>          | <b>483,490</b>                               | <b>8.77</b>   | <b>243,183</b>                               |

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.

|                                  | <b>Number of<br/>Warrants</b> | <b>Weighted Average<br/>Exercise Price</b> |
|----------------------------------|-------------------------------|--|
| 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.





4,453,601 Shares

**CLEVELAND BIOLABS, INC.**

**Common Stock, \$0.005 Par Value**

—————  
**PROSPECTUS**  
—————

April \_\_\_\_, 2007

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**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION**

The following table sets forth the costs and expenses. All amounts are estimates except the SEC registration fee.

|                                 |           |               |
|---------------------------------|-----------|---------------|
| SEC registration fee            | \$        | 2,278         |
| Blue Sky Expenses               | \$        | 5,000         |
| Printing and engraving expenses | \$        | 15,000        |
| Legal fees and expenses         | \$        | 40,000        |
| Accounting fees and expenses    | \$        | 10,000        |
| Miscellaneous expense           | \$        | 10,000        |
| <b>Total</b>                    | <b>\$</b> | <b>82,278</b> |

**INDEMNIFICATION**

Section 102 of the General Corporation Law of the State of Delaware (the “DGCL”) allows a corporation to eliminate the personal liability of directors to a corporation or its stockholders for monetary damages for a breach of a fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase or redemption in violation of Delaware corporate law or obtained an improper personal benefit. As permitted by Section 102(b)(7) of the DGCL, CBL’s Certificate of Incorporation contains a provision eliminating the personal liability of a director to CBL or its stockholders to the fullest extent permitted by the DGCL.

Section 145 of the DGCL empowers a Delaware corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation) by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise. The indemnity may include expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person’s conduct was unlawful. A Delaware corporation may indemnify directors, officers, employees and other agents of such corporation in an action by or in the right of a corporation under the same conditions against expenses (including attorneys’ fees) actually and reasonably incurred by the person in connection with the defense and settlement of such action or suit, except that no indemnification is permitted without judicial approval if the person to be indemnified has been adjudged to be liable to the corporation. Where a present or former director or officer of the corporation is successful on the merits or otherwise in the defense of any action, suit or proceeding referred to above or in defense of any claim, issue or matter therein, the corporation must indemnify such person against the expenses (including attorneys’ fees) which he or she actually and reasonably incurred in connection therewith. CBL’s Certificate of Incorporation contains provisions that provide for indemnification of officers and directors and each person who is or was serving at the request of CBL as a director, officer, trustee, employee or agent of another corporation, partnership, joint venture, trust or other enterprise to the full extent permitted by the DGCL.

Section 174 of the DGCL provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption, may be held liable for such actions. A director who was either absent when the unlawful actions were approved or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered into the books containing the minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

CBL maintains, at its expense, a policy of insurance which insures its directors and officers, subject to exclusions and deductions as are usual in these kinds of insurance policies, against specified liabilities which may be incurred in those capacities.

#### **RECENT SALES OF UNREGISTERED SECURITIES**

During the past three years, we have issued unregistered securities to the persons, as described below. None of these transactions involved any underwriters, underwriting discounts or commissions, except as specified below, or any public offering, and we believe that each transaction was exempt from the registration requirements of the Securities Act of 1933 by virtue of Section 4(2) thereof and/or Regulation D. All recipients had adequate access to information about us.

On September 30 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.

We issued on March 15, 2005 and March 28, 2005, pursuant to the closing of the Series A Preferred Stock financing, 3,000,000 shares of our Series A Preferred Stock to 29 different purchasers at a price of \$2.00 per share, raising a total of \$6 million, on March 15, 2005 and March 28, 2005, we also issued 308,000 shares of common stock to nine individuals and entities related to Sunrise Securities Corp. and warrants to purchase 300,000 shares of common stock to 10 individuals and entities related to Sunrise Securities Corp. both for consideration for services rendered by Sunrise Securities Corp. as placement agent in the Series A Preferred Stock financing.

From March 2005 to March 2006, we issued to 26 employees and third party consultants options to purchase 500,590 shares of common stock with exercise prices ranging from \$0 to \$4.50 per share.

We also issued in March 2005, pursuant to the conversion of \$102,438 principal amount of outstanding promissory notes, 51,219 shares of Series A Preferred Stock to two investors.

On August 1, 2005, payment of the first part of the accrued dividends on the Series A Preferred Stock were made in the form of 69,201 shares of common stock to 31 holders of the Series A Preferred Stock. On February 1, 2006, we issued 91,776 shares of common stock as accrued dividends on the Series A Preferred Stock to the same preferred stockholders. On July 20, 2006, we issued 92,407 shares of common stock as accrued dividends on the Series A Preferred Stock.

On September 30, 2005, we issued 59,600 shares of common stock to an outside consultant upon the exercise of a fully vested stock option.

On January 27, 2006, we issued 240,000 shares of Series A Preferred Stock to 29 holders of the Series A Preferred Stock and 54,060 shares of common stock to 33 holders of our common and preferred stock in connection with certain provisions of the Series A Rights Agreement dated as of March 15, 2005.

On June 21, 2006, we issued 60,000 shares of Series A Preferred Stock to 29 holders of the Series A Preferred Stock and 15,295 shares of common stock to 33 holders of our common and preferred stock in connection with certain provisions of the Series A Rights Agreement dated as of March 15, 2005, as amended February 17, 2006.

On July 20, 2006, the effective date of our initial public offering, we issued 124,206 shares of common stock to three convertible note holders upon the automatic conversion of notes in the principal amount of \$283,500 plus accrued interest.

On July 20, 2006, we issued warrants to purchase 170,000 shares of common stock to Sunrise Securities Corp., Roth Capital Partners, LLC and their designees at a cost of \$100.00. The warrants have an exercise price of \$8.70 per share.

On July 20, 2006, we issued options to purchase an aggregate of 45,000 shares of common stock with an exercise price of \$6.00 per share to our three new independent directors.

On July 27, 2006, we issued 625 shares of common stock to an employee upon the exercise of a stock option, which was partially vested.

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.

On February 26, 2007, we issued 55,000 warrants to an outside consultant in connection with capital raising activities. These warrants are immediately exercisable into common shares of the Company and have an exercise price of \$9.19 per share and an expiration date of February 26, 2012.

**EXHIBITS**

**Exhibit**

| <b>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 *****  |
| 5.1        | Opinion of Katten Muchin Rosenman LLP (incorporated by reference to Amendment No. 1 to this Registration Statement on Form SB-2 as filed on September 8, 2006 (File No. 333-136904)). |
| 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*   |
| 10.4       | Library Access Agreement by and between ChemBridge Corporation and Cleveland BioLabs, Inc., effective as of April 27, 2004*   |
| 10.5       | Restricted Stock and Investor Rights Agreement between Cleveland BioLabs, Inc. and ChemBridge Corporation, dated as of April 27, 2004*  |

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- 10.6 Common Stockholders Agreement by and among Cleveland BioLabs, Inc. and the stockholders named therein, dated as of July 1, 2004\*
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- 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\*\*



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- 10.12 Form of Stock Purchase Agreement between Cleveland BioLabs, Inc. and the Purchasers party thereto, dated as of March 15, 2005\*
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- 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\*\*\*\*\*
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- 16.1 Letter on change in certifying accountant\*
- 23.1 Consent of Meaden & Moore, Ltd.
- 23.2 Consent of Katten Muchin Rosenman LLP (included in Exhibit 5.1).

24.1 Power of Attorney (incorporated by reference to signature page of this Registration Statement on Form SB-2 as filed on August 25, 2006 (File No. 333-136904)).

---

\* 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.

## UNDERTAKINGS

The undersigned registrant hereby undertakes that it will:

(1) File, during any period in which it offers or sells securities, a post-effective amendment to this registration statement to:

(i) Include any prospectus required by section 10(a)(3) of the Securities Act;

(ii) Reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) Include any additional or changed material information on the plan of distribution.

(2) For determining any liability under the Securities Act of 1933, treat each post-effective amendment as a new registration statement to the securities offered in the U.S., and the offering of the securities at that time as the initial bona fide offering of those securities.

(3) File a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.

Insofar as indemnification by the undersigned small business issuer for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the small business issuer pursuant to the foregoing provisions, or otherwise, the small business issuer has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act of 1933, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Cleveland, Cuyahoga County, State of Ohio, on the 11<sup>th</sup> day of April, 2007.

### CLEVELAND BIOLABS, INC.

By:

/s/ Michael Fonstein

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Michael Fonstein  
Chief Executive Officer and President



**EXHIBIT INDEX**

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