CLEVELAND BIOLABS INC
Form SB-2
June 14, 2007

As filed with the Securities and Exchange Commission on June 14, 2007
Registration Number 333-_____

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

FORM SB-2

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

Delaware	**8731**	**20-0077155**
(State or jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(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 and principal place of business)

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)

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

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CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To Be Registered	Amount To Be Registered (1)	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, par value $0.005 per share	5,952,713(2)	$ 9.35(3)	$ 55,657,866.55	$ 1,708.70
Common Stock, par value $0.005 per share	3,075,186(4)	$ 9.35(5)	$ 28,752,989.10	$ 882.72
Common Stock, par value $0.005 per share	347,196(6)	$ 9.35(7)	$ 3,246,282.60	$ 99.66
Total	9,375,095	—	$ 87,657,138.25	$ 2,691.08

(1) This registration statement shall also cover any additional shares of common stock of the Registrant that may become issuable in conversion of Series B Convertible Preferred Stock (the “Series B Preferred”) or exercise of the Series B or Series C Warrants (collectively, the “Warrants”), by reason of any issuance of shares of common stock, options to purchase shares of common stock or securities convertible into or exercisable for shares of common stock, in each case at a price deemed lower than the conversion price of the Series B Preferred or the exercise price of the Warrants then in effect, or by reason of any other transaction that triggers the anti-dilution provisions of the Series B Preferred or the Warrants.

(2) Represents 130% of the 4,579,010 shares of common stock issuable upon conversion of the Series B Preferred at an initial conversion price of $7.00 per share.

(3) Computed in accordance with Rule 457(c) of the Securities Act of 1933, as amended. The offering price of $9.35 represents the average of the high and low prices, as reported on the Nasdaq Capital Market, for Cleveland BioLabs. Inc.'s common stock on June 7, 2007.

(4) Represents approximately 130% of the 2,365,528 shares of common stock issuable upon exercise of the Series B Warrants at an initial exercise price of $10.36 per share.

(5) Computed in accordance with Rule 457(c) of the Securities Act of 1933, as amended. The offering price of $9.35 represents the average of the high and low prices, as reported on the Nasdaq Capital Market, for Cleveland BioLabs. Inc.'s common stock on June 7, 2007.

(6) Represents approximately 130% of the 267,074 shares of common stock issuable upon exercise of the Series C Warrants at an initial exercise price of $11.00 per share.

(7) Computed in accordance with Rule 457(c) of the Securities Act of 1933, as amended. The offering price of $9.35 represents the average of the high and low prices, as reported on the Nasdaq Capital Market, for Cleveland BioLabs. Inc.'s common stock on June 7, 2007.

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.

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 JUNE 14, 2007

9,375,095 Shares

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

This prospectus relates to up to 9,375,095 shares of our common stock that may be offered for sale from time to time by the selling stockholders named in this prospectus. This number represents approximately 130% of the 7,211,612 shares of common stock issuable upon the conversion or exercise of the securities issued in our private placement at the current conversion and exercise prices. Of these 7,211,612 shares of common stock:

- 4,579,010 shares are issuable upon conversion of Series B Convertible Preferred Stock, par value $0.005 per share (the "Series B Preferred");
- 2,365,528 shares are issuable upon exercise of the Series B Warrants; and
- 267,074 shares of common stock are issuable upon exercise of the Series C Warrants (together with the Series B Warrants, the "Warrants").

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 the exercise in cash of the Warrants by the selling stockholders. 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 81. 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 and the Boston Stock Exchange under the symbol "CBLI." The last reported sales price of our common stock on the Nasdaq Capital Market on June 13, 2007 was $10.05 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:

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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. Our response to this RFP was submitted in April 2007. Information regarding an anticipated contract award is expected 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 gastrointestinal 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.

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.

Private Placement

On March 16, 2007, pursuant to a Securities Purchase Agreement of the same date, we consummated a transaction with various accredited investors in which we agreed to sell to the investors, in a private placement, Series B Preferred convertible into an aggregate of approximately 4,288,712 shares of common stock, and Series B Warrants to purchase approximately 2,144,356 shares of our common stock . 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.

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 (or its designees) received compensation as follows: SSC received Series B Preferred convertible into an aggregate of 290,298 shares of common stock, 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 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 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, approximately 6,944,538 shares of common stock (subject to adjustments in the event of certain corporate events such as stock splits, or issuances of securities at a price below the conversion price of the Series B Preferred or the exercise price of the Warrants, as the case may be). 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 was submitted for approval and was approved by our stockholders at our 2007 annual stockholders meeting.

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. The holders of Series C Warrants may exercise at any time after September 16, 2007 until expiration.

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, together with holders of the Series B Preferred that were eligible to vote at the 2007 annual stockholders meeting, held approximately 63% of all votes entitled to be cast as of the record date.

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. This registration statement is being filed to satisfy the registration rights granted under that Registration Rights Agreement.

SEP, one of the investors, together with its affiliates is a holder of more than 10% of our outstanding common stock. In the transaction, SEP purchased Series B Preferred convertible into 600,000 shares of common stock and received Series B Warrants to purchase 300,000 shares of common stock. As mentioned above, we also issued Series B Preferred convertible into 290,298 shares of common stock, 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 trading symbol on the Boston Stock Exchange was later changed to “CBLI”. 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	Up to 9,375,095 shares
Common stock currently outstanding	12,065,152 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	CBLI

The number of shares of common stock currently outstanding is based on the number of shares outstanding as of June 13, 2007 and excludes:

- 4,579,010 shares of common stock issuable upon conversion of outstanding shares of Series B Preferred at the current conversion rate;
- 2,365,528 shares of common stock issuable upon exercise of Series B Warrants at the current exercise price of $10.36;
- 267,074 shares of common stock issuable upon exercise of Series C Warrants at the current exercise price of $11.00;
- 875,490 shares of common stock issuable upon exercise of outstanding options with exercise prices ranging from $0.66 to $9.40 per share;
- 825,219 shares of common stock issuable upon exercise of warrants with exercise prices ranging from $1.13 to $10.00 per share; and
- 1,368,000 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 and the summary financial data for the three months ended March 31, 2007 and March 31, 2006 from our unaudited interim 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

	Three Months Ended March 31, 2007	Three Months Ended March 31, 2006	Fiscal year Ended December 31, 2006	Fiscal year Ended December 31, 2005	Fiscal year Ended December 31, 2004
Total Revenues	**$ 321,445**	**$ 578,424**	**$ 1,708,214**	**$ 1,138,831**	**$ 636,341**
Operating Expenses					
Research and Development	**$ 3,528,600**	**$ 1,502,364**	**$ 6,989,804**	**$ 2,640,240**	**$ 2,892,967**
General and Administrative	**$ 994,319**	**$ 352,898**	**$ 2,136,511**	**$ 986,424**	**$ 262,817**
Income (Loss) from Operations	**$ (4,201,474)**	**$ (1,276,838)**	**$ (7,418,101)**	**$ (2,487,833)**	**$ (2,519,443)**
Net Income (Loss)	**$ (4,106,133)**	**$ (1,252,145)**	**$ (7,222,644)**	**$ (2,386,455)**	**$ (2,523,142)**

Balance Sheet Data

	March 31, 2007	December 31, 2006	December 31, 2005	December 31, 2004
Cash and Cash Equivalents	**$ 11,968,017**	**$ 3,061,993**	**$ 1,206,462**	**$ 94,741**
Total Assets	**$ 32,497,045**	**$ 6,416,529**	**$ 4,253,333**	**$ 382,219**
Total Liabilities	**$ 1,639,271**	**$ 823,375**	**$ 696,729**	**$ 756,433**
Total Stockholders' Equity	**$ 30,857,774**	**$ 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. From our inception through May 2007, we have received fundable scores for grants totaling $5,545,000. We have also received $1 million in funding from the State of New York and

will receive an additional $2 million from the State of New York over the next 12 months. Also, we plan to submit new applications for grants totaling $6,610,000.

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 June 13, 2007, we have 37 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.

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.

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 also 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 pre