CLEVELAND BIOLABS INC
Form 424B4
December 11, 2007
PROSPECTUS

As filed Pursuant to Rule 424(b)(4)
Registration No. 333-143755

5,514,999 Shares

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

This prospectus relates to up to 5,514,999 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 5,514,999 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 5,514,999 shares of common stock:

- 3,717,515 shares are issuable upon conversion of Series B Convertible Preferred Stock, par value $0.005 per share (the "Series B Preferred"); and

- 1,797,484 shares are issuable upon exercise of the Series B 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 Series B Warrants upon the exercise in cash of the Series B 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 87. 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 Global Market under the symbol "CBLI." The last reported sales price of our common stock on the Nasdaq Global Market on December 7, 2007 was $9.29 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 December 10, 2007.

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

PROSPECTUS SUMMARY

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

Our Company

Our company is engaged in drug discovery. Our goal is to identify and develop new types of drugs for protection of normal tissues from exposure to radiation and other stresses, such as toxic chemicals and for cancer treatment. Our initial target, and most promising opportunity, is to develop a drug to protect humans from the effects of exposure to radiation, whether as a result of military or terrorist acts or as a result of a nuclear accident. Recent acts of terrorism and the proliferation of nuclear weapons programs in rogue states have created a more immediate demand for further research and development, or R&D, in this area. Other potential applications of our drug candidates include reducing the side effects of cancer treatment, destroying tumor cells and generating adult stem cells.

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

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

If the need is to protect healthy tissues against an external event such as exposure to nuclear radiation, we attempt to suppress apoptosis in those healthy tissues, thereby imitating the apoptotic-resistant tendencies displayed by cancer cells. A drug with this effect would also be useful in ameliorating the often severe side effects of anticancer drugs and radiation that cause collateral damage to healthy tissues during cancer treatment. Because the severe side effects of anticancer drugs and radiation often limit their dosage in cancer patients, an apoptosis suppressant drug may enable a more aggressive treatment regimen using anticancer drugs and radiation and thereby increase their effectiveness.

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

Our Products and Technology

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

- Protectans are modified factors 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 later in the year.

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 late 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 218,890 cases were projected to be diagnosed with prostate cancer in 2007. The American Cancer Society estimates that there will be about 51,190 new cases of RCC in the United States in 2007 and about 12,890 people will die from this disease. Soft-tissue sarcomas are rare, representing only about 1% of all cancer cases. According to the American Cancer Society, approximately 9,220 new cases of soft-tissue sarcoma were projected to be diagnosed in the United States in 2007, which were projected to be responsible for approximately 3,560 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 at an exercise price of $10.36 per share. 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 (together with the Series B Warrants, the "Warrants"); 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 Warrants issued in the transaction are convertible for and exercisable into, as of the date hereof, 7,211,612 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 Series B Warrants, as the case may be). Based on the closing price of our common stock on March 16, 2007 of $10.19, the common stock issuable upon conversion of the Series B Preferred and exercise of the Warrants had a market value of approximately $73,486,326. 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 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 and exercise of the Warrants. This registration statement is being filed to satisfy the registration rights granted under that Registration Rights Agreement and registers 3,717,515 of the 4,579,010 shares of common stock issuable upon conversion of the Series B Preferred and 1,797,484 of the 2,365,528 shares of common stock issuable upon the exercise of the Series B Warrants. In accordance with the Registration Rights Agreement, shares issuable upon exercise of the Series C Warrants, as well as shares issuable upon conversion of the Series B Preferred and exercise of the Series B Warrants that are not registered hereunder, will be registered in a subsequent registration statement.

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) and its designees in consideration for its services as lead placement agent. We also engaged SSC as our exclusive management agent regarding all exercises of the Series B Warrants, for which we will pay SSC a fee equal to 3.5% of the aggregate exercise price of each Series B 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”. On August 28, 2007, trading of our stock moved from the Nasdaq Capital Market to the Nasdaq Global Market. In September 2007, we ceased our listing on the Boston Stock Exchange. Our principal executive offices are located at 73 High Street, Buffalo, New York 14203 and our telephone number is (716) 849-6810. 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	5,514,999 shares
Common stock currently outstanding	12,183,998 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, although we will receive proceeds from the exercise of Warrants into common stock for cash
Nasdaq Global Market Symbol	CBLI

The number of shares of common stock currently outstanding is based on the number of shares outstanding as of November 1, 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;
- 891,240 shares of common stock issuable upon exercise of outstanding options with exercise prices ranging from $0.66 to $17.00 per share;
- 820,666 shares of common stock issuable upon exercise of warrants with exercise prices ranging from $1.13 to $10.00 per share; and
- 1,222,000 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 and nine months ended September 30, 2007 and September 30, 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 September 30, 2007	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2007	Nine Months Ended September 30, 2006	Fiscal year Ended December 31, 2006	Fiscal year Ended December 31, 2005	Fiscal year Ended December 31, 2004
Total Revenues	**$ 660,544**	**$ 323,368**	**$ 1,617,996**	**$ 1,476,787**	**$ 1,708,214**	**$ 1,138,831**	**$ 636,341**
Operating Expenses							
Research and Development	**$ 4,105,480**	**$ 1,281,055**	**$ 11,663,054**	**$ 4,341,535**	**$ 6,989,804**	**$ 2,640,240**	**$ 2,892,967**
General and Administrative	**$ 1,442,669**	**$ 708,776**	**$ 6,968,565**	**$ 1,367,457**	**$ 2,136,511**	**$ 986,424**	**$ 262,817**
Income (Loss) from Operations	$ (4,887,605)	$ (1,666,463)	$ (17,013,623)	$ (4,232,205)	$ (7,418,101)	$ (2,487,833)	$ (2,519,443)
Net Income (Loss)	$ (5,787,709)	$ (1,587,531)	$ (17,709,413)	$ (4,117,684)	$ (7,222,644)	$ (2,386,455)	$ (2,523,142)

Balance Sheet Data

	September 30, 2007	December 31, 2006	December 31, 2005	December 31, 2004
Cash and Cash Equivalents	**$ 20,278,556**	**$ 3,061,993**	**$ 1,206,462**	**$ 94,741**
Total Assets	**$ 23,795,796**	**$ 6,416,529**	**$ 4,253,333**	**$ 382,219**
Total Liabilities	**$ 3,210,123**	**$ 823,375**	**$ 696,729**	**$ 756,433**
Total Stockholders' Equity	**$ 20,585,673**	**$ 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 9-21 months. Upon expiration of this 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 November 15, 2007, we have received fundable scores for grants totaling $5,545,000. We have also received $2 million in funding from the State of New

York and will receive an additional $1 million from the State of New York over the next 12 months. Also, we plan to submit new applications for grants totaling $4,110,000.

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 RCC, soft-tissue sarcoma, and multiple myeloma. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first designated orphan drug approved by the FDA will be granted a seven-year period of marketing exclusivity for that drug. There is no assurance that we will receive orphan drug status for Curaxin CBLC102. Even if we do receive orphan drug status, while the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same compound for the same indication, it would not prevent other types of drugs from being approved for the same indication and therefore may not provide sufficient protection against competitive products.

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 valid 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 valid 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 November 1, 2007, we have 44 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 RxBio, Inc., Exponential Biotherapies Inc., Osiris Therapeutics, Inc., ImmuneRegen BioSciences, Inc. and Humanetics Corporation are developing biopharmaceutical products that potentially directly compete with our non-medical application drug candidates even though their approaches to such treatment are different.

We 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 prevent the product from being commercialized.

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

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

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

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

- price and volume fluctuations in the overall stock market from time to time;

- fluctuations in stock market prices and trading volumes of similar companies;

- actual or anticipated changes in our earnings or fluctuations in our operating results or in the expectations of securities analysts;

- general economic conditions and trends;

- major catastrophic events;

· sales of large blocks of our stock;

· departures of key personnel;

· changes in the regulatory status of our drug candidates, including results of our clinical trials;

· events affecting the Cleveland Clinic, Roswell Park Cancer Institute, ChemBridge Corporation or any other collaborators;

· announcements of new products or technologies, commercial relationships or other events by us or our competitors;

· regulatory developments in the United States and other countries;

· failure of our common stock to be listed or quoted on the Nasdaq Global Market, other national market system or any national stock exchange;

· changes in accounting principles; and

· discussion of us or our stock price by the financial and scientific press and in online investor communities.

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

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

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

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

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

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

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

Our common stock has been approved for listing on the Nasdaq Global Market. The listing of our common stock on the Nasdaq Global Market does not assure that a meaningful, consistent and liquid trading market will exist, and in recent years, the market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility. Sales of substantial amounts of common stock, or the perception that such sales might occur, could adversely affect the prevailing market prices of our common stock. Our stock price may decline substantially in a short time and our

stockholders could suffer losses or be unable to liquidate their holdings.

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

As of November 1, 2007, our officers and directors, in the aggregate, beneficially owned (calculated in accordance with Rule 13d-3 under the Exchange Act) approximately 31.32% of the outstanding shares of our voting stock. As a result, such persons, acting together, have the ability to substantially influence all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets, and to control our management and affairs. Accordingly, such concentration of ownership may have the effect of delaying, deferring or preventing a change in discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would be beneficial to other stockholders. Our founders and certain of our stockholders have agreed during the 24 months after July 20, 2006, the effective date of our initial public offering, not to sell, transfer or otherwise dispose of their shares in a tender offer, merger or other sale transaction unless such transaction is approved by a majority of the other stockholders.

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

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

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

We are authorized to issue 40,000,000 shares of our common stock and 10,000,000 shares of our preferred stock. As of November 1, 2007, we had 12,183,998 shares of our common stock issued and outstanding, excluding shares issuable upon the exercise of our outstanding warrants and options, and 4,579,010 shares of our common stock issuable upon conversion of our Series B Preferred. As of November 1, 2007, we had outstanding 891,240 options to purchase shares of our common stock with exercise prices ranging from $0.66 to $17.00 per share of which 593,930 options have vested or will vest within 60 days of November 1, 2007, and outstanding warrants to purchase 3,453,268 shares of our common stock with exercise prices ranging from $1.13 to $11.00 per share, all of which are exercisable within 60 days of November 1, 2007. To the extent the shares of common stock are issued or options and warrants are exercised, holders of our common stock will experience dilution. In addition, in the event of any future financing of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution.

Shares eligible for future sale may adversely affect the market.

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 promulgated under the Securities Act of 1933, as amended, or Securities Act, subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a minimum holding period may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitations, by a non-affiliate of our company who has satisfied a minimum holding period. Any substantial sale

of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have an adverse effect on the market price of our securities.

An aggregate of 6,153,601 shares of common stock have been registered with the SEC. An additional 5,514,999 shares of common stock are being registered pursuant to the registration statement of which this prospectus forms a part. All of these shares would otherwise be eligible for future sale under Rule 144 after passage of the minimum holding period for holders who are not officers, directors or affiliates of the company.

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

We have not paid any cash dividends on our common stock and do not intend to pay cash dividends on our common stock in the foreseeable future. We will pay dividends on our Series B Preferred at the annual rate of 5% in two semi-annual installments. We intend to retain future earnings, if any, for reinvestment in the development and expansion of our business. Any credit agreements, which we may enter into with institutional lenders, may restrict our ability to pay dividends. Whether we pay cash dividends in the future will be at the discretion of our board of directors and will be dependent upon our financial condition, results of operations, capital requirements and any other factors that the board of directors decides is relevant.

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

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

USE OF PROCEEDS

All proceeds from the sale of the shares offered by this prospectus will be received by the selling stockholders, although we will receive proceeds from the exercise of the Warrants into common stock for cash. We intend to use the proceeds from the exercise of the Warrants for general corporate and working capital purposes.

DIVIDEND POLICY

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

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

PRICE RANGE OF COMMON STOCK

From July 21, 2006 through August 27, 2007, our common stock was quoted on the Nasdaq Capital Market, and since August 28, 2007, our common stock has been listed on the Nasdaq Global Market, in each case under the symbol "CBLI". From July 21, 2006 until September 2007, our common stock was also listed on the Boston Stock Exchange. The following table sets forth, for the period indicated, the high and low closing sale prices for our common stock as reported by the Nasdaq Capital Market or Nasdaq Global Market, as applicable.

2007	**High**	**Low**
Fourth Quarter (through December 7, 2007)	$ 13.05	$ 9.29
Third Quarter	$ 13.68	$ 9.30
Second Quarter	$ 11.50	$ 8.28
First Quarter	$ 13.38	$ 4.56
2006		
Fourth Quarter	$ 5.87	$ 4.25
Third Quarter (from July 21, 2006)	$ 6.00	$ 4.17

On December 7, 2007, the last reported sales price of our common stock as reported on the Nasdaq Global Market was $9.29 per share. As of November 1, 2007, we had 42 holders of record of our common stock, and 82 holders of record of our Series B Preferred.

CAPITALIZATION

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

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

The above table excludes as of December 31, 2006:

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

SELECTED FINANCIAL DATA

We have derived the following 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 and nine months ended September 30, 2007 and September 30, 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 September 30, 2007	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2007	Nine Months Ended September 30, 2006	Fiscal year Ended December 31, 2006	Fiscal year Ended December 31, 2005	Fiscal year Ended December 31, 2004
Total Revenues	**$ 660,544**	**$ 323,368**	**$ 1,617,996**	**$ 1,476,787**	**$ 1,708,214**	**$ 1,138,831**	**$ 636,341**
Operating Expenses							
Research and Development	**$ 4,105,480**	**$ 1,281,055**	**$ 11,663,054**	**$ 4,341,535**	**$ 6,989,804**	**$ 2,640,240**	**$ 2,892,967**
General and Administrative	**$ 1,442,669**	**$ 708,776**	**$ 6,968,565**	**$ 1,367,457**	**$ 2,136,511**	**$ 986,424**	**$ 262,817**
Income (Loss) from Operations	$ (4,887,605)	$ (1,666,463)	$ (17,013,623)	$ (4,232,205)	$ (7,418,101)	$ (2,487,833)	$ (2,519,443)
Net Income (Loss)	$ (5,787,709)	$ (1,587,531)	$ (17,709,413)	$ (4,117,684)	$ (7,222,644)	$ (2,386,455)	$ (2,523,142)

Balance Sheet Data

	September 30, 2007	December 31, 2006	December 31, 2005	December 31, 2004
Cash and Cash Equivalents	**$ 20,278,556**	**$ 3,061,993**	**$ 1,206,462**	**$ 94,741**
Total Assets	**$ 23,795,796**	**$ 6,416,529**	**$ 4,253,333**	**$ 382,219**
Total Liabilities	**$ 3,210,123**	**$ 823,375**	**$ 696,729**	**$ 756,433**
Total Stockholders' Equity	**$ 20,585,673**	**$ 5,593,154**	**$ 3,556,604**	$ (374,214)

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

This management's discussion and analysis of financial condition and results of operations and other portions of this filing contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking information. Factors that may cause such differences include, but are not limited to, availability and cost of financial resources, results of our R&D efforts and clinical trials, product demand, market acceptance and other factors discussed in the Company's other SEC filings under the heading "Risk Factors". This management's discussion and analysis of financial condition and results of operations should be read in conjunction with our financial statements and the related notes included elsewhere in this filing and in our Annual Report on Form 10-KSB for the year ended December 31, 2006.

Overview

General Overview

We commenced business operations in June 2003. We are a drug discovery and development company leveraging our proprietary scientific research and discoveries relating to programmed cell death to treat cancer and protect normal tissues from exposure to radiation and other stresses.

Technology

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

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

If the need is to protect healthy tissues against an external event such as exposure to nuclear radiation, we focus our research efforts on attempting to temporarily and reversibly suppress apoptosis in those healthy tissues, thereby imitating the apoptotic-resistant tendencies displayed by cancer cells. A drug with this effect would also be useful in ameliorating the often severe side effects of anticancer drugs and radiation that cause collateral damage to healthy tissues during cancer treatment. Because the severe side effects of anticancer drugs and radiation often limit their dosage in cancer patients, an apoptosis suppressant drug may enable a more aggressive treatment regimen using anticancer drugs and radiation and thereby increase their effectiveness.

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

Products In Development

Protectans

Protectans are modified factors of microbes that protect cells from apoptosis, and have a broad spectrum of potential applications. These potential applications include non-medical applications such as protection from exposure to radiation, whether as a result of military or terrorist action or as a result of a nuclear accident, as well as medical applications such as reducing cancer treatment side effects.

Protectan CBLB502

Protectan CBLB502 is our leading radioprotectant molecule in the protectans series. Protectan CBLB502 represents a rationally designed derivative of the microbial protein, flagellin. Flagellin is secreted by *Salmonella typhimurium* and acts as a natural activator of NF-kB. Protectan CBLB502 is administered through intramuscular injection.

Biodefense Applications

In collaboration with the Cleveland Clinic, our scientists have demonstrated that injecting Protectan CBLB502 into mice protects them from lethal doses of total body gamma radiation. An important advantage of Protectan CBLB502, above any other radioprotectant known to us, is the ability to effectively protect not only the hematopoietic system, but also the gastrointestinal, or GI, tract, which are among the most sensitive areas of the human body to radiation. High levels of radiation, among other effects, induce moderate to severe bone marrow damage. The immune and blood stem cells are also depleted and death is caused by anemia, infection, bleeding and poor wound healing. Protectan CBLB502's ability to effectively protect the hematopoietic system and GI tract may make Protectan CBLB502 uniquely useful as a radioprotective antidote. Protectan CBLB502 was shown to be safe at its therapeutic doses in rodents and non-human primates. In addition, Protectan CBLB502 has proved to be a stable compound for storage purposes. It can be stored at temperatures close to freezing, room temperature or extreme heat. Manufacture of Protectan CBLB502 is relatively inexpensive, due to its high yield bacterial producing strain and simple purification process.

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

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

As in the protection regimen, a single-dose injection of Protectan CBLB502 given one hour after exposure (the mitigation regimen) to a lethal whole-body gamma irradiation increased the survival of rhesus monkeys from 20% in the control group to 70% in the treated group. Radiomitigation by Protectan CBLB502 was accompanied with less severe thrombocytopenia and neutropenia as well as reduced GI damage.

We have responded to the Request for Proposal (RFP) issued in March 2007, by The Department of Defense (DoD) for the Advanced Development of Medical Radiation Countermeasures (MRC) to treat gastrointestinal effects of acute radiation syndrome (ARS) using CBLB502. The objective of the RFP is to develop a post-exposure Medical Radiation Countermeasure through approval/licensure with the U.S. Food and Drug Administration (FDA) and procure quantities sufficient to achieve Initial Operational Capability (IOC). A range of 50,000 to 500,000 doses was specified. The RFP award would provide funding for development of the countermeasure through FDA approval, leading to purchase. We are anticipating the contract decision from the Department of Defense this year.

Also in March 2007, we received a $1.3 million contract from the Defense Threat Reduction Agency (DTRA) of the Department of Defense (DoD) to fund "development leading to the acquisition" of Protectan CBLB502, in

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

We have submitted responses to two Requests for Information (RFI) from the Department of Health and Human Services (HHS) and National Institute of Allergy and Infectious Diseases (NIAID) addressing medical countermeasures for neutropenia (low levels of neutrophils, a type of white blood cell) and thrombocytopenia (low platelet count) arising from Acute Radiation Syndrome (ARS).

The RFI from HHS noted the agency's intention to pursue initial acquisition of 100,000 treatment courses of a medical countermeasure for neutropenia arising as a consequence of ARS. The RFI further stated that there would be options for up to an additional 100,000 treatment courses to meet the HHS requirement of at least 200,000 treatment courses. We expect the RFP to be issued by HHS in the fourth quarter of 2007 with proposals due 60-90 days after the RFP is issued.

The RFI from NIAID requested the identification of therapeutics likely to be effective in preventing or reducing the development of thrombocytopenia, when administered after acute exposure to radiation. The NIAID RFI was distributed on behalf of the National Institutes of Health (NIH) and indicated that data obtained from this RFI would be used by the NIH in making recommendations and decisions regarding research and development of radiation countermeasures to meet the nation's biodefense needs. On September 27, 2007, NIAID announced a new grant initiative focused on the development of medical countermeasures to enhance platelet regeneration and thereby, increase survival after radiation exposure. The Company plans to submit the proposal in response to this solicitation by January 9, 2008.

Anticancer Applications

In addition to its military or other non-medical applications, we have found that Protectan CBLB502, on a preliminary research basis, has been observed to dramatically increase the efficacy of radiotherapy of experimental tumors in mice. Protectan CBLB502 appears to increase the tolerance of mice to radiation while having no effect on the radiosensitivity of tumors, thus opening the possibility of combining radiotherapy with Protectan CBLB502 treatment to improve the overall anticancer efficacy of radiotherapy. Our animal efficacy studies have demonstrated that up to 100% of mice treated with Protectan CBLB502 prior to being exposed to radiation survived, without any associated signs of toxicity. This compares to a 100% mortality rate in the animal group that received a placebo drug. While protecting mice from lethal irradiation, Protectan CBLB502 had no effect on the radiosensitivity of tumor cells.

The use of Protectan CBLB502 to ameliorate the side effects of radiation treatment and anticancer drugs will be subject to the full FDA approval process.

Manufacturing

Together with our manufacturing partner, SynCo Bio Partners, we have completed the technology transfer and the production of the first cGMP batch of Protectan CBLB502 on schedule. The yields from the process and the purity of the final product exceeded our expectations. We currently have drug substance corresponding to over 100,000 projected human doses, or potentially many more, depending on the final therapeutic dose to be used, which will be determined in the coming months through our Phase I safety trial. The process we developed gives us the ability to manufacture up to five million estimated doses within a year without any additional scale-up; and, if necessary, scale-up could be implemented relatively easily.

Protectan CBLB612

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

Moreover, through our research in the area of radiation protection, we have discovered a unique property of the Protectans 600 series, which has led to a potential breakthrough in the rapidly emerging arena of stem cell research. A single administration of CBLB612 resulted in a three-fold increase in the number of progenitor stem cells in mouse bone marrow within 24 hours after administration. We also found that the number of these stem cells in peripheral blood was increased ten-fold within four days of administration. A study of the effects of Protectan CBLB612 on nonhuman primates regarding the proliferation and mobilization to peripheral blood of pluripotent hematopoietic stem cells in a primate model (Rhesus macaques) was recently completed. CBLB612 was found to be highly efficacious in stimulating proliferation and mobilization of hematopoietic stem cells into peripheral blood in these primates. A single injection of CBLB612 in Rhesus macaques resulted in a 20- fold increase of hematopoietic progenitor cells in blood.

Our research indicates that CBLB612 and the other compounds in the 600 series are not only potent stimulators of bone marrow stem cells, but also cause their mobilization and proliferation throughout the blood. This important discovery creates a new and innovative business opportunity for us to address a broad spectrum of human diseases, some of which currently lack effective treatment.

In a study of the efficacy of Protectan CBLB612, blood from healthy mice treated by Protectan CBLB612 was transplanted into mice that received a lethal dose of radiation that killed hematopoietic (bone marrow/blood production) stem cells. A small amount of blood from the CBLB612 treated mice successfully rescued the mice with radiation-induced bone marrow stem cell deficiency. 100% of the deficient mice transplanted with blood from CBLB612 treated mice survived past the 90 day mark, while 85% of the untreated deficient mice died within the first three weeks of the experiment. The 90 day mark is considered to be the critical point in defining the presence of long-term, adult bone marrow stem cells, which are capable of completely restoring lost or injured bone marrow function. The rescuing effect of the peripheral blood of the treated mice was equivalent to that of conventional bone marrow transplantation. This transplant study in particular, has advanced our research into clinical applications and suggests multiple potential uses within the field of regenerative medicine.

Curaxins

Curaxins are small molecules that destroy tumor cells by simultaneously targeting two regulators of apoptosis. Our initial test results indicate that curaxins can be effective against a number of malignancies, including hormone refractory prostate cancer, renal cell carcinoma, or RCC, (a highly fatal form of kidney cancer), and soft-tissue sarcoma.

The original focus of our drug development program was to develop drugs to treat one of the most treatment-resistant types of cancer, RCC. Unlike many cancer types that frequently mutate or delete p53, one of the major tumor suppressor genes, RCC belongs to a rare category of cancers that typically maintain a wild type form of this protein. Nevertheless, RCC cells are resistant to apoptosis, suggesting that in spite of its normal structure, p53 is functionally disabled. Our research has shown that p53 function is indeed inhibited in RCC by an unknown dominant factor. We have established a drug discovery program to identify small molecules that selectively destroy tumor cells by restoring the normal function to functionally impaired p53 in RCC. This program yielded a series of chemicals with the desirable properties named curaxins (CBLC100 series). We have isolated three chemical classes of curaxins. One of them includes relatives of 9-aminoacridine, the compound that is the core structure of many existing drugs. Pre-existing information about this compound has allowed us to bypass the preclinical development and Phase I studies and bring one of our drug candidates into Phase IIa clinical trials, saving years of R&D efforts and improving the probability of success.

One of the most important outcomes of this drug discovery program was the identification of the mechanism by which curaxins deactivate NF-kB. This mechanism of action makes curaxins potent inhibitors of the production and the activity of NF-kB not only in its stimulated form, but also in its basal form. The level of active NF-kB is usually also increased in cancer cells. Moreover, due to curaxin-dependent functional conversion of NF-kB DNA complexes, the cells with the highest basal or induced NF-kB activity are supposed to be the most significantly affected by curaxins. Clearly, this paradoxical activity makes deactivation of NF-kB by curaxins more advantageous compared to conventional strategies targeting NF-kB activators.

The discovery of the mechanism of action of curaxins allowed us to predict and later experimentally verify that curaxins could be used for treatment of multiple forms of cancers, including hormone refractory prostate cancer, hepatocellular carcinoma, multiple myeloma, acute lymphocytic leukemia, acute myeloid leukemia, soft-tissue sarcomas and several others.

Curaxin CBLC102

One of the curaxins from the 9-aminoacridine group is a long-known, anti-infective compound known as quinacrine, which we refer to as Curaxin CBLC102. It has been used for over 40 years to treat malaria, osteoarthritis and autoimmune disorders. However, we have discovered new mechanisms of action for quinacrine in the area of apoptosis. Through assay testing performed at Dr. Andrei Gudkov's laboratories at the Cleveland Clinic beginning in 2002 and continued at our research labs in Buffalo, NY which included testing in a variety of human tumor-derived cell lines representing cancers of different tissue origin (including RCC sarcomas, prostate, breast and colon carcinomas), we have observed that Curaxin CBLC102 behaves as a potent NF-kB suppressor and activator of p53 in these types of cancer cells. It has favorable pharmacological and toxicological profiles and demonstrates the anticancer effect in transplants of human cancer cells into primates. These features make Curaxin CBLC102 our prime IND drug candidate among other curaxins. The drug candidate is currently in Phase II clinical trials for treatment of hormone refractory prostate cancer. We also intend to conduct additional Phase II clinical trials with Curaxin CBLC102 for RCC and multiple myeloma.

We intend to seek orphan drug status with respect to Curaxin CBLC102. The orphan drug provisions of the Federal Food, Drug, and Cosmetic Act provide incentives to drug and biologic manufacturers to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in

the U.S. We believe that Curaxin CBLC102 may qualify as an orphan drug for purposes of treatment of RCC, soft-tissue sarcoma, and multiple myeloma. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first designated orphan drug approved by the FDA will be granted a seven-year period of marketing exclusivity for that drug. There is no assurance that we will receive orphan drug status for Curaxin CBLC102. Even if we do receive orphan drug status, while the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same compound for the same indication, it would not prevent other types of drugs from being approved for the same indication and therefore may not provide sufficient protection against competitive products.

We have an agreement with Regis Technologies, Inc., a GMP manufacturer, to produce sufficient quantities of Curaxin CBLC102 according to the process previously used for the production of this drug when it was in common use. On May 26, 2006, we filed our IND application with the FDA to begin clinical trials in patients with hormone refractory prostate cancer. On June 26, 2006, the FDA advised us that we may initiate clinical Phase II studies after making additional minor modifications to the protocol. On June 5, 2007, we filed an amendment to the IND to include protocols for RCC Phase II clinical trials which are planned to start in November 2007.

Our Phase II efficacy study for Curaxin CBLC102 in advanced, hormone-refractory (androgen independent) prostate cancer has progressed to the next phase. The Phase II study will involve a total of 31 patients with advanced, hormone refractory prostate cancer. Primary endpoints for the study are reduction in PSA levels, reduction in tumor size, and disease-free survival. The duration of the study is two years; however certain preliminary data may be available earlier. The study is being conducted at the University of Chicago, the Cleveland Clinic, the University Hospitals of Cleveland, and the University of Pittsburgh.

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

Other Curaxins

As mentioned above, screening of the chemical library for compounds capable of restoring normal function to wild type p53 in the context of RCC yielded three chemical classes of compounds. Generation of focused chemical libraries around the hits from one of these classes and their structure-activity optimization brought about a new generation of curaxins. These molecules have a chemical structure different from 9-aminoacridine (Curaxin CBLC102) and are more active and appear to be more selective of tumor cells than the representatives of the first generation of curaxins (e.g., Curaxin CBLC102).

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

Roswell Park Cancer Institute

In January 2007, we entered into a strategic research partnership with Roswell Park Cancer Institute (RPCI) to develop our cancer and radioprotectant drug candidates.

RPCI, founded in 1898, is a world-renowned cancer research hospital and the nation's first cancer research, treatment and education center. RPCI is a member of the prestigious National Comprehensive Cancer Network, an alliance of the nation's leading cancer centers, and is one of only ten free-standing cancer centers in the nation.

RPCI and various agencies of the state of New York will provide us with up to $5 million of grant and other funding. We have established a major research/clinical facility at the RPCI campus in Buffalo, New York, which is the foundation for several of our advanced research and clinical trials. Dr. Andrei Gudkov, our Chief Scientific Officer, agreed to become Senior Vice President of Research Programming and Development for RPCI effective May 2007.

Our partnership with RPCI will enhance the speed and efficiency of our clinical research, and will provide us with access to state-of-the-art clinical development facilities in partnership with a globally recognized cancer research center. We believe that our proprietary technology, combined with the assistance of RPCI, and our continuing strong relationship with the Cleveland Clinic, will position us to become a leading oncology company. A key element of our long-term business strategy is to partner with world-class institutions to aid us in accelerating our drug development timeline. We believe that our firm alliances with both RPCI and the Cleveland Clinic provide us with a significant competitive advantage.

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Financial Overview

We secured a $6,000,000 investment via a private placement of Series A Preferred stock in March 2005. On July 20, 2006, we sold 1,700,000 shares of common stock in our initial public offering at $6.00 per share. The net proceeds from this offering were approximately $8,300,000. Beginning July 21, 2006, our common stock was listed on the Nasdaq Capital Market and on the Boston Stock Exchange under the symbols “CBLI” and “CFB” respectively. On August 28, 2007, trading of our stock moved from the Nasdaq Capital Market to the Nasdaq Global Market. In September 2007, we ceased our listing on the Boston Stock Exchange. In connection with the initial public offering, we issued warrants to purchase 170,000 shares of common stock to the underwriters and their designees. The warrants have an exercise price of $8.70 per share.

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

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

On March 16, 2007, the Company entered into a Securities Purchase Agreement with various Buyers, pursuant to which the Company agreed to sell to the Buyers Series B Preferred convertible into an aggregate of 4,288,712 shares of common stock and Series B Warrants that are exercisable for an aggregate of 2,144,356 shares of common stock. The aggregate purchase price paid by the Buyers for the Series B Preferred and Series B Warrants was approximately $30,000,000. After related fees and expenses, the Company received net proceeds of approximately $29,000,000. The Company is using the proceeds for general corporate and working capital purposes.

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

The Company also issued to the Agents in the private placement, as compensation for their services, Series B Preferred, Series B Warrants, and Series C Warrants. The Agents collectively received Series B Preferred that are convertible into an aggregate of 290,298 shares of common stock, Series B Warrants that are exercisable for an aggregate of 221,172 shares of the Company’s common stock, and Series C Warrants that are exercisable for 267,074 shares of the Company’s common stock. The Series C Warrants have an exercise price of $11.00 per share, and are also subject to anti-dilution protections that could increase the number of shares of common stock for which they are exercisable.

In total, the securities issued in the private placement will be convertible into, or exercisable for, up to approximately 7,211,612 shares of common stock, which amount is subject to adjustment 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 exercise price of the warrants, as the case may be.

Critical Accounting Policies and the Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with generally accepted accounting principles in the U.S., or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues, expenses and other reported disclosures. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances.

Note 2 to our financial statements includes disclosure of our significant accounting policies. While all decisions regarding accounting policies are important, we believe that our policies regarding revenue recognition, R&D expenses, intellectual property related costs and stock-based compensation expenses could be considered critical.

Revenue Recognition

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

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

Fixed-cost grants require no proof of costs and are paid as a request for payment is submitted for expenses. The grant revenue under these fixed cost grants is recognized using a percentage-of-completion method, which uses assumptions and estimates. These assumptions and estimates are developed in coordination with the principal investigator performing the work under the government fixed-cost grants to determine key milestones, expenses incurred, and deliverables to perform a percentage-of-completion analysis to ensure that revenue is appropriately recognized. Critical estimates involved in this process include total costs incurred and anticipated to be incurred during the remaining life of the grant.

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

R&D Expenses

R&D costs are expensed as incurred. These expenses consist primarily of our proprietary R&D efforts, including salaries and related expenses for personnel, costs of materials used in our R&D, costs of facilities and costs incurred in connection with our third-party collaboration efforts. Pre-approved milestone payments made by us to third parties under contracted R&D arrangements are expensed when the specific milestone has been achieved. As of September 30, 2007, $50,000 has been paid for milestone payments relating to the filing of an IND with the FDA for Curaxin CBLC102 and $250,000 has been paid as a result of commencing Phase II clinical trials for Curaxin CBLC102. Once a drug receives regulatory approval, we will record any subsequent milestone payments in identifiable intangible assets, less accumulated amortization, and amortize them evenly over the remaining agreement term or the expected drug life cycle, whichever is shorter. We expect our R&D expenses to increase as we continue to develop our drug candidates.

Intellectual Property Related Costs

We capitalize costs associated with the preparation, filing and maintenance of our intellectual property rights. Capitalized intellectual property is reviewed annually for impairment. If a patent application is approved, costs paid by us associated with the preparation, filing and maintenance of the patent will be amortized on a straight line basis over the shorter of 17 years or the anticipated useful life of the patent. If the patent application is not approved, costs paid by us associated with the preparation, filing and maintenance of the patent will be expensed as part of selling, general and administrative expenses at that time.

Through December 31, 2006, we have capitalized $252,978 in expenditures associated with the preparation, filing and maintenance of certain of our patents, which were incurred through the year ended December 31, 2006. We capitalized an additional $153,417 relating to these costs incurred for the nine months ended September 30, 2007,

totaling $406,395.

Stock-based Compensation

We value stock-based compensation pursuant to the provisions of SFAS 123(R). Accordingly, effective January 1, 2005, all stock-based compensation, including grants of employee stock options, are recognized in the statement of operations based on their fair values.

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

The fair value of each stock option granted is estimated on the grant date using accepted valuation techniques such as the Black Scholes Option Valuation model or Monte Carlo Simulation depending on the terms and conditions present within the specific option being valued. The assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect our experience. We use a risk-free rate based on published rates from the St. Louis Federal Reserve at the time of the option grant; assume a forfeiture rate of zero; assume an expected dividend yield rate of zero based on our intent not to issue a dividend in the foreseeable future; use an expected life based on the safe harbor method; and compute an expected volatility based on similar high-growth, publicly-traded, biotechnology companies. Compensation expense is recognized using the straight-line amortization method for all stock-based awards.

During the quarter ended September 30, 2007, the Company granted 18,000 options pursuant to stock award agreements to a key consultant.

We recognized a total of $395,129 and $72,489 in expense for options for the quarter ended September 30, 2007, and 2006 respectively. The weighted average, estimated grant date fair values of stock options granted during the quarters ended September 30, 2007 and 2006 were $4.95 and $3.76, respectively.

Impact of Recently Issued Accounting Pronouncements

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

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

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

In December 2004, the FASB issued SFAS 153, Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29 (SFAS 153). The guidance in APB Opinion No. 29, Accounting for Nonmonetary Transactions, is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in APB Opinion No. 29, however, included certain exceptions to that principle. SFAS 153 amends APB Opinion No. 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change

significantly as a result of the exchange. SFAS 153 is effective for nonmonetary asset exchanges in fiscal periods beginning after June 15, 2005. We do not believe that the adoption of SFAS 153 will have a material impact on our results of operations or financial position.

Results of Operations

Our operating results for the past three fiscal years have been nominal. The following table sets forth our statement of operations data for the quarter and nine months ended September 30, 2007 and September 30, 2006, and the year ended December 31, 2006 and December 31, 2005, and should be read in conjunction with our financial statements and the related notes appearing elsewhere in this filing and in our Annual Report on Form 10-KSB for the year ended December 31, 2006.

	Quarter Ended September 30, 2007 (unaudited)	Quarter Ended September 30, 2006 (unaudited)	Nine Months Ended September 30, 2007 (unaudited)	Nine Months Ended September 30, 2006 (unaudited)	Year Ended December 31, 2006	Year Ended December 31, 2005
Revenues	$ 660,544	$ 323,368	$ 1,617,996	$ 1,476,787	$ 1,708,214	$ 1,138,831
Operating expenses	5,548,149	1,989,831	18,631,619	5,708,992	9,126,315	3,626,664
Other Expense (income)	1,205,672	-	1,456,351	-	-	-
Net interest expense (income)	(305,568)	(78,933)	(760,561)	(114,521)	(195,457)	(101,378)
Net income (loss)	$ (5,787,709)	$ (1,587,530)	$ (17,709,413)	$ (4,117,684)	$ (7,222,644)	$ (2,386,455)

Nine Months Ended September 30, 2007 Compared to Nine Months Ended September 30, 2006

Revenue

Revenue increased from $1,476,787 for the nine months ended September 30, 2006 to $1,617,996 for the nine months ended September 30, 2007 representing an increase of $141,209 or 9.6% resulting primarily from an increase in revenue from various grants including the Collaborative Research Agreement with the Roswell Park Cancer Institute, the DTRA contract, and the NCI contract. As the term of the BioShield grant ended, the proceeds from the BioShield grant were $0 for the nine months ended September 30, 2007 as compared to $1,100,293 for the nine months ended September 30, 2006.

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

Agency	Program	Amount	Period of Performance	Revenue 2007 (thru September 30) (unaudited)	Revenue 2006 (thru September 30) (unaudited)	Revenue 2006
NIH	BioShield program (NIAID)	$ 1,500,000	07/2005-01/2007		$ 1,100,293	$ 1,100,293
NIH	Phase I NIH SBIR program	$ 100,000	08/2005-01/2006		$ 33,334	$ 33,334
NASA	Phase I NASA STTR program	$ 100,000	01/2006-01/2007	$ 33,196	$ 33,197	$ 66,393
NIH	Phase II NIH SBIR program	$ 750,000	07/2006-06/2008	$ 280,461	$ 88,320	$ 212,713
NIH	NCI Contract	$ 750,000	09/2006-08/2008	$ 394,780	$ 16,643	$ 90,481
DoD	DTRA Contract	$ 1,300,000	03/2007-02/2009	$ 466,322		
NY State	RPCI Research Agreement	$ 3,000,000	03/2007-02/2012	$ 153,238		
Totals				$ 1,327,997	$ 1,271,787	$ 1,503,214

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

Operating Expenses

Operating expenses have historically consisted of costs relating to R&D and general and administrative expenses. R&D expenses have consisted mainly of supporting our R&D teams, process development, sponsored research at the Roswell Park Cancer Institute and Cleveland Clinic, clinical trials and consulting fees. General and administrative expenses include all corporate and administrative functions that serve to support our current and future operations while also providing an infrastructure to support future growth. Major items in this category include management and staff salaries, rent/leases, professional services and travel-related expenses. We anticipate these expenses to increase as a result of increased legal and accounting fees anticipated in connection with our compliance with ongoing reporting and accounting requirements of the SEC and the expansion of our business.

Operating expenses increased from $5,708,992 for the nine months ended September 30, 2006 to $18,631,619 for the nine months ended September 30, 2007, an increase of $12,922,627 or 226.4%. The Company recognized a total of $4,445,737 of noncash compensation for stock based compensation for the nine months ended September 30, 2007 compared to $410,044 for the nine months ended September 30, 2006. If these noncash stock based compensation expenses were excluded, operating expenses would have increased from $5,298,948 for the nine months ended September 30, 2006 to $14,185,882 for the nine months ended September 30, 2007. This represents an increase in operating expenses of $8,886,934 or 167.7%.

Research and development costs increased from $4,341,535 for the nine months ended September 30, 2006 to $11,663,054 for the nine months ended September 30, 2007. This represents an increase of $7,321,519 or 168.6%. The higher research and development expenses were incurred as a result of increasing the number of research and development personnel, commencing clinical trials for CBLC102 and completing the cGMP manufacturing of CBLB502. The Company recognized a total of $199,609 of noncash compensation for R&D stock based compensation for the nine months ended September 30, 2006 compared to $711,296 for the six months ended September 30, 2007 in R&D stock based compensation. Without the noncash stock based compensation, the R&D expenses increased from $4,141,926 for the nine months ended September 30, 2006 to $10,951,758 for the nine months ended September 30, 2007; an increase of $6,809,832 or 164.4%.

Selling, general and administrative costs increased from $1,367,457 for the nine months ended September 30, 2006 to $6,968,565 for the nine months ended September 30, 2007. This represents an increase of $5,601,108 or 409.6%. The company recognized a total of $43,617 of noncash compensation for selling, general and administrative stock based compensation for the nine months ended September 30, 2006 compared to $3,754,273 for the nine months ended September 30, 2007. Without the noncash stock based compensation, the selling, general and administrative expenses increased from $1,323,840 for the nine months ended September 30, 2006 to $3,214,292 for the nine months ended September 30, 2007; an increase of $1,890,452 or 142.8%. The higher general and administrative expenses were incurred as a result of operating as a public company and improving the infrastructure of the Company.

Until we introduce a product to the market, we expect these expenses in the categories mentioned above will be the largest categories in our income statement.

Year Ended December 31, 2006 Compared to Year Ended December 31, 2005

Revenue

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

Operating Expenses

Operating expenses increased from $3,626,664 for the year ended December 31, 2005 to $9,126,315 for the year ended December 31, 2006. This represents an increase of $5,499,651 or 152%. This increase resulted primarily from an increase in R&D expenses from $2,640,240 for the year ended December 31, 2005 to $6,989,804 for the year ended December 31, 2006, an increase of $4,346,564 or 165%, as we increased the number of research scientists and related projects and started a number of clinical trials. In addition, general and administrative expenses increased from $986,424 for the year ended December 31, 2005 to $2,136,511, for the year ended December 31, 2006. This represents an increase of $1,150,087 or 117%. These higher general and administrative expenses were incurred as a

result of creating and improving the infrastructure of the company and the costs associated with being a publicly traded company.

Liquidity and Capital Resources

We have incurred annual operating losses since our inception, and, as of September 30, 2007, we had an accumulated deficit of $31,293,236. Our principal sources of liquidity have been cash provided by sales of our securities and government grants, contracts and agreements. Our principal uses of cash have been R&D and working capital. We expect our future sources of liquidity to be primarily government grants, equity financing, licensing fees and milestone payments in the event we enter into licensing agreements with third parties, and research collaboration fees in the event we enter into research collaborations with third parties.

Net cash used in operating activities totaled $10,796,750 for the nine months ended September 30, 2007, compared to $3,538,512 used in operating activities for the nine months ended September 30, 2006. Net cash used in operating activities totaled $6,653,602 for the year ended December 31, 2006, compared to $1,730,513 used in operating activities for the year ended December 31, 2005. For all periods, the increase in cash used was primarily attributable to increased R&D activities and creating, maintaining and improving the infrastructure necessary to support these R&D activities.

Net cash used in investing activities was $238,716 for the nine months ended September 30, 2007, compared to net cash used in investing activities of $749,752 for the nine months ended September 30, 2006. The decrease in cash used in investing activities resulted primarily from the liquidation of short term investments of $996,131 as compared to a purchase of a short term investment of $500,000 that was made during the nine months ended September 30, 2006 . This was partially offset due to the increase in cash used for the issuance of the Notes Receivable, and increase in cash used to purchase equipment related to the company relocation. Net cash used in investing activities was $14,281 for the year ended December 31, 2006 and $2,805,113 used for the year ended December 31, 2005. The decrease in cash used for investing activities resulted primarily from the maturing of short-term investments that converted to cash.

Net cash provided by financing activities totaled $28,252,029 for the nine months ended September 30, 2007, compared to net cash provided by financing activities of $8,523,413 for the nine months ended September 30, 2006 The increase in cash provided by financing activities was attributed to the proceeds from the issuance of preferred stock and warrants in the private placement offering. Net cash provided by financing activities totaled $8,523,414 for the year ended December 31, 2006, compared to $5,647,347 provided by financing activities for the year ended December 31, 2005. The increase in cash provided by financing activities was attributed to the proceeds from the issuance of common stock from the initial public offering.

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

File IND application for Protectan CBLB502	$	50,000
Complete Phase I studies for Protectan CBLB502	$	100,000
File NDA application for Protectan CBLB502	$	350,000
Receive regulatory approval to sell Protectan CBLB502	$	1,000,000
File IND application for Curaxin CBLC102 (completed May 2006)	$	50,000
Commence Phase II clinical trials for Curaxin CBLC102 (completed January 2007)	$	250,000
Commence Phase III clinical trials for Curaxin CBLC102	$	700,000
File NDA application for Curaxin CBLC102	$	1,500,000
Receive regulatory approval to sell Curaxin CBLC102	$	4,000,000

As of September 30, 2007, we have paid $50,000 for the milestone payment relating to the filing of the IND application for Curaxin CBLC102 and paid $250,000 for commencing Phase II clinical trials for Curaxin CBLC102. The $50,000 milestone payment was made May 3, 2007 and the $250,000 milestone was paid on August 21, 2007 as per the terms of the agreement.

Our agreement with the CCF also provides for payment by us to CCF of royalty payments calculated as a percentage of the net sales of the drug candidates ranging from 1-2%, and sublicense royalty payments calculated as a percentage of the royalties received from the sublicenses ranging from 5-35%. However, any royalty payments and sublicense royalty payments assume that we will be able to commercialize our drug candidates, which are subject to numerous risks and uncertainties, including those associated with the regulatory approval process, our R&D process and other factors.

Although we believe that existing cash resources will be sufficient to finance our currently planned operations for the near-term (9-21 months), such amounts will not be sufficient to meet our longer-term cash requirements, including our cash requirements for the commercialization of certain of our drug candidates currently in development. We may be required to issue equity or debt securities or enter into other financial arrangements, including relationships with corporate and other partners, in order to raise additional capital. Depending upon market conditions, we may not be successful in raising sufficient additional capital for our long-term requirements. In such event, our business, prospects, financial condition and results of operations could be materially adversely affected.

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

Impact of Inflation

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

Impact of Exchange Rate Fluctuations

We believe that our results of operations are somewhat dependent upon changes in foreign currency exchange rates. We have entered into a manufacturing agreement with a foreign third party to produce one of our drug compounds and are required to make payments in the foreign currency. We also expect to enter into additional agreements with foreign third parties, increasing the risk. As a result, our financial results could be affected by changes in foreign currency exchange rates. Currently, our exposure primarily exists with the Euro. As of September 30, 2007, we are obligated to make payments under the agreement of 539,017 Euros. We have established means to purchase forward contracts to hedge against this risk. As of September 30, 2007, hedging transactions totaling 197,847 Euros are in place.

Off-Balance Sheet Arrangements

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

BUSINESS

Our Company

Our company is engaged in drug discovery. Our goal is to identify and develop new types of drugs for protection of normal tissues from exposure to radiation and other stresses, such as toxic chemicals and for cancer treatment. Our initial target is to develop a drug to protect humans from the effects of exposure to radiation, whether as a result of military or terrorist acts or as a result of a nuclear accident. Recent acts of terrorism and the proliferation of nuclear weapons programs in rogue states have created a more immediate demand for further research and development in this area. Other potential applications of our drug candidates include reducing the side effects of cancer treatment as well as killing tumor cells.

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

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

If the need is to protect healthy tissues against an external event such as exposure to nuclear radiation, we focus our research efforts on attempting to temporarily and reversibly suppress apoptosis in those healthy tissues thereby imitating the apoptotic-resistant tendencies displayed by cancer cells. A drug with this effect would also be useful in ameliorating the often severe side effects of anticancer drugs and radiation that cause collateral damage to healthy tissues during cancer treatment. Because the severe side effects of anticancer drugs and radiation often limit their dosage in cancer patients, an apoptosis suppressant drug may enable a more aggressive treatment regimen using anticancer drugs and radiation and thereby increase their effectiveness.

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

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

Product Development

Process

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

· target discovery — finding what part of the cell is affected by the drug;

· validation — confirmation that hitting the target does what we think and nothing else;

· isolation of prototype drugs using high throughput screening — applying robotics to large collections of chemicals to find the ones that hit the target or effect whole cells in a desirable way;

· hit-to-lead optimization — improving properties of selected chemicals to make drug prototypes by generating chemical derivatives of initial hit and testing properties in an array of assays;

· formal preclinical pharmacological and toxicological drug product characterization — testing safety and efficiency of drugs in primates using highly regulated standard approaches; and

· clinical trials — testing drug safety and actions using humans.

Scientific Foundation

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

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

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

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

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

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

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

Protectans

Protectans are modified factors of microbes that protect cells from apoptosis, and have a broad spectrum of potential applications. These potential applications include non-medical applications such as protection from exposure to radiation, whether as a result of military or terrorist action or as a result of a nuclear accident, as well as medical applications such as reducing cancer treatment side effects.

Protectan CBLB502

Protectan CBLB502 is our leading radioprotectant molecule in the protectans series. Protectan CBLB502 represents a rationally designed derivative of the microbial protein, flagellin. Flagellin is secreted by *Salmonella typhimurium* and acts as a natural activator of NF-kB. Protectan CBLB502 is administered through intramuscular injection.

Non-Medical Applications

In collaboration with the Cleveland Clinic, our scientists have demonstrated that injecting Protectan CBLB502 into mice protects them from lethal doses of total body gamma radiation. An important advantage of Protectan CBLB502 above any radioprotectant known to us is its ability to effectively protect not only the hematopoietic system but also the gastrointestinal tract, which are among the most sensitive areas of the human body to radiation. High levels of radiation, among other effects, induce moderate to severe bone marrow damage. The immune and blood stem cells are also depleted and death is caused by anemia, infection, bleeding and poor wound healing. Protectan CBLB502's ability to effectively protect the hematopoietic system and gastrointestinal tract may make Protectan CBLB502 uniquely useful as a radioprotective antidote. In addition, Protectan CBLB502 has proved to be a stable compound for storage purposes. It can be stored at temperatures close to freezing and room temperature, and can tolerate extreme heat for a short period of time. Manufacture of Protectan CBLB502 is relatively inexpensive due to its high yield bacterial producing strain and simple purification process.

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

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

As in the protection regimen, a single-dose injection of Protectan CBLB502 given one hour after exposure to a lethal whole-body gamma irradiation increased the survival of rhesus monkeys from 20% in the control group to 70% in the treated group. Radiomitigation by Protectan CBLB502 was accompanied with less severe thrombocytopenia and neutropenia as well as reduced GI damage.

Regulatory Status

Extraordinary radioprotective properties, an excellent toxicity profile, outstanding stability and inexpensive production of Protectan CBLB502 make it a primary candidate for entering formal preclinical studies. Initially, Protectan CBLB502 will be developed for non-medical purposes — as a radioprotectant antidote for the protection of people from severe doses of ionizing radiation. This drug development strategy complies with recently adopted FDA rules for investigational drugs that address situations such as radiation injury, where it would be unethical to conduct efficacy studies in humans. While Phase II and Phase III human clinical trials are normally required for the marketing approval of an investigational new drug, under the new FDA rules Protectan CBLB502 would be considered for approval for this indication based on Phase I safety studies in humans and efficacy studies in two animal species (rodents and non-human primates). Based upon this expedited approval process, Protectan CBLB502 could be approved for non-medical applications within 24-36 months. Because Phase II and Phase III testing, which each involve testing a drug candidate on large numbers of participants who suffer from the targeted disease and condition, can last for a total of anywhere from three to six or more years, bypassing these phases represents a significant time and savings in getting FDA approval.

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

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

- manufacture our drug candidate according to current Good Manufacturing Practices, or cGMP guidelines;
- file an IND and receive a response from the FDA;
- perform a Phase I Human Study and pivotal efficacy animal study with the GMP manufactured drug candidate; and
- file Biologic License Application, or BLA.

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

The Project BioShield Act of 2004, which further expedites approval of drug candidates for certain uses, is aimed to bolster the nation's ability to provide protections and countermeasures against biological, chemical, radiological or nuclear agents that may be used in a military, terrorist or nuclear attack. The principal provisions of this law are to:

- facilitate R&D of biomedical countermeasures by the National Institutes of Health, or NIH;
- provide for the procurement of needed countermeasures through a special reserve fund of $5.6 billion over ten years; and
- authorize, under limited circumstances, the emergency use of medical products that have not been approved by the FDA.

The law also allows the use of expedited peer review when assessing the merit of grants and contracts of up to $1,500,000 for countermeasure research. We have been awarded a $1,500,000 research grant pursuant to this law.

Market Opportunities

Recent acts of terrorism and the proliferation of nuclear weapons programs in rogue states have magnified the importance of radioprotectants in military applications. The potential threat of a terrorist attack using a conventional explosive embedded with radioactive material, or "dirty bomb", or a nuclear device has caused the U.S. government to appropriate significant dollars in the area of Homeland Security and Emergency Preparedness. In a recent legislative act, the Project BioShield Act of 2004, the U.S. government allocated an extra $5.6 billion over ten years for countermeasures against these threats. As of September 15, 2007, under the Project BioShield Act of 2004, there have only been three contracts awarded for the treatment of radiation, which accounted for approximately $38 million of the over approximately $1.4 billion awarded.

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

Currently, the only drug that is considered appropriate for stockpiling for protection against radiation injury is potassium iodide (KI). While KI is useful in protecting the thyroid from the long-term risk of thyroid cancer, it is not useful in protecting against the acute effects of radiation injury and ensuing infections. In Europe, KI has been stockpiled for years in sufficient quantities to treat all civilians living within a number of miles of any of the 300 nuclear power plants in the event of a nuclear accident. Stockpiling of KI has also recently begun for civilians living within 10-50 miles of the 103 active nuclear power plants in the U.S. For example, California recently announced plans to buy 880,000 doses of KI to protect people living close to either of the state's two nuclear plants. Procurement by the U.S. Department of Defense is conducted on the basis of full and open competition that cannot be limited, unless the DoD determines that the public requesting policy would otherwise seriously jeopardize national security. Prior to determining the best treatment, the DoD issues a Request for Information, or RFI, for treatments available or in development for a specific condition resulting from an identified threat. The RFI provides an incentive for companies to research and develop countermeasures that are superior to those selected for stockpiling. Through the RFI, companies may compete for future contracts that will revise and update stockpile content for emerging threats, advanced technologies and new countermeasures. Following its review of the responses it receives, the DoD issues a Request for Proposal, or RFP. The RFP solicits proposals for the manufacturing of specified treatments for a defined number of doses to be delivered within a specified timeframe (a maximum of eight years).

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

has:

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

- determined that the product is authorized for emergency use.

The DoD, through the U.S. Army Space and Missile Defense Command, recently issued a RFP for the Advanced Development of Medical Radiation Countermeasures, or MRC. According to the RFP, the objective of the MRC project is to develop a post-exposure MRC through a Phase I clinical trial and, pending successful completion of the Phase I clinical trial, develop the MRC product through approval/licensure with the FDA and procure quantities of the MRC sufficient to achieve Initial Operational Capability, or IOC. A range of 50,000 to 500,000 doses has been specified to achieve IOC. The RFP stated that MRC must be safe, efficacious, quick acting, free from performance-decrementing side effects, relatively non-invasive, approved by the FDA, compatible with current military countermeasures, and usable on the battle field. The MRC should not require refrigeration, nor have other significant logistical burdens, and should have a relatively long shelf life.

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

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

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

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

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

Medical Applications

In addition to military or other non-medical applications, we have found that Protectan CBLB502, on a preliminary research basis, has been observed to dramatically increase the efficacy of radiotherapy of experimental tumors in mice. Protectan CBLB502 appears to increase the tolerance of mice to radiation while having no effect on the radiosensitivity of tumors, thus opening the possibility of combining radiotherapy with Protectan CBLB502 treatment to improve overall anticancer efficacy of radiotherapy. Our animal efficacy studies have demonstrated that up to 100% of mice treated with Protectan CBLB502 prior to being exposed to radiation survived, without any associated signs of toxicity. This compares to a 100% mortality rate in the animal group that received the placebo drug.

A pilot study conducted from December 2005 to July 2006 by Frontier Biotechnologies, Inc. at the National Chengdu Center for Safety Evaluation of Traditional Chinese Medicine in China in which 20 non-human primates received lethal doses of radiation demonstrated a 10-day delay of radiation-associated mortality and a significant reduction in death rates (from 75% to 25%) in the group of animals treated with Protectan CBLB502 without any associated signs of toxicity. An equal degree of protection was achieved in a subgroup of non-human primates that were previously exposed to Protectan CBLB502 demonstrating that Protectan CBLB502 is effective despite multiple administrations, which is not always the case with most protein based drugs. In addition, in the Protectan CBLB502 treated group, half of the non-human primates that survived radiation showed no gross pathologies. In the rest of the survivors from this group, radiation-induced damage to the lymphoid organs and gastrointestinal tract was significantly less pronounced

than that suffered by survivors in the control group, which received no radioprotectants. The observed radioprotective efficacy of Protectan CBLB502 may be attributed to a rapid and substantial increase in the blood concentration of a number of tissue protecting growth factors and cytokines following its injection. Although these results are preliminary in nature and results discovered in animal trials are often not indicative of results in humans, they are encouraging because they indicate that Protectan CBLB502 has radioprotective properties.

The use of Protectan CBLB502 to ameliorate the side effects of radiation treatment and anticancer drugs is subject to the full FDA approval process.

Market Opportunities

Radiotherapy is the most common modality for treating human cancers. Approximately 50%-60% of cancer patients need radiotherapy at some stage of treatment, either for curative or palliative purposes. To obtain optimal results, a judicious balance between the total dose of radiotherapy delivered and the threshold of the surrounding normal critical tissues is required. In order to obtain better control with a higher dose, normal tissue must be protected against radiation injury. Thus, the role of radioprotective compounds is very important in clinical radiotherapy.

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

The U.S. market for anticancer therapeutics is large and growing. The National Institutes of Health estimates overall costs for cancer in 2006 in the United States at $206.3 billion: $78.2 billion for direct medical costs, $17.9 billion for indirect morbidity costs, and $110.2 billion for indirect mortality costs. Treatment of breast, lung and prostate cancer accounts for over half of the direct medical costs. The market for anticancer drugs, valued at more than $24 billion in 2004, is projected to reach $55 billion in 2009.

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

Protectan CBLB612

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

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

A single administration of CBLB612 resulted in a three-fold increase in the number of progenitor stem cells in mouse bone marrow within 24 hours after administration. Furthermore, the number of these stem cells in peripheral blood was increased ten-fold within four days of administration. Our research indicates that CBLB612 and the other compounds in the 600 series are not only potent stimulators of bone marrow stem cells, but also cause their mobilization and proliferation throughout the blood. This discovery opens a new and innovative way for us to address a broad spectrum of human diseases, some of which currently lack effective treatment.

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

A report published by the NIH division of the Department of Health and Human Services entitled "Regenerative Medicine 2006," notes that hematopoietic stem cells have been used clinically since 1959 and are used routinely for transplantations, albeit almost exclusively in a non-pure form. More than 40,000 transplants were performed annually worldwide by 1995. Currently, the main indications for bone marrow transplantation are either hematopoietic cancers (leukemias and lymphomas), or the use of high-dose chemotherapy for nonhematopoietic malignancies (cancers in other organs). Other indications include diseases that involve genetic or acquired bone marrow failure, such as aplastic anemia, thalassemia sickle cell anemia, and increasingly, autoimmune diseases. Producing a ready supply of hematopoietic stem cells for an individual, without painful procedures, risk of contamination, or side effects, would be

tantamount to enabling the body to repair itself from any damage to its blood-forming system.

The development of our Protectans 600 series has been supported by a grant from the Defense Advanced Research Projects Agency of the Department of Defense.

Curaxins

Curaxins are small molecules that destroy tumor cells by simultaneously targeting two regulators of apoptosis. Our initial test results indicate that Curaxins can be effective against a number of malignancies, including hormone refractory prostate cancer, RCC, and soft-tissue sarcoma.

The original focus of our drug development program was to develop drugs to treat one of the most treatment-resistant types of cancer, RCC. Unlike many cancer types that frequently mutate or delete p53, one of the major tumor suppressor genes, RCC belongs to a rare category of cancers that typically maintain a wild type form of this protein. Nevertheless, RCC cells are resistant to apoptosis, suggesting that in spite of its normal structure, p53 is functionally disabled. The work of our founders has shown that p53 function is indeed inhibited in RCC by an unknown dominant factor. We have established a drug discovery program to identify small molecules that selectively destroy tumor cells by restoring the normal function to functionally impaired p53 in RCC. This program yielded a series of chemicals with the desirable properties named curaxins (CBLC100 series). We have isolated three chemical classes of curaxins. One of them includes relatives of 9-aminoacridine, the compound that is the core structure of many existing drugs. Pre-existing information about this compound has allowed us to bypass the preclinical development and Phase I studies and bring one of our drug candidates into Phase IIa clinical trials, saving years of R&D efforts and improving the probability of success.

One of the most important outcomes of this drug discovery program was the identification of the mechanism by which curaxins deactivate NF-kB. This mechanism of action makes curaxins potent inhibitors of the production and the activity of NF-kB not only in its stimulated form, but also in its basal form. The level of active NF-kB is usually also increased in cancer cells. Moreover, due to curaxin-dependent functional conversion of NF-kB DNA complexes, the cells with the highest basal or induced NF-kB activity are supposed to be the most significantly affected by curaxins. Clearly, this paradoxical activity makes deactivation of NF-kB by curaxins more advantageous compared to conventional strategies targeting NF-kB activators.

The discovery of the mechanism of action of curaxins allowed us to predict and later experimentally verify that curaxins could be used for treatment of multiple forms of cancers, including hormone refractory prostate cancer, hepatocellular carcinoma, multiple myeloma, acute lymphocytic leukemia, acute myeloid leukemia, soft-tissue sarcomas and several others.

Curaxin CBLC102

One of the curaxins from the 9-aminoacridine group is a long-known anti-infective compound known as quinacrine which we refer to as Curaxin CBLC102. It has been used for over 40 years to treat malaria, osteoarthritis and autoimmune disorders. But we have discovered new mechanisms of action for quinacrine in the area of apoptosis. Through assay testing performed in Dr. Gudkov's laboratories beginning in 2002, which included testing in a variety of human tumor-derived cell lines representing cancers of different tissue origin, including RCC, sarcomas, prostate, breast and colon carcinomas, we have observed that Curaxin CBLC102 behaves as a potent NF-kB suppressor and activator of p53 in these types of cancer cells. It has favorable pharmacological and toxicological profiles and demonstrates the anticancer effect in transplants of human cancer cells into primates. These features make Curaxin CBLC102 our prime IND drug candidate among other curaxins. The drug candidate is currently in Phase II clinical trials for treatment of hormone refractory prostate cancer. We also intend to conduct additional Phase II clinical trials with Curaxin CBLC102 for RCC and multiple myeloma.

Clinical trials with Curaxin CBLC102 began in January 2007 at the University of Chicago, Cleveland Clinic and the Case Western Reserve University Hospital in advanced hormone-refractory (androgen-independent) prostate cancer. We apply our therapy to patients who have failed to respond satisfactorily after undergoing established cancer treatments and will use the suppression of tumor growth and prolonged patient survival as major endpoints. An additional endpoint, prostate-specific antigen, or PSA, level reduction, will be used in the prostate trials. Elevated PSA levels are indicative of the progression of prostate cancer.

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

We have an agreement with Regis Technologies, Inc., a GMP manufacturer, that has produced sufficient quantities of Curaxin CBLC102 according to the process previously used for production of this drug when it was in common use. In preparation for the IND clinical studies, a stability program for API will be conducted by the producers. For Phase IIb, Phase III and final production, several other vendors will also be reviewed on a competitive basis to select the site

for large-scale manufacturing. On May 26, 2006, we filed our IND application with the FDA to begin clinical trials in patients with androgen-independent prostate cancer. On June 26, 2006, the FDA advised us that we may initiate clinical Phase II studies after making additional minor modifications to the protocol. On June 5, 2007, we filed an amendment to the IND to include protocols for RCC Phase II trials, which are scheduled to start in November 2007.

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

Market Opportunities

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

Prostate cancer is the most common cancer in men in the United States. According to the American Cancer Society, an estimated 218,890 cases were projected to be diagnosed with prostate cancer in 2007. The majority of patients who are diagnosed with localized prostate cancer are treated and cured with either radiation or surgery. Patients in whom treatment with curative intent is unsuccessful and those who present with metastasis are candidates for androgen suppression. The majority of men who are deprived of androgens, however, ultimately progress to an androgen-independent phase where the initial androgen suppression regimen no longer controls the tumor. As a result, treatment for the androgen-independent phase of prostate cancer is a clear unmet medical need.

RCC is a niche cancer that accounts for 3% of all cancer cases in the United States, but is the most common type of kidney cancer in adults. The American Cancer Society estimates that there will be about 51,190 new cases of RCC in the United States in the year 2007 and that about 12,890 people will die from this disease. For early-stage cancer, the five-year survival rate is 60% to 70%. If the cancer has spread to the lymph nodes, the five-year survival rate is 5% to 15%. If it has spread to other organs, the five-year survival rate is less than 5%. Although the market for RCC treatment is relatively small and large pharmaceutical companies generally are unlikely to enter into the market with their own products that compete directly with us, we may see competition in the RCC market from Wyeth Research, Genentech and GlaxoSmithKline, which are in the late stage development of second-line therapies to combat RCC. These products are aimed at achieving better toxicity profiles and greater survival benefits than conventional treatments for stage IV RCC. Nevertheless, the high mortality rate and small market size may cause other large pharmaceutical companies to license products from a company such as us instead of developing their own products.

Soft-tissue sarcomas are rare, representing only about 1% of all cancer cases. According to the American Cancer Society, approximately 9,220 new cases of soft-tissue sarcoma were projected to be diagnosed in the United States in 2007, which were projected to be responsible for approximately 3,560 deaths per year. If detected early, before it has had a chance to spread, the five-year survival rate is approximately 90%. Treatment requires surgery and radiation therapy with chemotherapy used as an additional means to deal with distant reoccurrences and metastases.

Other Curaxins

As mentioned above, screening of the chemical library for compounds capable of restoring normal function to wild type p53 in the context of RCC yielded three chemical classes of compounds. Generation of focused chemical libraries around the hits from one of these classes and their structure-activity optimization brought about a new generation of curaxins. These molecules have a chemical structure different from 9-aminoacridine (Curaxin CBLC102) and are more active and appear to be more selective of tumor cells than the representatives of the first generation of curaxins (e.g., Curaxin CBLC102).

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

Product Development Schedule and Capital Requirements

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

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

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

- Phase I safety clinical trials for non-medical applications of Protectan CBLB502;

- pivotal study of Protectan CBLB502 using primates for non-medical applications (an equivalent of Phase II/III clinical study);

- filing an IND followed by an NDA to receive all necessary regulatory approvals to manufacture and sell Protectan CBLB502 for non-medical applications;

- preclinical studies, IND filing and Phase I clinical studies for the medical use of Protectan CBLB502;

- clinical studies for Curaxin CBLC102 (Phase IIa in multiple cancers); and

- additional discovery, lead optimization and preclinical studies aimed at developing new generation of curaxins and protectans.

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

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

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

- *Grants* — Through November 15, 2007, we have received 13 government grant commitments from NIH, DOD, NASA and DTRA totaling $5,545,000 including the prestigious $1,500,000 R01 award from NIH and $750,000 R02 award from NIH. Each grant awarded is confined to the scope of work described in the grant application and the grant funds cannot be used for any other purpose. The grantee provides the grantor with a final report detailing the results of the work and, depending on the terms of the specific grant, may need to provide status reports on an ongoing basis. The table below lists each of the 13 government grants awarded to us to date.

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

	Use of CBLB502 against biologically harmful effects of ionizing radiation during space flight				
NIH	Radioprotectors targeting p53	$	750,000	Protectans	Funded
NIH	N-myc targeted therapeutics for childhood neuroblastoma	$	750,000	Curaxins	Funded
DTRA	Radioprotective mechanisms of CBLB502	$	1,300,000	Protectans	Funded

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

· validating our science by passing a rigorous review process; and

· creating awareness by exposure to a professional bio-medical community.

· *License of Early-Stage Leads* — In addition to Protectan CBLC502 and Curaxin CBLC102, we possess certain compound prototypes which we are developing with a view to offering them to a pharmaceutical or biotechnology company for strategic alliance or licensing transactions.

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

Research and Development

Over approximately two years of operations, we have been able to build an R&D team headed by our founder and Chief Scientific Officer, Dr. Andrei Gudkov, a distinguished scientist with numerous publications and patents. Our Vice President of Drug Development, Dr. Farrel Fort, who spent 20 years at Abbott Laboratories and TAP Pharmaceutical where he was the Director of Drug Safety, supervises our drug development efforts. Over the last 10 years, the labs of Drs. Gudkov and George Stark of the Cleveland Clinic have received more than $20 million of grant funding for the development of the basic science forming our technological foundation. Our fully equipped 20,000 square foot research facilities include a modern high-throughput screening, or HTS, core and versatile molecular biology and cell culture capabilities.

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

We have submitted 17 grant applications to NIH, DOD, NASA, DTRA and other governmental bodies. As of November 15, 2007, 13 of the 17 grant applications have been awarded to us bringing $5,545,000 in grant commitments to our R&D programs.

Licensing Revenues

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

Strategic Partnerships

CBL’s development is supported by its strategic partners and founders, the Cleveland Clinic and ChemBridge. Besides being a source of critical intellectual property, the leading physicians of the Cleveland Clinic are involved in the design of our clinical trials, which will take place at the Cleveland Clinic, among other locations, providing invaluable expertise in various cancer types and radiological treatment.

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

In January 2007, we entered into a strategic research partnership with RPCI to develop our cancer and radioprotectant drug candidates. RPCI, founded in 1898, is a world-renowned cancer research hospital and the nation's first cancer research, treatment and education center. RPCI is a member of the prestigious National Comprehensive Cancer Network, an alliance of the nation's leading cancer centers, and is one of only ten free-standing cancer centers in the nation.

RPCI and various agencies of the state of New York will provide us with up to $5 million of grant and other funding. We have established a major research/clinical facility at the RPCI campus in Buffalo, New York, which is the foundation for several of our advanced research and clinical trials. Andrei Gudkov, our Chief Scientific Officer, has agreed to become Senior Vice President of Research Programming and Development for RPCI effective May 2007. Under our agreement with RPCI, RPCI will provide lab services and personnel to CBL worth an approximate amount of $533,000.

Our partnership with RPCI will enhance the speed and efficiency of our clinical research, and will provide us with access to state-of-the-art clinical development facilities in partnership with a globally recognized cancer research center. We believe that our proprietary technology, combined with the assistance of RPCI, and our continuing strong relationship with the Cleveland Clinic, will position us to become a leading oncology company. A key element of our long-term business strategy is to partner with world-class institutions to aid us in accelerating our drug development timeline. We believe that our firm alliances with both RPCI and the Cleveland Clinic provide us with a significant competitive advantage.

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

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

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

Our Intellectual Property

Our intellectual property platform is based primarily on 13 patent applications exclusively licensed to us by the Cleveland Clinic and three patent applications, which we have filed and own, all in the field of regulating cell death that cover new cancer treatment concepts, methods of drug discovery and drug candidates isolated in the laboratory of Dr. Andrei Gudkov. Our license with the Cleveland Clinic is for an indefinite term and we may license additional intellectual property in the same licensed field from the Cleveland Clinic in the future. The Cleveland Clinic may terminate the license upon a material breach by us as specified in the agreement, however, we may avoid such termination if within 90 days of receipt of such termination notice we cure the breach. As consideration for this license, we issued the Cleveland Clinic 1,341,000 shares of common stock and agreed to make certain milestone, royalty and sublicense royalty payments. We have paid $50,000 in connection with milestone payments relating to the filing of an IND for Curaxin CBLC102 and an additional $250,000 in milestone payments relating to the commencement of Phase II clinical trials for curaxin CBLC102.

The aforementioned 13 patent applications licensed from the Cleveland Clinic are as follows:

- Methods of Inhibiting Apoptosis Using Latent TFGß;
- Methods of Identifying Modulators of Apoptosis From Parasites and Uses Thereof;
- Methods of Inhibiting Apoptosis Using Inducers of NF-kB;
- Methods of Protecting Against Radiation Using Inducers of NF-kB;
- Methods of Protecting Against Radiation Using Flagellin;
- Small Molecules Inhibitors of MRP1 and Other Multidrug Transporters;
- Flagellin Related Polypeptides and Uses Thereof;

· Modulation of Apoptosis Using Aminoacridenes;

· Activation of p 53 and Inhibition of NF-kB for Cancer Treatment;

· Modulation of Immune Responses;

· Methods of Protecting Against Apoptosis Using Lipopeptides;

· Modulation of Cell Growth; and

· Mitochondrial Cytochrome B

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

· Quinacrine Isomers;

· Modulation of Androgen Receptor for Treatment of Prostate Cancer; and

· Method of Increasing Hematopoietic Stem Cells (filed in January 2007).

Non-Medical Applications of Protectans

Recent acts of terrorism and the proliferation of nuclear weapons programs in rogue states have magnified the importance of radioprotectants in military applications. The potential threat of a terrorist attack using a conventional explosive embedded with radioactive material, or “dirty bomb”, or a nuclear device has caused the U.S. government to appropriate significant dollars in the area of Homeland Security and Emergency Preparedness. In a recent legislative act, the Project BioShield Act of 2004, the U.S. government allocated an extra $5.6 billion over ten years for countermeasures against these threats. As of September 15, 2007, under the Project BioShield Act of 2004, there have only been three contracts awarded for the treatment of radiation, which accounted for approximately $38 million of the over approximately $1.4 billion awarded.

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

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

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

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

Medical Applications of Protectans

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

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

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

The U.S. market for anticancer therapeutics is large and growing. The National Institutes of Health estimates overall costs for cancer in 2006 in the United States at $206.3 billion: $78.2 billion for direct medical costs, $17.9 billion for indirect morbidity costs, and $110.2 billion for indirect mortality costs. Treatment of breast, lung and prostate cancer accounts for over half of the direct medical costs. The market for anticancer drugs, valued at more than $24 billion in 2004, is projected to reach $55 billion in 2009.

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

New therapies aimed at cancer (Curaxins)

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

Prostate cancer is the most common cancer in men in the United States. According to the American Cancer Society, an estimated 218,890 cases were projected to be diagnosed with prostate cancer in 2007. The majority of patients who are diagnosed with localized prostate cancer are treated and cured with either radiation or surgery. Patients in whom treatment with curative intent is unsuccessful and those who present with metastasis are candidates for androgen suppression. The majority of men who are deprived of androgens, however, ultimately progress to an androgen-independent phase where the initial androgen suppression regimen no longer controls the tumor. As a result, treatment for the androgen-independent phase of prostate cancer is a clear unmet medical need.

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Soft-tissue sarcomas are rare, representing only about 1% of all cancer cases. According to the American Cancer Society, approximately 9,220 new cases of soft-tissue sarcoma were projected to be diagnosed in the United States in 2007, which were projected to be responsible for approximately 3,560 deaths per year. If detected early, before it has had a chance to spread, the five-year survival rate is approximately 90%. Treatment requires surgery and radiation therapy with chemotherapy used as an additional means to deal with distant reoccurrences and metastases.

Competition

Non-Medical Applications

In the area of radiation-protective antidotes, various companies, such as RxBio, Inc., Exponential Biotherapies Inc., Osiris Therapeutics, Inc., ImmuneRegen BioSciences, Inc. and Humanetics Corporation are developing biopharmaceutical products that potentially directly compete with our non-medical application drug candidates even though their approaches to such treatment are different.

Medical Applications

The arsenal of medical radiation-protectors is limited to ETHYOL™ (amifostine), sold by MedImmune. This radiation-protector is limited because of the serious side effects of the drug. Other radiation-protectors may enter the market.

Biomedical research for anticancer therapies is a large industry, with many companies, universities, research institutions and foreign government-sponsored companies competing for market share. The top ten public U.S.-based companies involved in cancer therapy have a combined market capitalization exceeding $1 trillion. In addition, there are several hundred biotech companies who have as their mission anticancer drug development. These companies account for the approximately 150 anticancer compounds currently in drug trials. However, despite the numerous companies in this field, there is still a clear, unmet need in the anticancer drug development market.

Each of the approximately 200 types of cancer recognized by the NCI has dozens of subtypes, both etiological and on a treatment basis. Due to this market segmentation, the paradigm of a one-size-fits-all, super-blockbuster approach to drug treatments does not work well in cancer therapy. Currently, even the most advanced therapeutics on the market do not provide substantial health benefits.

This suggests that innovative anticancer therapies are driven by the modest success of current therapeutics, the need for an improved understanding of the underlying science, and a shift in the treatment paradigm towards more personalized medicine. Our technology addresses this need for an improved understanding of the underlying science and implements a fundamental shift in the approach to developing anticancer therapies.

Stem Cell Mobilization

G-CSF (filgrastim, Amgen) is the current standard against which all other mobilization agents for stem cells are measured. This is because it has been shown to both mobilize more CD34+ stem cells and have less toxicity than any other single agent against which it has been tested to date. Use of G-CSF caused deaths attributed to thrombosis (acute myocardial infarction and stroke) in sibling donors. Other side effects include pain, nausea, vomiting, diarrhea, insomnia, chills, fevers, and night sweats.

Sargramostim (Berlex, Richmond, CA) as a single agent is used less often today for mobilization than G-CSF, because it mobilizes somewhat less well than G-CSF and because of a relatively higher incidence of both mild and severe side effects. Erythropoietin, now commonly used among cancer patients undergoing chemotherapy to maintain hemoglobin in the near normal range, also has some ability to mobilize CD34+ cells.

Other Sources of Competition

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

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

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

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

Our ability to sell to the government also can be influenced by indirect competition from other providers of products and services. For instance, a major breakthrough in an unrelated area of biodefense could cause a major reallocation of government funds from radiation protection. Likewise, an outbreak or threatened outbreak of some other form of disease or condition may also cause a reallocation of funds away from the condition that Protectan CBLB502 is intended to address.

Governmental Regulation

The Drug Regulation Process

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

The process of obtaining FDA approval for a new drug may take many years and generally involves the expenditure of substantial resources. The steps required before a new drug can be produced and marketed for human use include clinical trials and the approval of an NDA.

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

Preclinical Testing

In the preclinical phase of development, the promising compound is subjected to extensive laboratory and animal testing to determine if the compound is biologically active and safe.

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

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

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

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

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

Phase II. Phase II trials involve testing up to 200 participants at a time who may suffer from the targeted disease or condition. Phase II testing typically lasts an average of one to two years. In Phase II, the drug is tested to determine its safety and effectiveness for treating a specific illness or condition. Phase II testing also involves determining

acceptable dosage levels of the drug. If Phase II studies show that a new drug has an acceptable range of safety risks and probable effectiveness, a company will continue to study the substance in Phase III studies.

Phase II trials are sometimes combined with Phase III trials. These Phase II/III trials differ from Phase II trials in that the trials involved may include more patients and, at the sole discretion of the FDA, be considered the “pivotal” trials, or trials that will form the basis for FDA approval.

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

As described above, for several of the product opportunities we are pursuing, we may apply for approval based upon a rule adopted by the FDA in 2002, titled “Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible” (Part 314, Subpart I), which is also referred to as the two animal rule. Pursuant to this new rule, in situations where it would be unethical to conduct traditional Phase II and Phase III efficacy studies in humans, as is the case with countermeasures to a number of weapons of mass destruction, the FDA will review new drugs for approval on the basis of safety in humans and efficacy in relevant animal models.

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

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

The testing and approval process is likely to require substantial time and effort, and there can be no assurance that any FDA approval will be granted on a timely basis, if at all. The approval process is affected by a number of factors, primarily the side effects of the drug (safety) and its therapeutic benefits (efficacy). Additional preclinical or clinical trials may be required during the FDA review period and may delay marketing approval. The FDA may also deny an NDA if applicable regulatory criteria are not met.

The FDA reviews the results of the clinical trials and may order the temporary or permanent discontinuation of clinical trials at any time if it believes the drug candidate exposes clinical subjects to an unacceptable health risk.

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

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

approval of our drug candidates.

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

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

Following any initial regulatory approval of any drugs we may develop, we will also be subject to continuing regulatory review, including the review of adverse experiences and clinical results that are reported after our drug candidates are made commercially available. This will include results from any post-marketing tests or vigilance required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug candidates will also be subject to periodic review and inspection by the FDA. The discovery of any previously unknown problems with the drug, manufacturer or facility may result in restrictions on the drug, manufacturer or facility, including withdrawal of the drug from the market. We do not have, and currently do not intend to develop, the ability to manufacture material for our clinical trials or on a commercial scale. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured drugs ourselves, including reliance on the third-party manufacturer for regulatory compliance. Our drug promotion and advertising is also subject to regulatory requirements and continuing FDA review.

Sales outside the U.S. of products that we develop will also be subject to regulatory requirements governing human clinical trials and marketing for drugs and biological products and devices. The requirements vary widely from country to country, but typically the registration and approval process takes several years and requires significant resources. In most cases, even if the FDA has not approved a product for sale in the U.S., the product may be exported to any country if it complies with the laws of that country and has valid marketing authorization by the appropriate authority. There are specific FDA regulations that govern this process.

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

- The FDA or foreign regulators may interpret data from pre-clinical testing and clinical trials differently than we interpret them.
- If regulatory approval of a product is granted, the approval may be limited to specific indications or limited with respect to its distribution. In addition, many foreign countries control pricing and coverage under their respective national social security systems.
- The FDA or foreign regulators may not approve our manufacturing processes or manufacturing facilities.
- The FDA or foreign regulators may change their approval policies or adopt new regulations.
- Even if regulatory approval for any product is obtained, the marketing license will be subject to continual review, and newly discovered or developed safety or effectiveness data may result in suspension or revocation of the marketing license.
- If regulatory approval of the product candidate is granted, the marketing of that product would be subject to adverse event reporting requirements and a general prohibition against promoting products for unapproved or “off-label” uses.
- In some foreign countries, we may be subject to official release requirements that require each batch of the product we produce to be officially released by regulatory authorities prior to its distribution by us.
- We will be subject to continual regulatory review and periodic inspection and approval of manufacturing modifications, including compliance with current GMP regulations.

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

Other Regulations

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

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

Hazardous Materials

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