

CLEVELAND BIOLABS INC
Form SB-2/A
August 10, 2007

As filed with the Securities and Exchange Commission on August 10, 2007

Registration Number 333-143755

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

**AMENDMENT No. 1
to FORM SB-2**

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

Delaware
(State or jurisdiction of
incorporation or organization)

8731
(Primary Standard Industrial
Classification Code Number)

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

73 High Street
Buffalo, New York 14203
(716) 849-6810

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

Dr. Michael Fonstein
Chief Executive Officer & President
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Approximate date of commencement of proposed sale to the public:

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

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

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

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

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

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

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

PROSPECTUS

SUBJECT TO COMPLETION, DATED AUGUST 10, 2007

9,375,095 Shares

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

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

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

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

The shares of common stock to which this prospectus relates may be offered and sold from time to time directly by the selling stockholders or alternatively through ordinary brokerage transactions directly to market makers of our shares or through any other means described in “Plan of Distribution” beginning on page 81. The shares of common stock may be sold in one or more transactions, at fixed prices, at prevailing market prices at the time of sale or at negotiated prices.

Our common stock is quoted on the Nasdaq Capital Market and the Boston Stock Exchange under the symbol “CBLI.” The last reported sales price of our common stock on the Nasdaq Capital Market on August 7, 2007 was \$10.23 per share.

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

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

the contrary is a criminal offense.

The date of this prospectus is _____, 2007.

TABLE OF CONTENTS

	Page No.
PROSPECTUS SUMMARY	1
THE OFFERING	6
SUMMARY FINANCIAL DATA	7
RISK FACTORS	8
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	23
USE OF PROCEEDS	23
DIVIDEND POLICY	24
PRICE RANGE OF COMMON STOCK	24
CAPITALIZATION	25
SELECTED FINANCIAL DATA	26
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	27
BUSINESS	34
MANAGEMENT	53
SECURITY OWNERSHIP OF MANAGEMENT AND PRINCIPAL STOCKHOLDERS	59
SELLING STOCKHOLDERS	62
CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS	75
DESCRIPTION OF OUR COMMON STOCK	77
DESCRIPTION OF OUR SERIES B CONVERTIBLE PREFERRED STOCK	78
PLAN OF DISTRIBUTION	81
LEGAL MATTERS	82
EXPERTS	82
ADDITIONAL INFORMATION	83
FINANCIAL STATEMENTS	F-1 - F-37

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

PROSPECTUS SUMMARY

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

Our Company

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

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

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

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

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

Our Products and Technology

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

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

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

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

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

Our Markets

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

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

The solicitation specifically seeks a drug/biologic intended for use after exposure to ionized radiation, or IR, has occurred. It is anticipated that the countermeasure, when administered following exposure to IR, will prolong survival by treating the gastrointestinal syndrome of Acute Radiation Syndrome. Specifically, when administered following exposure to IR, the countermeasure should either prevent or reduce the extent of incipient radiation injury or promote repair of manifest radiation injury to allow the preservation or restoration of the anatomic integrity and normal physiologic functioning of the gastrointestinal tract. 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 234,460 cases were projected to be diagnosed with prostate cancer in 2006. RCC is a niche cancer that accounts for 3% of all cancer cases in the United States, but it is the most common type of kidney cancer in adults. In the United States, approximately 35,000 to 40,000 patients are diagnosed with RCC annually. Soft-tissue sarcomas are rare, representing only about 1% of all cancer cases. According to the American Cancer Society, approximately 9,400 new cases of soft-tissue sarcoma were projected to be diagnosed in the United States in 2006, which were projected to be responsible for approximately 3,500 deaths.

Our Industry

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

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

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

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

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

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

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

Our Strategies and Objectives

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

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

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

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

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

Private Placement

On March 16, 2007, pursuant to a Securities Purchase Agreement of the same date, we consummated a transaction with various accredited investors in which we agreed to sell to the investors, in a private placement, Series B Preferred convertible into an aggregate of approximately 4,288,712 shares of common stock, and Series B Warrants to purchase approximately 2,144,356 shares of our common stock 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; Reedland received Series B Warrants to purchase an aggregate of 63,543 shares of common stock and cash compensation (in lieu of Series B Preferred and additional Series B Warrants) of \$444,800; Basic Investors received Series B Warrants to purchase an aggregate of 12,480 shares of Common Stock and cash compensation (in lieu of Series B Preferred and additional Series B Warrants) of \$87,360.

In the aggregate, the Series B Preferred and the Series B Warrants issued in the transaction are convertible for and exercisable into, as of the date hereof, approximately 6,944,538 shares of common stock (subject to adjustments in the event of certain corporate events such as stock splits, or issuances of securities at a price below the conversion price of the Series B Preferred or the exercise price of the Warrants, as the case may be). Based on the closing price of our common stock on March 16, 2007 of \$10.19, the Series B Preferred sold to investors and issued to SSC had a market value of approximately \$46,660,112. Nasdaq Marketplace Rule 4350(i)(1)(D)(ii) requires that, for the sale, issuance or potential issuance by us of common stock (or securities convertible into or exercisable for common stock) equal to 20% or more of the common stock outstanding before the issuance, for less than the greater of book or market value of the common stock, we must obtain stockholder approval for the issuance. Accordingly, the conversion of the Series B Preferred and the exercise of the Warrants into common stock by their respective holders was submitted for approval and was approved by our stockholders at our 2007 annual stockholders meeting.

Notwithstanding the conversion rights of the Series B Preferred holders and us, and the exercise rights of the holders of Series B Warrants and us, we may not issue any shares of common stock in conversion of the Series B Preferred or in exercise of any Series B Warrant if the conversion or exercise would either (1) cause the applicable holder to beneficially own a number of shares of common stock that exceeds 9.99% of the number of shares of common stock outstanding after giving effect to the conversion or exercise, or (2) cause us to issue a number of shares of common stock that would exceed the number of shares of common stock that we can issue under the rules and regulations of the exchange on which those shares are traded. The holders of Series C Warrants may exercise at any time after September 16, 2007 until expiration.

In connection with obtaining stockholder approval of the foregoing issuances, on March 16, 2007 we entered into a Voting Agreement with Michael Fonstein, Andrei Gudkov, Yakov Kogan, the Cleveland Clinic, ChemBridge, Sunrise Equity Partners L.P., or SEP, and SSC, each of whom agreed to vote in favor of authorizing the issuance of the shares of common stock underlying all of the Series B Preferred and the Warrants. In the aggregate, these parties to the Voting Agreement, together with holders of the Series B Preferred that were eligible to vote at the 2007 annual stockholders meeting, held approximately 63% of all votes entitled to be cast as of the record date.

In connection with the Securities Purchase Agreement, we also entered into a Registration Rights Agreement with the Buyers, dated as of March 16, 2007. Under the Registration Rights Agreement, we granted the Buyers certain

registration rights with respect to common stock issuable upon conversion of the Series B Preferred or exercise of the Warrants. This registration statement is being filed to satisfy the registration rights granted under that Registration Rights Agreement.

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

Risk Factors

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

- We have a history of operating losses. We expect to continue to incur losses and may exhaust our financial resources before we are able to complete the development of our drug candidates.

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

Our Information

We were incorporated in Delaware in June 2003. On July 21, 2006, our stock began trading on the Nasdaq Capital Market under the symbol “CBLI” and on the Boston Stock Exchange under the symbol “CFB”. Our trading symbol on the Boston Stock Exchange was later changed to “CBLI”. Our principal executive offices are located at 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	Up to 9,375,095 shares
Common stock currently outstanding	12,139,943 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 Capital Market Symbol	CBLI
Boston Stock Exchange Symbol	CBLI

The number of shares of common stock currently outstanding is based on the number of shares outstanding as of August 7, 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;
- 957,490 shares of common stock issuable upon exercise of outstanding options with exercise prices ranging from \$0.66 to \$10.84 per share;
- 824,166 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.