

CLEVELAND BIOLABS INC
Form 424B3
October 25, 2006

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-136904

Prospectus Supplement No. 1
(to Prospectus dated September 21, 2006)

CLEVELAND BIOLABS, INC.
4,453,601 Shares

This Prospectus Supplement No. 1 supplements and amends the prospectus dated September 21, 2006, or the Prospectus, relating to the offer and sale of up to 4,453,601 shares of our common stock which may be offered from time to time by the selling stockholders identified in the Prospectus for their own accounts. This Prospectus Supplement is not complete without, and may not be delivered or used except in connection with the original Prospectus.

This Prospectus Supplement No. 1 includes the attached Current Report on Form 8-K of Cleveland BioLabs, Inc. dated October 25, 2006, as filed by us with the Securities and Exchange Commission.

This Prospectus Supplement No. 1 modifies and supersedes, in part, the information in the Prospectus. Any information that is modified or superseded in the Prospectus shall not be deemed to constitute a part of the Prospectus, except as modified or superseded by this Prospectus Supplement No. 1. We may amend or supplement the Prospectus from time to time by filing amendments or supplements as required. You should read the entire Prospectus and any amendments or supplements carefully before you make an investment decision.

Investing in our common stock involves risk. See “Risk Factors” beginning on page 8 of the Prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if the Prospectus or this Prospectus Supplement No. 1 is truthful or complete. Any representations to the contrary is a criminal offense.

The date of this Prospectus Supplement No. 1 is October 25, 2006.

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

FORM 8-K

CURRENT REPORT

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

Date of Report: (Date of earliest event reported): October 20, 2006

CLEVELAND BIOLABS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-12465
(Commission File Number)

20-0077155
(I.R.S. Employer
Identification Number)

11000 Cedar Ave., Suite 290
(Address of principal executive offices)

Registrant's telephone number, including area code: (216) 229-2251

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 1.01. Entry into a Material Definitive Agreement

On October 20, 2006, Cleveland BioLabs, Inc. (the “Company”) finalized an agreement with SynCoBio Partners B.V. to manufacture quantities of one of the Company’s lead product candidates, Protectan CBLB502, for clinical trials and, if approved by governmental authorities, for commercial distribution. A copy of the agreement is attached as Exhibit 10.01 and incorporated herein by reference.

Item 8.01. Other Events

On October 25, 2006, the Company sent to its stockholders a letter summarizing various developments regarding the Company and its business. A copy of the letter is attached as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits

Exhibit No.	Exhibit
10.01	Process Development and Manufacturing Agreement between Cleveland BioLabs, Inc. and SynCoBio Partners B.V. effective as of August 31, 2006.
99.1	Letter to Stockholders from Michael Fonstein, President and Chief Executive Officer dated October 25, 2006

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CLEVELAND BIOLABS, INC.

Date: October 25, 2006

By: /s/ Michael Fonstein

Michael Fonstein
President and Chief Executive Officer

EXHIBIT INDEX

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Dear Stockholder,

It has been just three months since Cleveland BioLabs Inc. (Nasdaq:CBLI) has become public and we are making great strides in our research and development. There have been several significant positive events recently and others are expected in the near future. We are encouraged by the recent appreciation in the price of our stock. We have undertaken an aggressive market communications strategy and retained investor relations consultants to help implement this strategy.

Over the last few months, CBLI achieved a number of important milestones:

- We received FDA approval to start a Phase II trial of our Curaxin CBLC102 compound for advanced, refractory prostate cancer;
- We reported highly successful preliminary results for our non-human primate efficacy trial of Protectan CBLB502 for radiation protection (injected prior to exposure);
- We received two Phase II awards from NIH totaling \$1,500,000 (and fundable scores for three more) bringing the total number of grants and contracts we received from NIH, DOD and NASA to 13; and
- We very recently achieved a breakthrough in our radiation protection program, demonstrating CBLB502's efficacy in mice after exposure to radiation and potentially expanding the market potential for this compound.

Cleveland BioLabs' mission is to develop drugs that treat cancer and protect us from radiation and other deadly diseases acting through similar molecular mechanisms. This development is based on our original research in the area of apoptosis (programmed cell death) and the discovery of a unique source of molecules modulating this process.

Apoptosis is a basic cellular defense mechanism that responds to DNA damage and various other stresses and determines whether a damaged cell should be repaired or killed. Through this mechanism, apoptosis prevents improperly repaired or damaged cells from becoming cancerous, which means that cancerous cells need to block this mechanism in order to successfully develop. If we unblock this mechanism in a mature cancer cell, it will recognize the cancer signals and kill the cell. Conversely, external stresses, like radiation, induce apoptosis and at high doses kill too many potentially repairable cells, causing damage in critical tissues and death of an organism. In this case, delaying the apoptotic response and enabling cells to recover can drastically reduce the negative impact of radiation on the organism.

CBLI's drugs act on both sides of this equation. Curaxins turn apoptosis on to kill cancer cells, and Protectans temporarily turn apoptosis off to protect against cell death as a result of radiation or other stresses.

Our lead Curaxin, CBLC102, is an oral drug that works in vitro, in animal models, and in live tumors removed from patients. The *FDA has approved a Phase II efficacy study* at the Cleveland Clinic and Case Western Reserve University Hospital and enrollment will start shortly for advanced, refractory prostate cancer. Independent research has shown that the majority of cancers can be targeted by our drug candidate based on this mechanism of suppression of apoptosis.

Our lead Protectan, CBLB502, shows unprecedented protection against radiation when injected into mice prior to exposure. This has resulted in the survival of the animals after exposure to super-killing doses of up to 14 Gy of total body irradiation. CBLB502 can prevent both hematopoietic (HP) and gastro-intestinal (GI) acute radiation syndromes and is the first known substance that protects against the lethal GI syndrome.

Very recently, we achieved a significant breakthrough in our radiation protection program. We demonstrated that CBLB502 is effective even when injected after mice have been exposed to radiation doses up to 9Gy. This could significantly expand the drug's market potential, adding the ability to use it for the general population following radiation exposure.

Experiments with cancer-bearing mice have also established the potential for Protectan CBLB502 to be used as an adjuvant to radiation therapy for cancer treatment. Its use allows an increase in tolerable doses of radiation, with no protective effect on tumors, thus strengthening the therapeutic effect of the treatment.

CBLB502 also showed strong radioprotection in non-human primates, enabling the survival of over 70% of animals that received deadly doses of whole-body radiation. This drug is undergoing an *accelerated development program under the FDA two-animal rule*, which requires us to show efficacy in two animal species (including primates) and only safety in humans.

Based on the efficacy demonstrated in primates and our progress in developing GMP manufacturing with SynCo Bio Partners B.V., we believe that we may be able to submit *an NDA to the FDA within approximately 24 months*. In addition, there is a possibility that we could receive orders from the Department of Defense in an even shorter timeframe. CBLB502 is initially being developed as a radiation antidote for the military, first responders, nuclear plant workers and eventually for all people who will be subject to nuclear attack or accident.

We are very excited about all of these advances and continue to leverage our strategic relationships with the Cleveland Clinic Foundation, ChemBridge Corporation and the Armed Forces Research Radiobiology Institute to further our development. Our partnership with the Cleveland Clinic has given us access to state of the art facilities and world-accomplished researchers to help develop our compounds. In fact, the company has the exclusive right to all intellectual property developed by two major labs at the Cleveland Clinic in the area of cancer and tissue protection. In addition, ChemBridge has provided a library of more than 250,000 chemical compounds which tremendously strengthens our research efforts. The Armed Forces Research Radiobiology Institute has been critical in advancing our research and development efforts with Protectans.

In summary, we believe CBLI will be successful because of the following factors:

- Proprietary technology platform supported by 14 patent applications;
 - Late-stage products with accelerated development pathways;
 - Extensive pipeline supported by 13 government grants and contracts; and
 - Near-term value drivers.
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We remain committed to delivering shareholder value and appreciate your support.

Sincerely,

Michael Fonstein
Chief Executive Officer
Cleveland BioLabs, Inc.

This letter contains forward-looking statements that reflect our current view with respect to various aspects of the events described above. Statements that use terms like “expect,” “could,” “believe,” and other similar expressions are intended to identify forward-looking statements. Actual results could be significantly different. Factors that could affect results those set forth in filings made by Cleveland BioLabs, Inc. with the Securities and Exchange Commission. These factors include, but are not limited to, those discussed in our Registration Statement on Form SB-2 under the caption “Risk Factors” We caution you not to place undue reliance on these forward-looking statements. Although forward-looking statements help provide complete information about future prospects, you should keep in mind that forward-looking statements are much less reliable than historical information.