

CLEVELAND BIOLABS INC
Form 424B3
January 04, 2008

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-143755

Prospectus Supplement No. 1
(to Prospectus dated December 10, 2007)

CLEVELAND BIOLABS, INC.
5,514,999 Shares

This Prospectus Supplement No. 1 supplements and amends the prospectus dated December 10, 2007 (the "Prospectus") relating to the offer and sale of up to 5,514,999 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 Form 8-K of Cleveland BioLabs, Inc. dated January 4, 2008, 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 Any information that is modified or superseded in the Prospectus shall not be deemed to constitute a part of the Prospectus, except as modified or superseded by this Prospectus Supplement No. 1.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 representation to the contrary is a criminal offense.

The date of this Prospectus Supplement No. 1 is January 4, 2008.

**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): January 4, 2008

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

| | | |
|---|--------------------------|--|
| Delaware | 001-12465 | 20-0077155 |
| (State or other jurisdiction of incorporation or organization) | (Commission File Number) | (I.R.S. Employer Identification Number) |

73 High Street, Buffalo, New York 14203
(Address of principal executive offices)

Registrant's telephone number, including area code: (716) 849-6810

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))

Item 8.01 Other Events

On January 4, 2008, the Company issued a press release announcing that it was notified by the U.S. Department of Defense that it was not selected for a contract award granted in connection with a U.S. Department of Defense request for proposal relating to medical radiation countermeasures. A copy of the press release is attached as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

| <u>Exhibit No.</u> | <u>Exhibit</u> |
|---------------------------|--------------------------------------|
| 99.1 | Press Release dated January 4, 2008. |

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: January 4, 2008

By: /s/ Michael Fonstein

Michael Fonstein
President and Chief Executive Officer

EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Exhibit</u> |
|---------------------------|--------------------------------------|
| 99.1 | Press Release dated January 4, 2008. |

FOR IMMEDIATE RELEASE

Cleveland BioLabs Not Selected for Defense Contract Award

Company to Host Conference Call to Discuss Ongoing Development Strategy for Pipeline of Compounds

Buffalo, NY — January 4, 2008 - Cleveland BioLabs, Inc. (NASDAQ:CBLI) today announced that it was informed by the Department of Defense (DoD) that Protectan CBLB502, the Company's candidate for the treatment of gastrointestinal (GI) effects of acute radiation syndrome was not selected for award under the request for proposal (RFP) No. W9113M-07-R-0002, entitled, "Medical Radiation Countermeasures Development and Delivery."

The Company is very surprised by the DoD's decision and has requested a debriefing in order to better understand the DoD's decision. In June 2007, based on the DoD's evaluation of the Company's technical and cost proposal, the DoD informed the Company that its proposal for Protectan CBLB502 was within the competitive range and invited Cleveland BioLabs for a face-to-face meeting on July 26, at which the details of the Company's proposal were discussed. The DoD reaffirmed this positive feedback in September 2007, when it requested an additional amendment asking for an increased development budget, as well as up to 1.5 million doses of a self or buddy-administered countermeasure for use in the battlefield.

Dr. Michael Fonstein, Chief Executive Officer and President of Cleveland BioLabs stated, "Given the aggressive nature and degree of detail of the DoD's responses and ensuing negotiations regarding our proposal, we are deeply disappointed by this unexpected decision. We intend to further develop CBLB502 and seek FDA approval and will respond to future DoD solicitations as they are announced. Cleveland BioLabs' research has demonstrated CBLB502's unique ability to mitigate the damaging effects of ionizing radiation on all major acute radiation syndromes, including gastrointestinal, as well as to demonstrate significant survival benefits. In addition, the compound's safety profile, stability and method of administration make it highly practical for field deployment, both for military and civilian populations."

Cleveland BioLabs Chief Scientific Officer, Andrei Gudkov, Ph.D, D. Sci., said, “We believe our Protectan CBLB502 is quite unique in three particular areas with strong supporting data: The first is prolonged survival or long-term survival benefits, which we have demonstrated in both mice and primates; the key FDA requirements for drug approval under the two-animal efficacy rule. The second is protection of the GI tract, which we have demonstrated in two animal species. The third is its remarkable stability, a significant shelf life and its suitability for easy self and buddy-administration in battlefield, civilian or hospital conditions. Moreover, the technology we developed for CBLB502 allowed cost-effective production of over 100,000 doses per manufacturing batch under cGMP conditions, which could provide protection for the numbers of military forces potentially exposed to radiation from tactical nuclear weapons in the field or terrorist attacks directed against civilian populations.”

“We remain committed to developing Protectan CBLB502 for both defense and medical uses,” added Dr. Gudkov. “We plan to continue our discussions with the Department of Health and Human Services and other friendly governments, who are interested in its potential to protect against terrorist threats and nuclear disaster. Our goal is to achieve FDA approval for CBLB502 in 2009 and market it as an effective and affordable radiation protector for defense use on the battlefield or in first responder or civilian emergencies.”

Protectan CBLB502 is undergoing an accelerated development program under the FDA two-animal rule for defense, which requires demonstrations of efficacy in two animal species and only safety in humans. As planned, the Company will submit an Investigational New Drug application to the FDA for a human safety study shortly.

The Defense Threat Reduction Agency of the DoD awarded Cleveland BioLabs a grant in March 2007, to fund ‘development leading to the acquisition’ of Protectan CBLB502 as a radiation countermeasure, in collaboration with the Armed Forces Radiobiology Research Institute, which has also received significant independent funding for work on Protectan CBLB502. The DoD also recently awarded a \$1 million grant to the Company’s founding partner, the Cleveland Clinic, to conduct pre-clinical studies on Protectan CBLB502 for use in tourniquet and other ligation-reperfusion battlefield injuries where blood flow is stopped and then restored after a prolonged period of time.

Potential medical applications for CBLB502 are broad and include reduction of radiation therapy side effects in cancer patients, and ischemic diseases such as acute organ failure, heart disease and stroke. Protectan CBLB502 has shown efficacy as a potential adjuvant for radiation therapy in mouse models of sarcoma and Company researchers in collaboration with investigators from Cleveland Clinic have demonstrated that a single injection of Protectan CBLB502 effectively prevents acute renal failure and subsequent death in a mouse model of ischemia-reperfusion renal injury.

Cleveland BioLabs’ scientific platform has yielded several other compounds in addition to Protectan CBLB502. These include other tissue protecting drugs, Protectans, as well as anticancer compounds, Curaxins. Among the more advanced of these compounds is Curaxin CBLC102, an orally administered small molecule designed to kill tumor cells in Phase II trials, and Protectan CBLB612, which has demonstrated strong potential efficacy as a stimulator and mobilizer of hematopoietic stem cells in peripheral blood.

The Company will host a conference call to discuss the DoD decision and its ongoing development strategy today at 8:30 a.m. Eastern Standard Time. Interested parties may participate by dialing 877-407-8033 (US) or 201-689-8033 (International) approximately five to ten minutes before the call start time. A live Webcast of the conference call will be available on the Cleveland BioLabs Web site at www.cbiolabs.com.

A replay of the call will be available starting on January 4, 2008, at 12:00 p.m. Eastern Standard Time through January 11, 2008 at 11:59 p.m. Eastern Standard Time. Interested parties may access the replay by dialing 877-660-6853 (US) or 201-612-7415 (International) and entering account number 286 and conference ID number 268331. An archived Webcast of the conference call will be available on the Cleveland BioLabs Web site at www.cbiolabs.com.

About Cleveland BioLabs, Inc.

Cleveland BioLabs, Inc. is a drug discovery and development company leveraging its proprietary discoveries about programmed cell death to treat cancer and protect normal tissues from exposure to radiation and other stresses. The Company has strategic partnerships with the Cleveland Clinic, Roswell Park Cancer Institute, ChemBridge Corporation and the Armed Forces Radiobiology Research Institute. To learn more about Cleveland BioLabs Inc., please visit the company's website at <http://www.cbiolabs.com>.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management's current expectations, as of the date of this press release, and involve certain risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors. Some of the factors that could cause future results to materially differ from the recent results or those projected in forward-looking statements include the "Risk Factors" described in our filings with the Securities and Exchange Commission.

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