

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

## CLEVELAND BIOLABS INC

**Form: 8-K**

**Date Filed: 2015-09-02**

Corporate Issuer CIK: 1318641

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): September 2, 2015

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

DELAWARE  
(State of incorporation)

001-32954  
(Commission File Number)

20-0077155  
(IRS Employer Identification No.)

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

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 September 2, 2015, the Company issued a press release titled “Department of Defense Awards Cleveland BioLabs a \$9.2 Million Contract for Advanced Development of Entolimod as a Medical Radiation Countermeasure.” A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated September 2, 2015.

## SIGNATURES

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.

Date: September 2, 2015

CLEVELAND BIOLABS, INC.

By: /s/ Yakov Kogan

Yakov Kogan

Chief Executive Officer



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**FOR IMMEDIATE RELEASE**

**Department of Defense Awards Cleveland BioLabs a \$9.2 Million  
Contract for Advanced Development of Entolimod as a Medical  
Radiation Countermeasure**

***Pre-Emergency Use Authorization Dossier under Review with FDA***

**Buffalo, NY – September 2, 2015 – Cleveland BioLabs, Inc. (NASDAQ:CBLI)** today announced that the Department of Defense (DoD) office of Congressionally Directed Medical Research Programs (CDMRP) Joint Warfighter Medical Research Program (JWMP) has awarded CBLI a contract valued at up to \$9.2 million to support further development of entolimod as a medical radiation countermeasure. Entolimod is a novel, broad-spectrum investigational drug being developed to mitigate the life-threatening consequences of a radiological attack.

The Company has submitted an application for pre-Emergency Use Authorization (pre-EUA) to the Food and Drug Administration (FDA) in support of use of entolimod as a medical radiation countermeasure. Pre-EUA is the regulatory path through which the FDA determines that certain unapproved medical products may be used in an emergency when there are no adequate, approved, and available alternatives. Products with pre-EUA status can be purchased by certain US government stakeholders for stockpiling in the event of a disaster.

The DoD contract will fund pivotal animal studies designed to support future submission of a Biologics License Application (BLA) for entolimod for reducing the risk of death following exposure to potentially lethal irradiation occurring as the result of a radiation disaster. BLA approval, if received, would be the final step necessary to reach full marketing authorization.

Yakov Kogan, Ph.D., Chief Executive Officer for Cleveland BioLabs, stated, "We are excited to continue our work to advance development of entolimod towards full licensure. We believe entolimod, if approved, will offer a highly effective solution for protecting our nation's military personnel and civilians from the potentially deadly effects of radiation."

**About Cleveland BioLabs, Inc.**

Cleveland BioLabs, Inc. is an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. The company's proprietary platform of Toll-like immune receptor activators has applications in radiation mitigation, oncology immunotherapy, and vaccines. The company's most advanced product candidate is entolimod, which is being developed for a biodefense indication and as an immunotherapy for oncology and other indications. The company conducts business in the United States and in the Russian Federation through a wholly-owned subsidiary, BioLab 612, LLC and a joint venture with OJSC Rusnano, Panacela Labs, Inc. The company maintains strategic relationships with the Cleveland Clinic and Roswell Park Cancer Institute. To learn more about Cleveland BioLabs, Inc., please visit the Company's website at <http://www.cbiolabs.com>.

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*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. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors.*

*These factors include, among others, the potential that the Company is unable to successfully negotiate the funding of entolimod with the DoD or that the DoD will decline to provide funding due to lack of funds or other reasons; the potential for the loss of funding from the Company's research and development grants and contracts, including the contract that is the subject of this press release, and its ability to win additional funding under such grants and contracts; the risks inherent in the early stages of drug development and in conducting clinical trials; the Company's inability to obtain regulatory approval of a pre-EUA or BLA filing in a timely manner or at all; the Company's failure to successfully and timely develop new products; the Company's collaborative relationships and the financial risks related thereto; the Company's ability to comply with its obligations under license agreements; the potential for significant product liability claims; and the Company's ability to comply with various safety, environmental and other governmental regulations; the Company's history of operating losses and the potential for future losses, which may lead the Company to not be able to continue as a going concern; the Company's need for substantial additional financing to meet its business objectives;. Some of these factors could cause future results to materially differ from the recent results or those projected in forward-looking statements. See also the "Risk Factors" and "Forward-Looking Statements" described in the Company's periodic filings with the Securities and Exchange Commission.*

Contact:

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