CLEVELAND BIOLABS INC
Form 8-K
March 16, 2016

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): March 16, 2016

Cleveland BioLabs, Inc.
(Exact Name of Issuer as Specified in Charter)

DELAWARE	001-32954	20-0077155
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File Number)	(I.R.S. Employer Identification Number)

73 High Street
Buffalo, NY 14203
(Address of Principal Executive Offices and zip code)

(716) 849-6810
(Registrant's Telephone Number, Including Area Code)

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o 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 March 16, 2016, Cleveland BioLabs, Inc. issued a press release providing an update to its pre-Emergency Use Application on file with the United States Food and Drug Administration. A copy of the press release is filed as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description
99.1	Press Release titled “Cleveland BioLabs provides update on pre-EUA Review of Entolimod as Radiation Countermeasure”, dated March 16, 2016

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.

Cleveland BioLabs, Inc.

Date: March 16, 2016 By: /s/ YAKOV KOGAN
Name: Yakov Kogan
Title: Chief Executive Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

Cleveland BioLabs Provides Update on pre-EUA Review of Entolimod as Radiation Countermeasure

Buffalo, NY - March 16, 2016 - Cleveland BioLabs, Inc. (NASDAQ:CBLI), today announced an update on the regulatory review of its pre-Emergency Use Authorization (pre-EUA) submission for entolimod as a radiation countermeasure following the receipt of minutes from a recent meeting with the U.S. Food and Drug Administration (FDA).

As part of the company's response to pre-EUA review comments received from the FDA, a meeting was held with the Agency to discuss various aspects of entolimod manufacturing. At this meeting, and subsequently confirmed by the FDA's official minutes of the meeting, it was determined that an in vivo study will be necessary to establish bio-comparability between the entolimod drug formulation proposed for use under the pre-EUA and the drug formulation used in previously conducted preclinical and clinical studies. The FDA indicated that further review of the pre EUA dossier would not proceed until these bio-comparability data have been evaluated by the Agency. The design of the bio-comparability study is currently in development and will need to be agreed upon with the FDA before the study is executed.

Yakov Kogan, PhD, MBA, Chief Executive Officer of Cleveland BioLabs, commented, "While this FDA request has temporarily slowed our progress, we remain fully committed to the pursuit of pre EUA status and commercialization for entolimod. We will provide further updates regarding the estimated timing for performance and reporting of the study once the design is finalized. Our goals are to satisfy the FDA's request and facilitate continued regulatory review of the pre-EUA dossier for entolimod as soon as possible."

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.

This press release contains certain forward-looking information about Cleveland BioLabs that is intended to be covered by the safe harbor for "forward-looking statements" provided by the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that do not relate strictly to historical or current facts. Words and phrases such as "potential," "may," "future," "will," "plan," "anticipate," "believe," "intend" and similar expr are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding the company's future

financial position, business strategy, new products, budgets, liquidity, cash flows, projected costs, regulatory approvals or the impact of any laws or regulations applicable to the company, and plans and objectives of management for future operations. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the company, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements.

These factors include, among others, the risks inherent in the early stages of drug development and in conducting clinical trials; the company's plans and expectations with respect to future clinical trials and commercial scale-up activities; the company's ability to attract collaborators with development, regulatory and commercialization expertise and the financial risks related to those relationships; the company's ability to comply with its obligations under license agreements; the company's inability to obtain regulatory approval in a timely manner or at all; the commercialization of the company's product candidates, if approved; the company's plans to research, develop and commercialize its product candidates; future agreements with third parties in connection with the commercialization of any approved product; the size and growth potential of the markets for the company's product candidates, and its ability to serve those markets; the rate and degree of market acceptance of the company's product candidates; 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; regulatory developments in the United States and foreign countries; the performance of the company's third-party suppliers and manufacturers; and the success of competing therapies that are or may become available. 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.

Contacts:
Cleveland BioLabs, Inc.
Rachel Levine, Vice President, Investor Relations
T: 917-375-2935
E: rlevine@cbiolabs.com