

CLEVELAND BIOLABS INC

Form 8-K

October 11, 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): October 4, 2016

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

DELAWARE 001-32954 20-0077155
(State or Other Jurisdiction of Incorporation) (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:

- 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 1.01. Entry into a Material Definitive Agreement.

On October 4, 2016, Cleveland BioLabs, Inc. (the “Company”) and the U.S. Department of Defense (the “DoD”) office of Congressionally Directed Medical Research Programs (“CDMRP”) agreed to amend the current Joint Warfighter Medical Research Program contract (the “Agreement”) previously entered into between the parties. The Agreement, entered into on September 1, 2015, was valued at up to \$9.2 million and supports the further development of the Company’s entolimod candidate as a medical radiation countermeasure. The amendment modifies the original statement of work under the Agreement by eliminating certain tasks the parties no longer deem critical for preparing a Biologics License Application for entolimod as a radiation countermeasure and establishes new tasks to address questions raised by the U.S. Food and Drug Administration. The new tasks include the conducting of a pharmacokinetic/pharmacodynamic biocomparability study in nonhuman primates and certain other drug manufacturing related activities. In the amendment to the Agreement, the DoD office of the CDMRP agreed to shift the costs allocated for the eliminated non-critical activities to the new tasks. Accordingly, the aggregate amount of consideration payable to the Company by the DoD is unaffected. All other material terms and conditions of the Agreement remain unchanged.

Other than the Agreement and an additional agreement between the Company and the DoD’s CDMRP office (also related to the further development of entolimod as a medical radiation countermeasure), neither the Company or any of its affiliates have a material relationship with the DoD.

Item 8.01. Other Events.

On October 11, 2016, the Company issued a press release titled “Cleveland BioLabs Announces a \$1.1 million Cost Realignment with the Department of Defense.” A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statement and Exhibits.

Exhibit No. Description

99.1 Press release of Cleveland BioLabs, Inc. dated October 11, 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: October 11, 2016 By: /s/ YAKOV KOGAN

Name: Yakov Kogan

Title: Chief Executive Officer