

CLEVELAND BIOLABS INC
Form 8-K
May 31, 2011

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): May 31, 2011

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

Delaware
(State or other jurisdiction
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

(Former Name or Former Address, if Changed Since Last Report)

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

In 2010, Cleveland BioLabs, Inc. (the “Company”) submitted a proposal (the “2010 Proposal”) for the further development of Protectan CBLB502 to the Biomedical Advanced Research and Development Authority (“BARDA”) of the Department of Health and Human Services. The Company and BARDA recently concluded advanced stages of contract negotiations for funding of the activities proposed in the 2010 Proposal. BARDA has indicated that further contract-related negotiations will require clarification of the development path for CBLB502 with the U.S. Food and Drug Administration (“FDA”), which is in the process of actively reviewing the Company’s IND for CBLB502 as part of its recent transfer to a new FDA Division. This review, which is an anticipated step in the drug development process, is currently underway. BARDA has indicated that the Company may resubmit an updated proposal upon confirmation from the FDA there are no objections to the Company proceeding with its development plan as a result of this review. The Company is actively working toward obtaining this confirmation in the shortest time period possible. As with any federal contract proposal, there is no assurance that the Company’s new proposal will result in an award from BARDA.

The Company will update its stockholders on the present state of the Company and its progress with development programs at its annual stockholders meeting on June 7, 2011 at 10:00 a.m. ET, and investor day on June 8, 2011 at 9:45 a.m. ET.

Item 9.01

Financial Statements and Exhibits

(d) Exhibits

| Exhibit No. | Exhibit |
|-------------|----------------------------------|
| 99.1 | Press Release dated May 31, 2011 |

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 thereunto duly authorized.

CLEVELAND BIOLABS, INC.

By: /s/ John A. Marhofer, Jr.
Name: John A. Marhofer, Jr.
Title: Chief Financial Officer

Date: May 31, 2011

EXHIBIT INDEX

| Exhibit No. | Exhibit |
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