

CLEVELAND BIOLABS INC  
Form 8-K  
September 23, 2011

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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 23, 2011 (September 19, 2011)

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

DELAWARE  
(State or Other Jurisdiction of  
Incorporation or Organization)

001-32954  
(Commission File Number)

20-0077155  
(I.R.S. Employer Identification  
Number)

73 High Street  
Buffalo, NY  
(Address of Principal Executive Offices)

14203  
(Zip Code)

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

Not Applicable  
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K 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
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act

Item 1.01 Entry Into a Material Definitive Agreement.

Investment Agreement

On September 19, 2011, Cleveland BioLabs, Inc., a Delaware corporation (the “Company”), entered into an Investment Agreement (the “Investment Agreement”) with Panacela Labs, Inc., a Delaware corporation (“Panacela”), and Open Joint Stock Company “Rusnano”, an open joint stock company organized under the laws of the Russian Federation (“Rusnano”), to provide funding to Panacela for the Project (as defined below).

Pursuant to the Investment Agreement, subject to the terms and conditions therein, the Company will invest \$3.0 million and, together with certain third-party owners, assign and/or provide exclusive licenses, as applicable, to Panacela in respect of certain intellectual property necessary for the Project (the “Transferred IP”) prior to the closing date. Rusnano will provide up to \$26.0 million or 780.0 million Russian Rubles (as to be determined by Rusnano) to Panacela over a four-year period, with \$9.0 million to be provided on the closing date. The additional amounts will be provided by Rusnano upon the achievement of certain development milestones. The Company and Rusnano will also receive warrants in Panacela that will provide them with an option to increase their respective investments at two and four years following the initial investment. The Company has also agreed to use its best efforts to obtain an investment of at least \$6.0 million in Panacela from third parties within 15 months after the closing date.

Immediately after the closing, the Company will have an initial ownership stake of approximately 55% in Panacela. It is anticipated that the Company will retain an ownership stake of approximately 51% in Panacela after giving effect to all subsequent investments by Rusnano, the exercise of all the warrants and the completion of the third party investment.

The Investment Agreement contains customary representations and warranties and covenants. The Company and Panacela agreed, jointly and severally, to defend, indemnify and hold harmless Rusnano and its affiliates and their respective employees, agents, officers and directors against certain liabilities.

Pursuant to the Investment Agreement, as a condition to closing, the Company must enter into certain agreements in respect of the Transferred IP as described below. The Investment Agreement also contains customary conditions to the respective obligations of the parties to consummate the transactions contemplated thereby.

Panacela was incorporated on March 18, 2011 in anticipation of the transactions contemplated by the Investment Agreement and, in particular, to carry out a complete cycle of development, research, performance of clinical trials, production and sales of a line of pharmaceutical drugs for the treatment of oncological, infectious or other diseases (collectively, the “Project”). The current pharmaceutical drug candidates are:

- Mobilan, an adenovirus-based treatment inducing an immune response to cancer;
- Revercom, a combination of a proprietary inhibitor of a multidrug resistance transporter and a conventional chemotherapeutic agent;
  - Xenomycins, a family of compounds for both topical and systemic anti-infective treatment;
  - Antimycon, an inhibitor of the universal transcription factor Myc; and
- Arkil, an androgen receptor inhibitor being developed as a prostate cancer treatment.

Agreements Relating to Transferred IP

As contemplated by the Investment Agreement, and in partial consideration of the issuance by Panacela to the Company of shares of Panacela’s common stock, the Company and Panacela expect to enter into the following agreements in order to transfer the Transferred IP to Panacela:



- a direct license agreement among Panacela and Health Research, Inc., Roswell Park Institute Division and Roswell Park Cancer Institute Corporation (collectively, “RPCI”) pursuant to which RPCI will provide a license to Panacela for seven families of patent applications relating to the Transferred IP;
- a direct license agreement between Panacela and Children Cancer Institute of Australia (“CCIA”) pursuant to which CCIA will provide a license to Panacela for two families of patent applications relating to the Transferred IP;
- an exclusive sublicense between CBLI and Panacela pursuant to which CBLI will sublicense to Panacela four families of patent applications licensed from the Cleveland Clinic Foundation (“CCF”), one family of patent applications licensed from CCIA and one family of patent applications licensed from Incuron, LLC, a majority owned subsidiary of the Company; and
  - an assignment agreement between CBLI and Panacela pursuant to which CBLI will assign its interest in eight families of patent applications relating to the Transferred IP.

All of the agreements described above provide Panacela with exclusive rights for the field in the Transferred IP. Each of the license and sublicense agreements is expected to be for a term of 20 years and is expected to require Panacela to make royalty payments, payments for sublicensing the Transferred IP to third parties, and developmental milestone-based payments to the respective licensor. Each of the license and sublicense agreements is also anticipated to contain customary termination provisions, including termination for material breaches of the respective agreements, the bankruptcy or insolvency of Panacela and, in certain instances, the failure to diligently develop and commercialize the related products.

The execution and delivery of these agreements are conditions precedent to the closing of the transactions contemplated by the Investment Agreement.

#### Second Amendment to Cleveland Clinic Exclusive License

On September 22, 2011, the Company entered into the Second Amendment (the “Second Amendment”) to Exclusive License Agreement (the “Original CCF License Agreement”) by and between the Company and CCF in anticipation of the transactions contemplated by the Investment Agreement. The Original CCF License Agreement was previously filed with the Commission on the Company’s Registration Statement on Form SB-2 (No. 333-131918) and is incorporated herein by reference.

The Second Amendment amends certain provisions of the Original CCF License Agreement to take into account the transfer of certain intellectual property rights to Panacela, such as adding provisions to cover royalty and milestone payments for products developed by Panacela using the intellectual property covered by the Original CCF License Agreement and to clarify the amount payable for milestones achieved in countries other than the United States.

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: September 23, 2011

By:

/s/ Michael Fonstein

Name: Michael Fonstein, Ph.D.

Title: Chief Executive Officer