CLEVELAND BIOLABS INC
Form 8-K
August 10, 2018

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): August 6, 2018

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:

- 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Item 1.01. Entry into a Material Definitive Agreement.

On August 6, 2018, Cleveland BioLabs, Inc. (the "Company") entered into a series of transactions with Genome Protection, Inc. ("GPI"), a Delaware corporation, and Everon BioSciences, Inc. ("Everon"), a New York corporation. GPI was formed by the Company for the purpose of creating a joint venture between the Company and Everon that would be focused on developing anti-aging medications and would seek investment capital from third parties. Andrei Gudkov, Ph.D., D. Sci., the Company's Chief Scientific Officer, is a minority shareholder, director and executive officer of Everon.

On August 6, 2018, the Company entered into a License Agreement with GPI (the "License Agreement") pursuant to which the Company agreed to license to GPI, on an exclusive basis, the right to develop, manufacture, commercialize and sell products utilizing the Company's intellectual property underlying the Company's entolimod drug candidate, solely in the field of use related to the prevention or treatment of any disease, disorder or frailty in humans caused by aging. As previously disclosed, the Company is currently seeking regulatory approval for entolimod for use as an acute radiation treatment medication, and under the License Agreement, this field of use is retained by the Company. The License Agreement provides for such intellectual property to be licensed pursuant to two separate licenses; the license of the Company's intellectual property underlying entolimod's oncology indication are being licensed on a paid-up, royalty-free basis while the license of the Company's intellectual property underlying entolimod's composition is being granted on a fee-bearing and royalty-bearing basis, with such fees and royalties comprising those included in the original license agreement pursuant to which the Company originally licensed such intellectual property from The Cleveland Clinic Foundation, with such fees and royalties payable to The Cleveland Clinic Foundation.

Under the License Agreement, GPI retains responsibility for its own development and commercialization activities, but is required to provide the Company with access to all clinical, safety and other data arising from its development activities. The Company must disclose and transfer all of its know-how pertaining to the licensed intellectual property and provide entolimod product samples to GPI for use in GPI's clinical trials. The License Agreement requires the parties to work together to coordinate efforts between them with respect to regulatory filings, proper reporting of adverse events, the development of standard clinical and quality assurance operating procedures and the amount of product to be supplied by the Company to GPI for the conduct of GPI's development activities. The License Agreement also contains mutual confidentiality covenants and representations and warranties made by each party. Unless terminated by the mutual consent of the Company and GPI, the License Agreement will remain in effect for so long as the patents remain protected by law.

Simultaneous with its entry into the License Agreement, the Company also entered into an Assignment Agreement with GPI, dated as of August 6, 2018 (the "Assignment Agreement"). Under the Assignment Agreement, the Company assigned certain intellectual property underlying its superentolimod product candidate and its entolimod vaccine product candidate and GPI licensed back to the Company, on an exclusive, irrevocable basis, the right to develop manufacture, commercialize and sell products relating to the assigned intellectual property for use as a medical countermeasure to treat acute radiation exposure or as a cancer treatment. Under the Assignment Agreement, the Company retains responsibility for its own development and commercialization activities, but GPI is required to use commercially reasonable efforts to supply to the Company at no surcharge the number of product samples that it has available for clinical trials that are sponsored by the Company and necessary in connection with the Company's efforts to obtain regulatory approval for any drug candidates. The Assignment Agreement requires the Company to pay a royalty to GPI of 2% of its net sales of any products covered by or using the assigned intellectual property subject to the license-back in each calendar year beginning on the date of the first commercial sale of any such product until patent protection is no longer available for the assigned intellectual property in the U.S., France, Germany, Italy, Japan, Spain, or the United Kingdom. The Company is further required to make payments to GPI upon the achievement of certain milestones in the development of product candidates utilizing the licensed intellectual property. The Assignment Agreement also contains mutual confidentiality covenants and representations and

warranties made by each party. Unless terminated by the mutual consent of the Company and GPI, the Assignment Agreement will remain in effect for so long as the patents remain protected by law.

As consideration for the licenses granted to GPI under the License Agreement and the assignment of the intellectual property to GPI under the Assignment Agreement, pursuant to a contribution and subscription agreement, GPI issued to the Company 1,000 shares of GPI's common stock. Contemporaneously with the Company's entry into the License Agreement and Assignment Agreement, Everon contributed certain of its intellectual property related to the potential development of treatments that address serious medical needs associated with human aging to GPI, also in exchange for 1,000 shares of GPI's common stock. As a result of each of the Company's and Everon's receipt of 1,000 shares of GPI's common stock, each of the Company and Everon became the owner of 50% of all of the outstanding capital stock of GPI.

The foregoing descriptions of the License Agreement and the Assignment Agreement do not purport to be complete and are qualified in their entirety by reference to the terms of the License Agreement and the Assignment Agreement, which are attached hereto as Exhibit 10.1 and 10.2, respectively, and incorporated herein by this reference.

Item 9.01. Financial Statement and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1	License Agreement, dated as of August 6, 2018, between Cleveland BioLabs, Inc. and Genome Protection, Inc.
10.2	Assignment Agreement, dated as of August 6, 2018, between Cleveland BioLabs, Inc. and Genome Protection, Inc.

Forward-Looking Statements

This Current Report contains certain forward-looking information about the Company 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," "would," "plan," "anticipate," "believe," "intend" and similar expressi 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.

Factors that could constitute to such differences include, among others, our need for additional financing to meet our business obligations, 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; the exercise of control by the Company's majority stockholder; and the success of competing therapies that are or may become available. Any forward-looking statements speak only as of the date on which such statements are made, and the Company undertakes no obligation to update any forward-looking statement to reflect events or circumstances occurring or arising after the date on which such statement is made, except as is required by law. See also the "Risk Factors" and "Forward-Looking Statements" described in the Company's periodic filings with the Securities and Exchange Commission.

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: August 10, 2018 By: /s/ YAKOV KOGAN
Name: Yakov Kogan
Title: Chief Executive Officer