CLEVELAND BIOLABS INC
Form 10-K
February 23, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K
(Mark One)
x Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2015
or
¨ Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from to
Commission file number 001-32954
CLEVELAND BIOLABS, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	20-0077155
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
73 High Street, Buffalo, NY 14203	(716) 849-6810
(Address of principal executive offices)	Telephone No.

Securities Registered Pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange which registered
Common Stock, par value $0.005 per share	NASDAQ Capital Market

Securities Registered Pursuant to Section 12(g) of the Act:
None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x
The aggregate market value of the voting and non-voting common equity held by non-affiliates, computed by reference to the price at which the common equity was last sold or the average bid and asked price of such common

equity, as of the last business day of the registrant's most recently completed second fiscal quarter was $13,983,177. There were 10,987,166 shares of common stock outstanding as of February 12, 2016.

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant's 2016 Annual Meeting of Stockholders is incorporated by reference in Part III to the extent described therein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2015.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. Forward-looking statements give our current expectations of forecasts of future events. All statements other than statements of current or historical fact contained in this annual report, including statements regarding our 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 us, and plans and objectives of management for future operations, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “should,” “estimate,” “expect,” “int “may,” “plan,” “project,” “will,” and similar expressions, as they relate to us, are intended to identify forward-looking statements.

Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the commercialization of our product candidates, if approved;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our plans and expectations with respect to future clinical trials and commercial scale-up activities;
- future agreements with third parties in connection with the commercialization of any approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates.

We have based these forward-looking statements on our current expectations about future events. While we believe these expectations are reasonable, such forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. Our actual future results may differ materially from those discussed here for various reasons. When you consider these forward-looking statements, you should keep in mind these risk factors and other cautionary statements in this annual report including in Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in Item 1A “Risk Factors.”

Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. We do not undertake any obligation to update any such statements or to publicly announce the results of any revisions to any of such statements to reflect future events or developments.

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PART I

Item 1. Business

When used in this Annual Report on Form 10-K, unless otherwise stated or the context otherwise requires, the terms "Cleveland BioLabs," the "Company," "CBLI" "we," "us" and "our" refer to Cleveland BioLabs, Inc. and its consolidated subsidiaries, BioLab 612, LLC and Panacela Labs, Inc.

GENERAL OVERVIEW

Cleveland BioLabs is an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. Our proprietary platform of Toll-like immune receptor activators has applications in mitigation of radiation injury and immuno-oncology. We combine our proven scientific expertise and our depth of knowledge about our products' mechanisms of action into a passion for developing drugs to save lives. Our most advanced product candidate is entolimod, an immuno-stimulatory agent, which we are developing as a radiation countermeasure and an immunotherapy for oncology and other indications.

Entolimod is a Toll-like receptor 5 ("TLR5"), agonist, which we are developing as a radiation countermeasure for prevention of death from Acute Radiation Syndrome ("ARS"), and as an oncology drug. We believe that entolimod is the most efficacious medical radiation countermeasure currently in development. Following is a summary of the clinical development of entolimod to date and regulatory status.

Entolimod is being developed under the United States Food & Drug Administration's ("FDA's"), Animal Efficacy Rule (the "Animal Rule"), for the indication of reducing the risk of death following exposure to potentially lethal irradiation occurring as a result of a radiation disaster (see "– Government Regulation – Animal Rule"). We have completed two clinical studies designed to evaluate the safety, pharmacokinetics and pharmacodynamics of entolimod in a total of 150 healthy volunteers. We have completed a Good Laboratory Practices ("GLPs"), randomized, blinded, placebo-controlled, pivotal study designed to evaluate the dose-dependent effect of entolimod on survival and biomarker induction in 179 non-human primates exposed to 7.2 Gy total body irradiation when entolimod or placebo were administered at 25 hours after radiation exposure. We have completed a GLP, randomized, open-label, placebo-controlled, pivotal study designed to evaluate the dose-dependent effect of entolimod on biomarker induction in 160 non-irradiated non-human primates. We met with the FDA in July 2014 to present our human dose-conversion and to discuss our intent to submit an application for pre-Emergency Use Authorization ("pre-EUA"). The FDA confirmed that our existing efficacy and safety data and animal-to-human dose conversion were sufficient to proceed with a pre-EUA application and agreed to accept a pre-EUA application for review, which was filed in the second quarter of 2015. If the FDA authorizes the application, then Federal agencies are free to procure drug product for stockpiling so that the drug is available to distribute in the event of an emergency, i.e. prior to the drug being formally approved by FDA under a Biologics License Application ("BLA").

In September 2015, we announced two awards totaling approximately $15.8 million in funding from the United States Department of Defense ("DoD"), office of Congressionally Directed Medical Research Programs to support further development of entolimod as a medical radiation countermeasure. These awards will fund additional pre-clinical and clinical studies of entolimod, which are needed for a BLA.

Additionally, we completed a Phase 1 open-label, dose-escalation trial of entolimod in 26 patients with advanced cancer in the U.S. Data for this study were presented at the 2015 annual meeting of the American Society of Clinical Oncology ("ASCO"), on May 30, 2015. A small expansion study in the Russian Federation ("Russia") was temporarily halted due to changes in a development contract with the Russian Federation Ministry of Industry and Trade ("MPT").

In February 2016, we announced the start of dosing in a new Phase 2 clinical study conducted in Russia of the safety and tolerability of entolimod as a neo-adjuvant therapy in treatment-naïve patients with primary colorectal cancer who are recommended for surgery. Our goal is to accumulate additional clinical data regarding immune cell response to administrations of entolimod in order to guide future oncology development. This study is supported by the development contract with MPT.

CORPORATE INFORMATION

We were incorporated in Delaware in June 2003 as a spin-off company from The Cleveland Clinic. We exclusively license our founding intellectual property from The Cleveland Clinic. In 2007, we relocated our operations to Buffalo,

New York and became affiliated with Roswell Park Cancer Institute ("RPCI"), through technology licensing and research collaboration relationships. Our common stock is listed on the NASDAQ Capital Market under the symbol “CBLI.”

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Our principal executive offices are located at 73 High Street, Buffalo, New York 14203, and our telephone number at that address is (716) 849-6810.

Since inception we have formed several subsidiaries to best capitalize on our unique ability to leverage financial and clinical development resources in Russia. In December 2009, we created Incuron LLC (“Incuron”) with BioProcess Capital Ventures ("BCV") to develop Curaxin compounds (defined below). In September 2011, we created Panacela Labs, Inc. (“Panacela”), a U.S. entity, with Open Joint Stock Company “Rusnano” ("Rusnano") to develop Mobilan and other product candidates (described below.) Simultaneous with the formation of Panacela, was the creation of a wholly-owned Russian subsidiary of Panacela named, Panacela Labs, LLC. Finally, we have a wholly-owned Russian subsidiary, BioLab 612, LLC. As more fully described in Note 5, “Noncontrolling Interests” in our audited financial statements included in Item 8: "Financial Statements and Supplementary Data," Incuron was included in our consolidated financial results through November 25, 2014, and then accounted for as an equity investment through April 29, 2015, after which our remaining equity interest in Incuron was sold by June 30, 2015. Currently we no longer own equity in Incuron, but do maintain a right to royalty payments, as later described. As such, we conduct drug development activities in the U.S. and Russia.

CBLI and Panacela, each have worldwide development and commercialization rights to product candidates in development, subject to certain financial obligations to our current licensors.

The CBLI logo and CBLI product names are proprietary trade names of CBLI, its subsidiaries. We may indicate U.S. trademark registrations and U.S. trademarks with the symbols “®” and “™”, respectively. Third-party logos and product/trade names are registered trademarks or trade names of their respective owners.

PRODUCT DEVELOPMENT PIPELINE

Our product development programs arise from both internally developed and in-licensed intellectual property from our innovation partners, The Cleveland Clinic and RPCI. In building the Company’s product development pipeline, we intentionally pursued targets with applicability across multiple therapeutic areas and indications. This approach gives us multiple product opportunities and ensures that our success is not dependent on any single product or indication. Our primary product development programs and their respective development stages are illustrated below:

CBLI

PRODUCT Indication	DISCOVERY	PRECLINICAL	PIVOTAL ANIMAL STUDIES	HUMAN SAFETY / DOSE CONVERSION
ENTOLIMOD-Biodefense Acute Radiation Syndrome				

PRODUCT Indication	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PHASE III
ENTOLIMOD-Oncology Advanced Solid Tumors					
ENTOLIMOD-Oncology Neo-adjuvant Therapy of Colorectal Cancer					
CBLB612 Chemotherapy-induced Myelosuppression					

Panacela

PRODUCT Indication	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PHASE III
MOBILAN Targeted Therapy of Prostate Cancer					

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Our product development efforts were initiated by discoveries related to apoptosis, a tightly regulated form of cell death that can occur in response to internal stresses or external events such as exposure to radiation or toxic chemicals. Apoptosis is a major determinant of the tissue damage that occurs in a variety of medical conditions involving ischemia, or temporary loss of blood flow, such as cerebral stroke, heart attack and acute renal failure. In addition, apoptotic loss of cells of the hematopoietic system and gastrointestinal tract is largely responsible for the acute lethality of high-dose radiation exposure. On the other hand, apoptosis is also an important protective mechanism that allows the body to eliminate defective cells such as those with cancer-forming potential.

We have developed novel strategies to target the molecular mechanisms controlling apoptotic cell death for therapeutic benefit. These strategies take advantage of the fact that tumor and normal cells respond to apoptosis-inducing stresses differently due to tumor-specific defects in cellular signaling pathways such as inactivation of p53 (a pro-apoptosis regulator) and constitutive activation of Nuclear Factor kappa-B ("NF-kB"), (a pro-survival regulator).

Thus, we designed two oppositely-directed general therapeutic concepts:

(a) temporary and reversible suppression of apoptosis in normal cells to protect healthy tissues from stress-induced damage using compounds we categorize as Protectans, which include entolimod and CBLB612; and,

(b) reactivation of apoptosis in tumor cells to eliminate cancer using compounds we categorize as Curaxins, which includes CBL0137, currently being developed by our former subsidiary, Incuron, LLC ("Incuron").

In recent years, our understanding of the mechanisms of actions underlying the activity of these compounds has grown substantially beyond the initial founding concepts around modulation of apoptosis.

Entolimod Biodefense Indication

Our most advanced Protectan product candidate is entolimod, an engineered derivative of the Salmonella flagellin protein that was designed to retain its specific TLR5-activating capacity while increasing its stability, reducing its immunogenicity and enabling high-yield production. We are developing entolimod for dual indications: (i) as a medical radiation countermeasure for prevention of death from ARS, which we refer to as a Biodefense Indication; and (ii) as an oncology immunotherapy (discussed in the following section).

The market for medical radiation countermeasures grew dramatically following the September 11, 2001 terrorist attacks and the subsequent use of anthrax in a biological attack in the U.S. Terrorist activities worldwide have continued in the intervening years and the possibility of chemical, biological, radiation and nuclear attacks continues to represent a perceived threat for governments world-wide. In addition to the U.S. government, which maintains a national stockpile of products for emergency use (the "National Stockpile"), we believe the potential markets for the sale of radiation countermeasures include U.S. federal, state and local governments, including defense and public health agencies; foreign governments; non-governmental organizations; multinational corporations; transportation and security companies; healthcare providers; and, nuclear power facilities.

Acute high-dose whole body or significant partial body radiation exposure induces massive apoptosis of cells of the hematopoietic system and gastrointestinal tract, which leads to ARS, a potentially fatal condition. The threat of ARS is primarily limited to emergency/defense scenarios and is significant given the possibility of nuclear/radiological accidents, warfare or terrorist incidents. The scale of possible exposure (number of people affected) has been estimated by the U.S. government to be in the range of 500,000 based on a modeled 10-kiloton device detonation in New York City. We believe the significant limitations of the two currently approved treatments to deal with such an event make entolimod a compelling product candidate. It is not feasible or ethical to test the efficacy of entolimod as a radiation countermeasure in humans. Therefore, we are developing entolimod under the FDA's Animal Rule guidance (see "– Government Regulation – Animal Rule"). The Animal Rule authorizes the FDA to rely on data from animal studies to provide evidence of a product's effectiveness under circumstances where there is a reasonably well-understood mechanism for the activity of the product. Under these requirements, and with the FDA's prior agreement, medical countermeasures, like entolimod, may be approved for use in humans based on evidence of effectiveness derived from appropriate animal studies, evidence of safety derived from studies in humans and any additional supporting data.

We met with the FDA in July 2014 to present our human dose-conversion and to discuss our intent to submit a pre-EUA application. As a result of this meeting, the FDA agreed to accept a pre-EUA application for review, which was filed in the second quarter of

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2015. If authorized by the FDA, pre-EUA status will allow entolimod to be sold into the National Stockpile and used under a state of emergency. Such authorization is not equivalent to full licensure through approval of a BLA, but precedes full licensure, and, importantly, would position entolimod for potential sales in advance of full licensure in the U.S. We further believe pre-EUA status will position us to explore sales opportunities with foreign governments.
Our pivotal efficacy study conducted in 179 non-human primates demonstrated with a high degree of statistical significance that injection of a single dose of entolimod given to rhesus macaques 25 hours after exposure to a 70% lethal dose of total body irradiation improved animal survival by nearly three-fold compared to the control group. Dose-dependence of entolimod's efficacy was demonstrated with doses above the minimal efficacious dose establishing a plateau at approximately 75% survival at 60 days after irradiation, as compared to 27.5% survival in the placebo-treated group.
Our pivotal study conducted in 160 non-irradiated non-human primates established the dose-dependent effect of entolimod on biomarkers for animal-to-human dose conversion.
Our clinical studies of entolimod in 150 healthy human subjects demonstrated the safety profile of entolimod and established the dose-dependent effect of entolimod on efficacy biomarkers in humans. In these studies, and in a Phase 1 oncology study in 26 patients with advanced cancer that was reported at ASCO in 2015, transient decrease in blood pressure and elevation of liver enzymes were observed along with transient mild to moderate flu-like syndrome. Such effects are the most common adverse events and they are linked to up-regulation of cytokines that are also biomarkers for efficacy.
The FDA has granted Fast Track status to entolimod (see "– Government Regulation – Fast Track Designation") and Orphan Drug status for prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster (see "– Government Regulation – Orphan Drug Des