

CLEVELAND BIOLABS INC

Form S-3

January 29, 2016

As filed with the Securities and Exchange Commission on January 29, 2016

**Registration No. 333-**

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM S-3**

**REGISTRATION STATEMENT**

**UNDER THE SECURITIES ACT OF 1933**

**Cleveland BioLabs, Inc.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

20-0077155

I.R.S. Employer Identification Number

73 High Street, Buffalo, NY 14203

(716) 849-6810

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(Address, including zip code, and telephone number, including area code of registrant's principal executive offices)

Yakov Kogan

Chief Executive Officer

Cleveland BioLabs, Inc.

73 High Street

Buffalo, New York 14203

(716) 849-6810

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Cecil E. Martin, III

McGuireWoods LLP

7 Saint Paul Street, Suite 1000

Baltimore, Maryland 21201-1671

Phone: (410) 659-4400

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box:

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box:

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If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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 the definitions 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

**CALCULATION OF REGISTRATION FEE**

Title of Class of Securities to be Registered	Amount To be Registered	Proposed Maximum Aggregate Price Per Share (1)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, \$0.005 par value per share	6,716,163 shares	\$ 3.72	\$24,950,546	\$ 2,513

(1) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, using the average of the high and low prices as reported on the NASDAQ Capital Market on January 28, 2016.

**The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.**

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**PRELIMINARY PROSPECTUS, SUBJECT TO COMPLETION, DATED JANUARY 29, 2016**

**CLEVELAND BIOLABS, INC.**

6,716,163 Shares of Common Stock

This prospectus relates to the public offering of up to 6,716,163 shares of common stock of Cleveland BioLabs, Inc. by the selling stockholders identified in this prospectus.

The selling stockholders may sell common stock from time to time in the principal market on which the stock is traded at the prevailing market price or in negotiated transactions.

We will not receive any of the proceeds from the sale of common stock by the selling stockholders. We will pay the expenses of registering these shares.

**Investing in our common stock involves a high degree of risk. You should consider carefully the risk factors beginning on page 6 of this prospectus and as described in our most recent Annual Report on Form 10-K filed with the SEC on February 27, 2015 and in our Quarterly Report on Form 10-Q filed with the SEC on November 9, 2015 before purchasing any of the shares offered by this prospectus.**

Our common stock is listed on the NASDAQ Capital Market under the symbol "CBLI". The last reported sale price of our common stock on the NASDAQ Capital Market on January 28, 2016, was \$3.69 per share.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

The date of this prospectus is \_\_\_\_\_, 2016.

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You may only rely on the information contained in this prospectus or to which we have referred you. We have not authorized anyone to provide you with different information. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the common stock offered by this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any common stock in any circumstances in which such offer or solicitation is unlawful. Neither the delivery of this prospectus nor any sale made in connection with this prospectus shall, under any circumstances, create any implication that there has been no change in our affairs since the date of this prospectus or that the information contained by reference to this prospectus is correct as of any time after its date.

## WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. You may also read and copy any document we file at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room.

This prospectus is part of a registration statement on Form S-3 that we filed with the SEC to register the securities offered hereby under the Securities Act of 1933, as amended (the "**Securities Act**"). This prospectus does not contain all of the information included in the registration statement, including certain exhibits and schedules. You may obtain the registration statement and exhibits to the registration statement from the SEC at the address listed above or from the SEC's internet site.

## INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information into this prospectus. This means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information that we incorporate by reference is considered to be part of this prospectus. Because we are incorporating by reference our future filings with the SEC, this prospectus is continually updated and those future filings may modify or supersede some or all of the information included or incorporated in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or in any document previously incorporated by reference have been modified or superseded. This prospectus incorporates by reference the documents listed below and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), (i) after the date of the initial registration statement and prior to effectiveness of the registration statement, and (ii) after the date of this prospectus, until the selling stockholders sell all of our securities registered under this prospectus:

our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the SEC on February 27, 2015;

our Quarterly Reports on Form 10-Q filed with the SEC on May 7, 2015, August 12, 2015 and November 9, 2015;

our Current Reports on Form 8-K filed with the SEC on January 13, 2015, January 27, 2015, January 28, 2015, February 4, 2015, February 9, 2015, February 20, 2015, March 13, 2015, April 17, 2015, May 4, 2015, May 11, 2015, May 18, 2015, June 24, 2015, June 25, 2015, July 7, 2015, July 9, 2015, July 10, 2015, July 13, 2015, September 2, 2015, September 21, 2015 and December 24, 2015; and



the description of our common stock, which is contained in the registration statement on Form 8-A filed with the SEC on July 20, 2006 (File No. 001-32954), including any amendments or reports filed for the purpose of updating that description.

Notwithstanding the foregoing, information furnished under Items 2.02 and 7.01 of any Current Report on Form 8-K, including the related exhibits, is not incorporated by reference in this prospectus.

The information about us contained in this prospectus should be read together with the information in the documents incorporated by reference. You may request a copy of any or all of these filings, at no cost, by writing or telephoning us at:

Cleveland BioLabs, Inc.

73 High Street

Buffalo, New York 14203

Attention: Corporate Secretary

Telephone: (716) 849-6810

## SUMMARY

This summary highlights information contained elsewhere in this prospectus. You should read the entire prospectus carefully, including the section titled “*Risk Factors*” before deciding to invest in our common stock. In this prospectus, unless otherwise stated or the context otherwise requires, the terms “**Cleveland BioLabs**” and “**CBLI**” refer to Cleveland BioLabs, Inc. and its wholly owned subsidiary BioLab 612, LLC, but not its joint venture Panacela Labs, Inc. The “**Company**,” “**we**,” “**us**” and “**our**” refer to Cleveland BioLabs, Inc. together with its consolidated subsidiaries BioLabs 612, LLC and Panacela Labs, Inc. Each of the trade names or service marks appearing or incorporated by reference in this prospectus are the property of their respective owners.

## The Company

We are 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 radiation mitigation and oncology immunotherapy. 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. We conduct business in the United States and the Russian Federation. CBLI and our joint venture, Panacela Labs, Inc. (“**Panacela**”), each have worldwide development and commercialization rights to product candidates in development, subject to certain financial obligations to our current licensors. CBLI’s most advanced product candidate is entolimod, which we are developing as a radiation countermeasure and an immunotherapy for oncology and other indications.

Our primary product development programs and their respective development stages are illustrated below:

## CBLI

## Panacela

**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 and as an oncology drug. We believe that entolimod is the most efficacious 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 U.S. Food & Drug Administration (“**FDA**”)’s Animal Efficacy Rule, for the indication of reducing the risk of death following exposure to potentially lethal irradiation occurring as a result of a radiation disaster. 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 (“**GLP**”) 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 a 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 submission and agreed to accept a pre-EUA submission for review, which was filed in the first half 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.

In September 2015, we announced two awards totaling \$15.8 million in funding from the Department of Defense 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 Biologics License Application.

Additionally, we completed a Phase 1 open-label, dose-escalation trial of entolimod in 26 patients with advanced cancer in the United States and continue dosing in a small expansion study in the Russian Federation, which is enrolling additional patients at the highest doses achieved in the US study. Both studies include evaluation of immune cell response to administrations of entolimod. Data for the US study were presented at the 2015 annual meeting of the American Society of Clinical Oncology on May 30, 2015. The Russian Federation clinical study is the first of two planned studies supported by a 149-million-ruble, matching funds development contract that we received in October 2013 from the Ministry of Industry and Trade of the Russian Federation (“**MPT**”).

We have worldwide development and commercialization rights to entolimod.

**CBLB612** is a proprietary compound based upon a natural activator of another tissue-specific component of the innate immune system, the TLR2/TLR6 heterodimeric receptor. CBLB612 is a pharmacologically optimized synthetic molecule that structurally mimics naturally occurring lipopeptides of Mycoplasma (a genus of parasitic bacteria) and activates NF- $\kappa$ B pro-survival and immunoregulatory signaling pathways via specific binding to TLR2 on a subset of body tissues and cell types that express this receptor. Preclinical studies have shown that CBLB612 stimulates white blood cell regeneration. More recent research indicates that stimulation of these toll-like receptors may also enhance anti-tumor efficacy. We believe an opportunity may exist for CBLB612 to offer a single-dose alternative to existing hemopoietic growth factors, such as filgrastim (Neupogen™), which comprises a multi-billion-dollar market in support

of chemotherapy administration. Filgrastim modestly shortens the duration of chemotherapy-related neutropenia, but does not improve thrombocytopenia or anemia, and does not provide antitumor efficacy.

In July 2015, we reported the results of a Phase 1, single-center, blind, placebo-controlled, single ascending dose study in the Russian Federation evaluating the safety and tolerability of CBLB612 in healthy volunteers and measuring response of various hematopoietic stem and progenitor cell types in order to gain a preliminary estimate of the drug's hematopoietic stem cell stimulatory efficacy. Analysis of data from the 56 healthy volunteers enrolled in the study indicates that single subcutaneous injections of CBLB612 in doses ranging from 0.5 to 4 micrograms were generally well-tolerated, with the 4 microgram dose identified as the max tolerated dose. Observed adverse events were typically mild or moderate in severity, transient, and related to the drug's mechanism of action. Single injections of CBLB612 induced dose-dependent increases in absolute neutrophil counts lasting approximately 20 hours. Administrations of CBLB612 also resulted in rapid, dose-dependent increases of plasma levels of the specified cytokines. Cytokine levels returned to baseline levels several hours after administration of the drug.

Currently, our development of CBLB612 is supported by the Russian Federation via a 139-million-ruble matching funds development contract that we received in July 2012 from MPT. We licensed CBLB612 to Zhejiang Hisun Pharmaceutical Co., Ltd. for the territories of China, Taiwan, Hong Kong and Macau. We have rest-of-world development and commercialization rights to CBLB612.

**Mobilan** is the lead product candidate of our consolidated joint venture Panacela. Mobilan is a nanoparticle-formulated recombinant non-replicating adenovirus that directs expression of TLR5 and its agonistic ligand, flagellin. In pre-clinical studies, delivery of Mobilan to tumor cells results in constitutive autocrine TLR5 signaling and strong activation of the innate immune system with subsequent development of adaptive anti-tumor immune responses. In March 2015, enrollment was opened in a Phase 1 multicenter, randomized, placebo-controlled, single-blinded study in the Russian Federation evaluating single injections of ascending doses of Mobilan administered directly into the prostate of patients with prostate cancer. This study is being performed under a 149-million-ruble matching funds development contract that Panacela received in October 2013 from MPT. Panacela holds worldwide development and commercialization rights to Mobilan. As of December 31, 2015, we owned 66.77% of Panacela.

### **Our Partners**

In October 2011, we entered into our Panacela joint venture with Rusnano to carry out a complete cycle of development and commercialization in the Russian Federation for the treatment of oncological, infectious or other diseases. We invested \$3.0 million in Panacela preferred shares and warrants, and, together with certain third-party owners, assigned and/or provided exclusive licenses, as applicable, to Panacela to provide Panacela with worldwide development and commercialization rights to five preclinical product candidates in exchange for Panacela common shares. Rusnano invested \$9.0 million in Panacela preferred shares and warrants. In 2013, Rusnano loaned Panacela \$1.5 million through a convertible term loan (the “**Panacela Loan**”) and revised its original investment agreement to remove the predetermined development milestones and timelines for further investment and provide that Rusnano may invest an additional \$15.5 million at its option. In December 2015, Panacela, Cleveland BioLabs and Rusnano entered into two stock subscription agreements, an acknowledgement agreement an amendment to the Panacela Loan documents that, in the aggregate, resulted in, among other things, the amount outstanding under the Panacela Loan being deemed fully paid and satisfied, each of Rusnano and Cleveland BioLabs purchasing additional shares of Panacela’s common stock and Rusnano purchasing shares of Cleveland Biolabs’ common stock. As of the date of this prospectus, we have an ownership stake of 66.77% in Panacela.

Additionally, we leverage close development relationships with Roswell Park Cancer Institute and The Cleveland Clinic. Together, our team of legal entities, financial partners and other collaborators engage in the collective development efforts necessary to advance all of our product candidates towards marketing approval and commercialization.

## **Corporate Information**

We were incorporated in Delaware on June 5, 2003. We conduct operations through several subsidiaries, including our wholly-owned subsidiary, BioLab 612, LLC, and our consolidated joint venture Panacela Labs, Inc.

Our principal executive offices are located at 73 High Street, Buffalo, New York 14203. Our telephone number is (716) 849-6810. Our website address is [www.cbiolabs.com](http://www.cbiolabs.com). We have included our website address as an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of this prospectus.

## Recent Developments

We previously disclosed that Panacela and BioLab 612 have restricted cash that includes certificates of deposit, denominated in Russian rubles, which collateralize Panacela and BioLab 612 contracts with the MPT and provide additional assurance that Panacela and BioLab 612 will satisfactorily perform their statements of work under the contracts. Some of our restricted cash deposits are on deposit at NOTA-Bank, a Russian depository institution. On October 13, 2015, due to liquidity concerns, the Bank of Russia appointed temporary management of NOTA-Bank and placed a three-month moratorium on all creditor claims. Subsequently, on November 24, 2015, the bank's license was revoked by the Bank of Russia, and on January 19, 2016, the Moscow Arbitration Court declared NOTA-Bank insolvent, noting a 70% deficiency in assets. As a result of these developments, the absence of deposit insurance coverage available to Panacela and the fact that what assets do remain will need to be settled according to priorities established by Russian law (i.e., corporate depositors are satisfied after individual depositors and state-sponsored organizations), we expect to write off the full value of our deposits, approximately \$1,000,000, with NOTA-Bank.

## The Offering

Common stock offered by the selling stockholders	6,716,163 shares of our common stock, par value \$0.05 per share
Common stock outstanding before and after the offering	10,987,166
Use of proceeds	We will not receive any proceeds from the sale or other disposition of the shares of common stock offered hereby.
Risk Factors	Investing in our common stock involves a high degree of risk. See the section of this prospectus titled " <i>Risk Factors</i> " on page 6 for a discussion of these factors.
NASDAQ Capital Market symbol	CBLI



## RISK FACTORS

Investing in our securities involves a high degree of risk. Before making an investment decision, you should consider carefully the risks, uncertainties and other factors described in our most recent Annual Report on Form 10-K, as supplemented and updated by subsequent quarterly reports on Form 10-Q and current reports on Form 8-K that we have filed or will file with the SEC, which are incorporated by reference into this prospectus.

Our business, affairs, prospects, assets, financial condition, results of operations and cash flows could be materially and adversely affected by these risks. For more information about our SEC filings, please see “*Where You Can Find More Information.*”

## FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”) that involve substantial risks and uncertainties. All statements, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “should,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “project,” “will,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements in this prospectus 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.

These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. We discuss many of these risks in greater detail under "*Risk Factors*" in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should read this prospectus and the documents we have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements by these cautionary statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

## **USE OF PROCEEDS**

This prospectus relates to shares of our common stock that may be offered and sold from time to time by the selling stockholders. We will not receive any of the proceeds resulting from the sale of common stock by any selling stockholder.

## **SELLING STOCKHOLDERS**

This prospectus relates to the offering by the selling stockholders of up to 6,716,163 shares of common stock.

The following table sets forth, based on information provided to us by the selling stockholders or known to us, the name of the selling stockholders and the number of shares of our common stock beneficially owned by the selling stockholders before this offering. The number of shares owned are those beneficially owned, as determined under the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership includes any shares of common stock as to which a person has sole or shared voting power or investment power and any shares of common stock which the person has the right to acquire within 60 days through the exercise of any option, warrant or right, through conversion of any security or pursuant to the automatic termination of a power of attorney or revocation of a trust, discretionary account or similar arrangement. No selling stockholder is a broker-dealer or an affiliate of a broker-dealer.

We have assumed all shares of common stock reflected on the table will be sold from time to time in the offering covered by this prospectus. Because the selling stockholders may offer all or any portions of the shares of common stock listed in the table below, no estimate can be given as to the amount of those shares of common stock covered by this prospectus that will be held by the selling stockholders upon the termination of the offering.

The selling stockholders of up to 6,716,163 shares of our common stock are David Davidovich and Open Joint Stock Company "Rusnano," a company organized under the laws of the Russian Federation ("**Rusnano**"). Mr. Davidovich

acquired 6,459,948 shares of the Company's common stock being offered under this prospectus on July 9, 2015 in a private placement transaction exempt from the registration requirements of the Securities Act pursuant to a Securities Purchase Agreement, dated June 24, 2015, between Mr. Davidovich and the Company (the "**Davidovich Purchase Agreement**"). Under the terms of the Davidovich Purchase Agreement, Mr. Davidovich was granted the right to designate seven new directors to be appointed to fill one then-existing and six newly created vacancies on the Company's board of directors (the "**Board**"). In accordance with this right, the Board appointed the following directors designated by Mr. Davidovich: Ivan Persiyanov, Yulia Lebedina, Konstantin Gorshkov, Tatiana Levina, Natalia Saraeva, Natalia Khudyk and Anna Evdokimova, all of whom are currently still serving on the Board. Under the Davidovich Purchase Agreement, Mr. Davidovich also has the right to nominate for election to the Board a majority of directors until such time when he no longer holds a majority of the issued and outstanding common stock of the Company.

In connection with Mr. Davidovich's purchase of our common stock, the Company also entered into a Registration Rights Agreement, dated July 9, 2015, with Mr. Davidovich (the "**Davidovich Registration Rights Agreement**"). Pursuant to the terms of the Davidovich Registration Rights Agreement, the Company agreed to file a registration statement under the Securities Act covering the resale of his shares within sixteen (16) months of the date of the agreement. The Company agreed to bear all expenses of such registration. The shares of common stock held by Mr. Davidovich are included as part of the registration statement of which this prospectus forms a part under the terms of the Davidovich Registration Rights Agreement. However, Mr. Davidovich is prohibited by the terms of the Davidovich Purchase Agreement from selling any of his shares until July 9, 2017.

Rusnano acquired the shares of the Company's common stock being offered under this prospectus on December 18, 2015 pursuant to the terms of a stock subscription agreement (the "**Rusnano Subscription Agreement**"), under which the Company agreed to issue and sell to Rusnano an aggregate of 256,215 shares of the Company's common stock. In lieu of paying the aggregate purchase price in cash, Rusnano agreed to apply the value of the shares to partially satisfy the obligations owed under the Panacela Loan. Prior to the date of the Rusnano Subscription Agreement, Rusnano was, and remains, a significant stockholder of Panacela.

The Rusnano Subscription Agreement also contains provisions providing that within 60 days of the closing of Rusnano's purchase of the Company's shares, the Company would file a registration statement under the Securities Act, registering the resale of the shares by Rusnano. The Company agreed to bear all expenses of such registration, other than any underwriting discounts, selling fees or commissions, in the case of an underwritten offering, or any stock transfer taxes. Each of the Company and Rusnano agreed to indemnify the other under certain circumstances and each made certain customary representations and warranties to one another. The shares of common stock held by Rusnano are included as part of the registration statement of which this prospectus forms a part under the terms of the Rusnano Subscription Agreement.

In connection with the sale of the shares of Company common stock to Rusnano, Rusnano also purchased additional shares in Panacela and the Company, Panacela and Rusnano entered into an Acknowledgement Agreement, also dated December 18, 2015, under the terms of which, among other things, Panacela agreed to undertake an offering of its own shares, the Company agreed to issue and sell certain of its shares of common stock to Rusnano under the Rusnano Subscription Agreement and Rusnano agreed that upon the closing of those transactions, (i) it will waive any accrued and unpaid interest on the principal of Panacela Loan from and after October 13, 2015 and (ii) the remaining amount outstanding under the Panacela Loan will be deemed fully paid and satisfied.

As of January 28, 2016, there were 10,987,166 shares of our common stock issued and outstanding. Except as indicated in footnotes to the following table, we believe that each selling stockholder listed below has sole voting power and sole investment power with respect to all shares of common stock shown to be beneficially owned by such person based on information provided by the selling stockholders.

Selling Stockholder	Number of Shares Beneficially Owned Before Offering	Number of Shares Offered	Number of Shares Beneficially Owned After Offering	Percentage of Shares Beneficially Owned After Offering	
David Davidovich	6,459,948	6,459,948	0	0	%
Open Joint Stock Company "Rusnano"	256,215	256,215	0	0	%



## PLAN OF DISTRIBUTION

Each selling stockholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the Nasdaq Capital Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling securities:

purchases by underwriters, dealers and agents who may receive compensation in the form of underwriting discounts, concessions or commissions from a selling stockholder and/or the purchasers for whom they may act as agent;

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales;

in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such securities at a stipulated price per security;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

a combination of any such methods of sale; or

any other method permitted pursuant to applicable law but not described in this prospectus.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the securities owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the securities, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b) or other applicable provision under the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer the securities in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders may also sell securities under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction, not in excess of a customary brokerage commission in compliance with FINRA Rule 2121, and, in the case of a principal transaction, a markup or markdown in compliance with Supplementary Material 0.2 to FINRA Rule 2121.



In connection with the sale of the securities or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

To the extent necessary, we may amend or supplement this prospectus from time to time to describe a specific plan of distribution. If required, we will file a supplement to this prospectus or a post-effective amendment to the registration statement that includes this prospectus upon being notified by the one or both of the selling stockholders that any material arrangement has been entered into with a broker-dealer for the sale of shares through a block trade, offering or a purchase by a broker or dealer. The applicable prospectus supplement or post-effective amendment will set forth the specific terms of the offering of the securities, and may include information concerning:

- the number of shares of common stock offered;
- the offering price of the common stock offered;
- the proceeds to the selling stockholder from the sale of the common stock offered;
- the names of the underwriters or agents, if any;
- any underwriting discounts, agency fees or other compensation to underwriters or agents; and
- any discounts or concessions allowed or paid to dealers.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

With respect to Mr. Davidovich's shares, under the terms of the Davidovich Registration Rights Agreement, we agreed to keep this prospectus effective for a period of up to one hundred eighty (180) days from the effective date of the registration statement or, if earlier, until the distribution contemplated in the prospectus has been completed. With respect to the shares held by Rusnano, we agreed to keep this prospectus effective until the earlier of the date that all shares covered by the registration statement of which this prospectus forms a part have been sold or can be sold publicly without any volume limitations under Rule 144 under the Securities Act.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

## **LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon for us by McGuireWoods LLP, Baltimore, Maryland.

## **EXPERTS**

The consolidated financial statements of Cleveland BioLabs, Inc. as of December 31, 2014 and 2013 and for each of the years in the two-year period ended December 31, 2014 appearing in Cleveland BioLabs' Annual Report on Form 10-K for the year ended December 31, 2014, have been audited by Meaden & Moore, Ltd., an independent registered public accounting firm, as set forth in its report thereon, included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

## **PART II**

### **INFORMATION NOT REQUIRED IN THE PROSPECTUS**

#### **Item 14. Other Expenses of Issuance and Distribution.**

We will pay all expenses in connection with the registration and sale of the common stock by the selling stockholders. The estimated expenses of issuance and distribution are set forth below.

SEC filing fee	\$2,543
Legal expenses	\$10,000
Accounting expenses	\$1,000
Miscellaneous	\$500
Total	\$14,043*

\* Estimate

#### **Item 15. Indemnification of Directors and Officers.**

The Company's certificate of incorporation and bylaws provide that each person who was or is made a party or is threatened to be made a party to or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was one of the Company's directors or officers or is or was serving at the Company's request as a director, officer, employee or agent of another corporation, or of a partnership, joint venture, trust or other enterprise shall be indemnified and held harmless by us to the fullest extent authorized or permitted by the DGCL against all expense, liability and loss (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action.

Section 145 of the DGCL permits a corporation to indemnify any director or officer of the corporation against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he

or she had no reasonable cause to believe his or her conduct was unlawful. In a derivative action, (*i.e.*, one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that the defendant is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

Pursuant to Section 102(b)(7) of the DGCL, Article ELEVENTH of the Company's certificate of incorporation eliminates the liability of a director to the Company's stockholders for monetary damages for such a breach of fiduciary duty as a director, except for liabilities arising:

from any breach of the director's duty of loyalty to the Company or the Company's stockholders;

from acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

under Section 174 of the DGCL; and

from any transaction from which the director derived an improper personal benefit.

The Company has entered into an agreement to indemnify one of the Company's directors. This agreement, among other things, provides that the Company will indemnify the director to the fullest extent authorized or permitted by the provisions of the Company's certificate of incorporation, bylaws or law for claims arising in his capacity as a director of the Company. The indemnification agreement also establishes the procedures that will apply in the event the director makes a claim for indemnification.

The Company maintains a general liability insurance policy which covers certain liabilities of directors and officers of the Company arising out of claims based on acts or omissions in their capacities as directors or officers.

The foregoing discussion of our certificate of incorporation, bylaws, indemnification agreements and Delaware law is not intended to be exhaustive and is qualified in its entirety by such certificate of incorporation, bylaws, indemnification agreements and law.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, offices or controlling persons of ours, pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by a director, officer or controlling person of ours in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered hereunder, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

#### **Item 16. Exhibits.**

A list of exhibits filed with this registration statement on Form S-3 is set forth on the Exhibit Index and is incorporated herein by reference.

#### **Item 17. Undertakings.**

1. The undersigned registrant hereby undertakes to file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act.

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the registration statement is on Form S-3, Form SF-3 or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in the registration statement or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

2. The undersigned registrant hereby undertakes that, for the purpose of determining any liability under the Securities Act each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3. The undersigned registrant hereby undertakes to remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

4. The undersigned registrant hereby undertakes that, for the purposes of determining liability to any purchaser,

(A) each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

5. The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.



6. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Buffalo, State of New York, on January 29, 2016.

Cleveland BioLabs, Inc.

By: /s/ C. Neil Lyons  
C. Neil Lyons  
Its: Chief Financial Officer

Each person whose signature appears below constitutes and appoints Yakov Kogan and C. Neil Lyons, and each of them severally, as his or her true and lawful attorney in fact and agent, with full powers of substitution and resubstitution, for such person and in such person's name, place and stead, in any and all capacities, to sign any or all amendments (including post effective amendments) to the Registration Statement, and to sign any registration statement for the same offering covered by this Registration Statement that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and all post effective amendments thereto, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, each acting alone, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

/s/ Yakov Kogan  
Yakov Kogan  
Chief Executive Officer and Director  
(principal executive officer) January 29, 2016

/s/ C. Neil Lyons  
C. Neil Lyons  
Chief Financial Officer  
(principal financial officer and principal accounting officer) January 29, 2016

/s/ James J. Antal  
James J. Antal  
Director

January 29, 2016

/s/ Anna Evdokimova  
Anna Evdokimova  
Director

January 29, 2016

/s/ Konstantin Gorshkov January 29, 2016  
Konstantin Gorshkov  
Director

/s/ Andrei Gudkov January 29, 2016  
Andrei Gudkov  
Director

/s/ Natalia Khudyk January 29, 2016  
Natalia Khudyk  
Director

/s/ Yulia Lebedina January 29, 2016  
Yulia Lebedina  
Director

/s/ Tatiana Levina January 29, 2016  
Tatiana Levina  
Director

/s/ Richard McGowan January 29, 2016  
Richard McGowan  
Director

/s/ Ivan Persiyarov January 29, 2016  
Ivan Persiyarov  
Director

/s/ Natalia Saraeva January 29, 2016  
Natalia Saraeva  
Director

## EXHIBIT INDEX

### Exhibit

#### Number Description of Document

- 4.1 Restated Certificate of Incorporation filed with the Secretary of State of Delaware on March 18, 2010 (incorporated by reference to Form 10-K for the year ended December 31, 2009, filed on March 22, 2010).
- 4.2 Certificate of Amendment of Restated Certificate of Incorporation, filed with the Secretary of State of Delaware on June 20, 2013 (incorporated by reference to Form 10-Q for the period ended June 30, 2013, filed on August 9, 2013).
- 4.3 Certificate of Amendment of Restated Certificate of Incorporation (incorporated by reference to Form 8-K filed on January 27, 2015).
- 4.4 Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Form 8-K filed on February 9, 2015).
- 4.5 Certificate of Amendment of Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Form 8-K filed on February 9, 2015).
- 5.1 Opinion of McGuireWoods LLP\*
- 23.1 Consent of Meaden & Moore, Ltd.\*
- 23.2 Consent of McGuireWoods LLP (contained in Exhibit 5.1)\*
- 24.1 Powers of Attorney (contained on the signature page to this registration statement)

\* Filed herewith