

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of Earliest Event Reported): March 11, 2014

Cleveland BioLabs, Inc.

(Exact Name of Issuer as Specified in Charter)

DELAWARE
(State or Other Jurisdiction of
Incorporation or Organization)

001-32954
(Commission
File Number)

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

73 High Street
Buffalo, NY 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:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition.

On March 11, 2014, Cleveland BioLabs, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2013. The information in this Item 2.02 of Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference.

Item 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On March 10, 2014, the Company received a deficiency letter from The NASDAQ Stock Market LLC ("NASDAQ") indicating that, based on the Company's closing bid price for the last 30 consecutive business days, the Company does not comply with the minimum bid price requirement of \$1.00 per share, as set forth in NASDAQ Listing Rule 5550(a)(2). The notification has no immediate effect on the listing of the Company's common stock on The Nasdaq Capital Market.

In accordance with NASDAQ Listing Rule 5810(c)(3)(A), the Company has a grace period of 180 calendar days, or until September 8, 2014, to regain compliance with the minimum closing bid price requirement for continued listing. In order to regain compliance, the minimum closing bid price per share of the Company's common stock must be at least \$1.00 for a minimum of ten consecutive business days. In the event the Company does not regain compliance by September 8, 2014, the Company may be afforded an additional 180-day compliance period, provided it demonstrates that it meets all other applicable standards for initial listing on The Nasdaq Capital Market (except the bid price requirement), and provides written notice of its intention to cure the minimum bid price deficiency during the second grace period, by effecting a reverse stock split, if necessary. If the Company fails to regain compliance after the second grace period, the Company's stock will be subject to delisting by NASDAQ.

The Company is considering actions that it may take in response to this notification in order to regain compliance with the continued listing requirements.

Item 9.01. Financial Statements and Exhibits.

(d)

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release titled "Cleveland BioLabs Reports Fourth Quarter and Fiscal 2013 Financial Results and Development Progress," dated March 11, 2014

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: March 11, 2014

By: /s/ YAKOV KOGAN

Name: Yakov Kogan

Title: Chief Executive Officer

INDEX TO EXHIBITS

**Exhibit
No.**

Description

99.1 Press Release titled "Cleveland BioLabs Reports Fourth Quarter and Fiscal 2013 Financial Results and Development Progress," dated March 11, 2014



FOR IMMEDIATE RELEASE

**CLEVELAND BIOLABS REPORTS FOURTH QUARTER AND FISCAL 2013
FINANCIAL RESULTS AND DEVELOPMENT PROGRESS**

Buffalo, NY — March 11, 2014 – Cleveland BioLabs, Inc. (NASDAQ:CBLI) today reported financial results and development progress for the fourth quarter and fiscal year ended December 31, 2013.

For the quarters ended December 31, 2013 and 2012, losses from operations were \$3.0 million and \$5.6 million, respectively. For the years ended December 31, 2013 and 2012, losses from operations were \$23.1 million and \$30.0 million, respectively. The decreases in the 2013 operating losses for both periods, as compared to the same periods in 2012 resulted from increases in revenue and reductions in research and development costs. Revenue increased in both periods in 2013 due to additional funding from both the Russian Federation and United States Department of Defense in support of our development efforts, while total research and development costs declined in 2013, largely due to the completion of an expensive study in irradiated non-human primates conducted for Entolimod as a radiation countermeasure.

For the quarters ended December 31, 2013 and 2012, other income was \$2.2 million and \$7.8 million, respectively, and for the years ended December 31, 2013 and 2012, reported other income was \$2.9 million and \$7.6 million, respectively. These amounts primarily consisted of noncash changes to the fair market value of accrued warrant liabilities.

The net loss attributable to Cleveland BioLabs for the fourth quarter of 2013 was \$0.4 million, or \$0.01 per share, as compared to net income attributable to Cleveland BioLabs of \$3.1 million, or \$0.07 per share, for the fourth quarter of 2012. The net loss attributable to Cleveland BioLabs for fiscal 2013 was \$17.3 million, or \$0.38 per share, as compared to \$18.2 million, or \$0.49 per share, for the same period in 2012.

At December 31, 2013, we had \$10.4 million in cash, cash equivalents and short-term investments, \$8.0 million of which was available for general use and \$2.4 million of which was restricted for the use of majority-owned subsidiaries. On January 16, 2014, we closed a registered direct offering with two institutional investors of 5,737,706 shares at a price of \$1.22 per share. Including estimated net proceeds from the offering of \$6.4 million and the \$10.4 million of available cash resources as of December 31, 2013, our available cash resources as of December 31, 2013 would have been approximately \$16.8 million.

Yakov Kogan, Ph.D., MBA, Chief Executive Officer, stated, “We are prioritizing our assets and positioning CBLI to capitalize on our most promising opportunities. We are focused on three primary objectives: Pursuing a meeting with the U.S. Food and Drug Administration (FDA) to evaluate the potential for a pre-emergency use authorization submission for the Entolimod radiation program; establishing pharmacodynamic support for Entolimod as a cancer immunotherapy; and achieving clinical proof of pharmacodynamic activity for CBL0137 as an enabler of oncogenic transcription. Simultaneously, we are securing senior drug development expertise to guide and execute our clinical strategy and help us optimize data readouts along the way.”

Operational Highlights

Completion of dose-conversion analysis and projection of an estimated efficacious human dose for Entolimod as a radiation countermeasure has been completed and a meeting with the FDA has been requested.

Dosing of Entolimod in patients with advanced cancer continues at RPCI, following amendment of the trial protocol in August to optimize immuno-stimulatory effects of the study drug. We are currently dosing the sixth cohort, which includes two cohorts post protocol amendment. To date, no drug-related serious adverse events have been reported in this trial. Preparations are in progress to initiate a healthy subject study with Entolimod in the Russian federation following a similar dosing regimen as the advanced cancer trial. This study is supported by a contract with the Ministry of Industry and Trade of the Russian Federation. Both of these studies will incorporate pharmacodynamic assays measuring response of specific types of immune cells to administrations of Entolimod.

Evaluation of the second cohort has been completed in a multi-center, Phase 1 trial assessing the intravenous administration of Curaxin CBL0137 in patients with metastatic or unresectable advanced solid cancers and lymphomas. In parallel, evaluation of the sixth cohort is ongoing in a multicenter, Phase 1 study assessing the oral administration of Curaxin CBL0137 in patients with advanced solid tumors that are resistant or refractory to current standard treatment. To date, no drug-related serious adverse events have been reported in either trial.

An Investigational New Drug application for CBLB612, a drug in development for the induction and mobilization of hematopoietic stem cells was filed with the regulatory authorities in the Russian Federation in the third quarter of 2013. A Phase 1 healthy subject study is planned to start mid-year, with the primary goal of establishing a maximally tolerated dose and a secondary objective of characterizing functional stem cell response. This study is funded by a contract from the Ministry of Industry and Trade of the Russian Federation.

Further Financial Highlights

Revenue for the fourth quarter of 2013 increased to \$3.9 million compared to \$2.2 million for the fourth quarter of 2012. Revenue for fiscal 2013 increased to \$8.5 million compared to \$3.6 million for the same period in 2012. These revenue increases were primarily due to increases in contract funding from the Russian Federation and the United States Department of Defense.

Research and development costs for the fourth quarter of 2013 decreased to \$4.6 million compared to \$5.6 million for the same period in 2012. Research and development costs for fiscal 2013 decreased to \$19.5 million compared to \$22.5 million for the same period in 2012. These net decreases result from reduced development costs of Entolimod as a radiation countermeasure as an irradiated non-human primate study was completed in 2012, offset by increases in development activities for several of our oncology drug candidates.

General and administrative costs for the fourth quarter of 2013 increased slightly to \$2.3 million compared to \$2.1 million for the same period in 2012. General and administrative costs for fiscal 2013 increased to \$12.0 million from \$11.1 million for the same period in 2012. These increases were primarily attributable to higher general and administrative costs for our Russian-based subsidiaries and higher corporate legal and intellectual property fees.

Cleveland BioLabs had approximately 45 million shares of common stock outstanding at December 31, 2013, and 51 million shares giving pro forma effect to the sale of equity in January 2014.

The Company also announced receipt of a letter citing a deficiency in continued listing requirements for The Nasdaq Capital Market, which requires listed securities to maintain a minimum bid price of \$1 per share. The Company has a period of 180 calendar days in which to regain compliance. In the event the Company does not regain compliance, the Company may be eligible for an extension.

Conference Call Information

Management will host a conference call at 10:00 a.m. ET today to provide updates and address investor questions regarding general business developments. Interested parties may participate by dialing 877-407-9205 (US) or 201-689-8054 (International), approximately five to ten minutes before the call start time. A live webcast of the conference call will be available on the investor page of the Cleveland BioLabs web site at www.cbiolabs.com. A replay of the call will be available starting on March 11, 2014, at 1:00 p.m. ET through March 28, 2014, at 11:59 p.m. ET. Interested parties may access the replay by dialing 877-660-6853 (US) or 201-612-7415 (International) and entering conference ID number 13576596. An archived webcast of the conference call will be available on the investor page of the Cleveland BioLabs web site at www.cbiolabs.com.

About Cleveland BioLabs

Cleveland BioLabs, Inc. is an innovative drug development company seeking to develop first-in-class pharmaceuticals designed to address diseases with significant medical need. The company's lead product candidates are Entolimod, which is being developed as a radiation countermeasure and a potential cancer treatment and Curaxin CBL0137, our lead oncology product candidate. The company conducts business in the United States and in the Russian Federation through its three operating subsidiaries, Incuron, LLC, BioLabs 612, LLC and Panacela Labs, Inc. The company maintains strategic relationships with the Cleveland Clinic, Roswell Park Cancer Institute, and the Children's Cancer Institute Australia for Medical Research. To learn more about Cleveland BioLabs, Inc., please visit the Company's website at <http://www.cbiolabs.com>.

This press release contains certain forward-looking information about Cleveland BioLabs 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 are not historical facts. Words such as "expect(s)," "feel(s)," "believe(s)," "will," "may," "anticipate(s)" and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding the likelihood of receiving funding; our ability to successfully develop and commercialize our therapeutic products; the conduct and results of our various clinical trials; and future performance. 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.

These factors include, among others, the decisions of third parties regarding whether or not to fund the Company through grants; the Company's failure to successfully and timely develop existing and new products; the Company's collaborative relationships and the financial risks related thereto; the Company's inability to obtain regulatory approval in a timely manner or at all; the risks inherent in

the early stages of drug development and in conducting clinical trials; the Company's ability to comply with its obligations under license agreements; 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. Some of these factors could cause future results to materially differ from the recent results or those projected in forward-looking statements. See also the "Risk Factors" and "Forward-Looking Statements" described in the Company's periodic filings with the Securities and Exchange Commission.

Contact:

Rachel Levine, Vice President, Investor Relations

Cleveland BioLabs, Inc.

T: (917) 375-2935

E: rlevine@cbiolabs.com

TABLES FOLLOW

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	<i>December 31,</i>	
	<u>2013</u>	<u>2012</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$10,048,466	\$25,652,083
Short-term investments	305,538	2,633,944
Accounts receivable	458,391	41,896
Other current assets	344,386	1,078,040
Total current assets	11,156,781	29,405,963
Equipment, net	457,912	986,553
Restricted cash	2,921,724	1,577,920
Other long-term assets	159,224	39,597
Total assets	\$14,695,641	\$32,010,033
LIABILITIES & STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 794,397	\$ 1,523,875
Accrued expenses	2,445,446	2,410,592
Deferred revenue	1,069,438	3,314,918
Accrued warrant liability	1,241,311	4,105,659
Current portion of note payable	351,527	—
Current portion of capital lease obligation	83,634	71,679
	5,985,753	11,426,723
Noncurrent portion of capital lease obligation	7,522	97,602
Long-term debt	7,121,388	—
Commitments and contingencies	—	—
Total liabilities	13,114,663	11,524,325
Stockholders' equity:		
Total Cleveland BioLabs, Inc. stockholders' equity (deficit)	(9,522,945)	6,333,167
Noncontrolling interest in stockholders' equity	11,103,923	14,152,541
Total stockholders' equity	1,580,978	20,485,708
Total liabilities and stockholders' equity	\$14,695,641	\$32,010,033

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	<i>Quarter Ended December 31</i>		<i>Year to Date December 31</i>	
	<i>2013</i>	<i>2012</i>	<i>2013</i>	<i>2012</i>
Revenues:				
Grants and contracts	\$ 3,871,632	\$ 2,161,501	\$ 8,487,966	\$ 3,570,710
Operating expenses:				
Research and development	4,616,068	5,581,405	19,525,950	22,501,805
General and administrative	2,251,722	2,141,562	12,038,775	11,115,511
Total operating expenses	<u>6,867,790</u>	<u>7,722,967</u>	<u>31,564,725</u>	<u>33,617,316</u>
Loss from operations	<u>(2,996,158)</u>	<u>(5,561,466)</u>	<u>(23,076,759)</u>	<u>(30,046,606)</u>
Other income:				
Interest and other income (expense)	(202,025)	(94,464)	83,127	(70,015)
Change in value of warrant liability	2,353,429	7,862,730	2,864,348	7,701,981
Total other income	<u>2,151,404</u>	<u>7,768,266</u>	<u>2,947,475</u>	<u>7,631,966</u>
Net income (loss)	<u>(844,754)</u>	<u>2,206,800</u>	<u>(20,129,284)</u>	<u>(22,414,640)</u>
Net loss attributable to noncontrolling interests	479,507	902,724	2,866,407	4,180,498
Net income (loss) attributable to Cleveland BioLabs, Inc.	<u>\$ (365,247)</u>	<u>\$ 3,109,524</u>	<u>\$ (17,262,877)</u>	<u>\$ (18,234,142)</u>
Net income (loss) available to common stockholders per share of common stock, basic	<u>\$ (0.01)</u>	<u>\$ 0.07</u>	<u>\$ (0.38)</u>	<u>\$ (0.49)</u>
Net income (loss) available to common stockholders per share of common stock, diluted	<u>\$ (0.01)</u>	<u>\$ 0.07</u>	<u>\$ (0.38)</u>	<u>\$ (0.49)</u>
Weighted average number of shares used in calculating net income (loss) per share, basic	<u>45,170,429</u>	<u>42,236,226</u>	<u>45,002,823</u>	<u>37,388,847</u>
Weighted average number of shares used in calculating net income (loss) per share, diluted	<u>45,170,429</u>	<u>42,565,945</u>	<u>45,002,823</u>	<u>37,388,847</u>

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	<i>For the Year Ended December 31</i>	
	<u>2013</u>	<u>2012</u>
Cash flows used in operating activities	\$(23,102,647)	\$(20,649,503)
Cash flows provided by investing activities	560,709	1,371,702
Cash flows provided by financing activities	7,261,942	21,519,249
Effect of exchange rate changes on cash and equivalents	<u>(323,621)</u>	<u>538,046</u>
Increase in cash and cash equivalents	<u>(15,603,617)</u>	<u>2,779,494</u>
Cash and cash equivalents at beginning of period	<u>25,652,083</u>	<u>22,872,589</u>
Cash and cash equivalents at end of period	<u>\$ 10,048,466</u>	<u>\$ 25,652,083</u>