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): May 8, 2014

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

DELAWARE	**001-32954**	**20-0077155**
(State or Other Jurisdiction of Incorporation or Organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

73 High Street **Buffalo, NY**	**14203**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

Check the appropriate box below if the Form 8-K 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))

Item 2.02. Results of Operations and Financial Condition.

On May 8, 2014, Cleveland BioLabs, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2014. 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 9.01. Financial Statements and Exhibits.

(d)

Exhibit No.	Description
99.1	Press Release titled “Cleveland Biolabs Reports First Quarter 2014 Financial Results And Development Progress,” dated May 8, 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: May 8, 2014

By: /s/ YAKOV KOGAN

Name: Yakov Kogan, Ph.D., M.B.A.

Title: Chief Executive Officer

Cleveland BioLabs

FOR IMMEDIATE RELEASE

CLEVELAND BIOLABS REPORTS FIRST QUARTER 2014 FINANCIAL RESULTS AND DEVELOPMENT PROGRESS

Buffalo, NY — May 8, 2014 – Cleveland BioLabs, Inc. (NASDAQ:CBLI) today reported financial results and development progress for the first quarter ended March 31, 2014.

Cleveland BioLabs reported a net loss for the first quarter of 2014 of $1.9 million, or $0.03 per share, which represents an improvement of $8.9 million as compared to the first quarter of 2013. $5.5 million of this improvement was due to a non-cash change in the fair market valuation of certain outstanding warrants, with the remaining $3.4 million of this improvement, due to a reduction in operating losses. The reduced operating losses were due to a narrowed focus of development activities, lower development costs for Entolimod as a radiation countermeasure and other cost saving measures.

At March 31, 2014, we had $13.7 million in cash, cash equivalents and short-term investments, $12.0 million of which was available for general use and $1.7 million of which was restricted for the use of majority-owned subsidiaries.

Yakov Kogan, Ph.D., MBA, Chief Executive Officer, stated, “Execution of our operational objectives for 2014 is on schedule. Preparations are well underway for our July meeting with the U.S. Food and Drug Administration to evaluate the potential for a pre-emergency use authorization (pre-EUA) submission for the Entolimod radiation countermeasure program. If appropriate, we plan to file a pre-EUA submission later this year. We recently reported the successful completion of a Phase 1 trial with CBL0102 and are planning to release an interim report on the oral study of our lead oncology drug candidate, Curaxin CBL0137 in the third quarter. Lastly, we are progressing with arrangements to initiate healthy subject studies supported by contracts with the Ministry of Industry and Trade of the Russian Federation for Entolimod and CBLB612, a drug candidate in development for the induction and mobilization of hematopoietic stem cells.”

Operational Highlights

A Phase 1 study of Entolimod in patients with advanced cancer at RPCI has reached dosing of the seventh cohort.

Dosing of the third cohort is underway 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, dose-escalation continues 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. Recruitment of the seventh cohort was recently initiated and an interim analysis of the first six cohorts in the oral study is being conducted. To date, no drug-related serious adverse events have been reported in either trial.

The Company recently reported the achievement of all objectives in a Phase 1 clinical trial of CBL0102, or quinacrine, an orally administered small molecule with a mechanism of action similar to CBL0137. The study was performed in patients with advanced cancers for which no standard care exists or which had become resistant to conventional therapies. All patients had tumors involving the liver. 32 patients were enrolled to receive sequentially higher starting doses of CBL0102 in seven cohorts. Study participants were treated with CBL0102 given orally daily. Patients could continue therapy for eight weeks (or longer if they appeared to be benefiting from therapy).

CBL0102 was generally well-tolerated and a recommended Phase 2 dose of 400 mg/day was established. By eight weeks of therapy, a partial tumor regression was recorded in one breast cancer patient, who experienced a 46% reduction in target lesion maximum dimensions. Disease stabilization was observed in four other patients (patients with breast cancer, hepatocellular carcinoma, salivary gland cancer, and rectal cancer). In the patient with hepatocellular carcinoma, long-term stabilization was observed for a period of 7.5 months, during which the patient remained on continuous CBL0102 treatment.

Further Financial Highlights

Revenue for the first quarter of 2014 was $1.3 million compared to $1.4 million for the first quarter of 2013. While the level of revenue was relatively flat between the periods, there was a shift in the underlying sources of revenue from the US government for the Entolimod radiation countermeasure program to the Russian Federation related to the new grant awards announced in the later part of 2013 for the development of Entolimod for oncology and Mobilan.

Research and development costs for the first quarter of 2014 decreased to $2.4 million compared to $5.3 million for the same period in 2013. This decrease was primarily due to completion of third-party service contracts for several compounds, as well as reduced compensation costs primarily attributable to our transfer of personnel to Buffalo BioLabs, Inc. in the fourth quarter of 2013.

General and administrative costs for the first quarter of 2014 decreased to $2.4 million compared to $3.5 million for the same period in 2013. This $1.1 million decrease was primarily due to a reduction of personnel, representing a reduction in compensation costs of $0.7 million, and $0.4 million through other cost saving actions.

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 May 8, 2014, at 1:00 p.m. ET through May 20, 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 13581192. An archived webcast of the conference call will be available for 90 days on the Investors page of the Cleveland BioLabs web site at www.cbiolabs.com.

About Cleveland BioLabs

Cleveland BioLabs, Inc. is an innovative biopharmaceutical 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 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 our 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)," "on schedule," "plan or planning," "progressing" and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding our ability to successfully develop and commercialize our therapeutic products; the conduct and results of our various clinical trials; our ability to obtain approval from the U.S. Food and Drug Administration of our product candidates; 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 Company's failure to successfully and timely develop existing and new products; the Company's collaborative relationships and the financial risks related thereto; 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 inability to obtain regulatory approval in a timely manner or at all; 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:

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TABLES FOLLOW

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	March 31, 2014	*December 31, 2013*
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$13,391,697	$10,048,466
Short-term investments	280,213	305,538
Accounts receivable	414,857	458,391
Other current assets	377,288	344,386
Total current assets	14,464,055	11,156,781
Equipment, net	384,366	457,912
Restricted cash	2,679,559	2,921,724
Other long-term assets	137,057	159,224
Total assets	$17,665,037	$14,695,641
LIABILITIES & STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 489,441	$ 794,397
Accrued expenses	2,972,849	2,445,446
Deferred revenue	1,086,720	1,069,438
Accrued warrant liability	1,436,845	1,241,311
Current portion of note payable	892,828	351,527
Current portion of capital lease obligation	71,350	83,634
	6,950,033	5,985,753
Noncurrent portion of capital lease obligation	—	7,522
Long-term debt	6,725,799	7,121,388
Commitments and contingencies	—	—
Total liabilities	13,675,832	13,114,663
Stockholders' equity:		
Total Cleveland BioLabs, Inc. stockholders' deficit	(6,697,442)	(9,522,945)
Noncontrolling interest in stockholders' equity	10,686,647	11,103,923
Total stockholders' equity	3,989,205	1,580,978
Total liabilities and stockholders' equity	$17,665,037	$14,695,641

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Quarter Ended March 31,	
	2014	***2013***
Revenues:		
Grants and contracts	$ 1,334,254	$ 1,367,472
Operating expenses:		
Research and development	2,439,773	5,331,615
General and administrative	2,413,543	3,483,372
Total operating expenses	4,853,316	8,814,987
Loss from operations	(3,519,062)	(7,447,515)
Other income (expense):		
Interest and other income (expense)	(317,922)	79,956
Foreign exchange gain (loss)	(151,771)	28,134
Change in value of warrant liability	2,087,558	(3,447,723)
Total other income (expense)	1,617,865	(3,339,633)
Net loss	(1,901,197)	(10,787,148)
Net loss attributable to noncontrolling interests	315,825	1,022,825
Net loss attributable to Cleveland BioLabs, Inc.	$ (1,585,372)	$ (9,764,323)
Net loss available to common stockholders per share of common stock, basic and diluted	$ (0.03)	$ (0.22)
Weighted average number of shares used in calculating net loss per share, basic and diluted	49,968,131	44,826,576

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

	Quarter Ended March 31,	
	2014	***2013***
Cash flows used in operating activities	$ (2,833,309)	$ (7,003,302)
Cash flows provided by (used in) investing activities	(10,805)	1,295,121
Cash flows provided by (used in) financing activities	6,335,195	(16,974)
Effect of exchange rate change on cash and equivalents	(147,850)	(157,915)
Increase (decrease) in cash and cash equivalents	3,343,231	(5,883,070)
Cash and cash equivalents at beginning of period	10,048,466	25,652,083
Cash and cash equivalents at end of period	$13,391,697	$19,769,013

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
NON-GAAP FINANCIAL MEASURES
(UNAUDITED)

We define net cash burn as the net increase (or decrease) in cash, cash equivalents and short-term investments excluding the effect of capital markets financing activities, and the net increase (or decrease) in restricted cash, as determined in accordance with generally accepted accounting principles or GAAP. And we separately track net cash burn for Cleveland BioLabs, Inc. and its wholly-owned subsidiary BioLab 612, LLC, which we refer to as CBLI Stand-alone, as well as for the consolidated entity which includes the accounts of Incuron, LLC, Panacela Labs, Inc. and Panacela Labs, LLC. This non-GAAP measure may be considered in addition to results prepared in accordance with GAAP, but should not be considered a substitute for, or superior to, GAAP results. We believe that net cash burn is relevant and useful information for the Company and our investors as it provides a simple method of determining net cash used by the Company. A calculation of net cash burn is provided below:

	Quarter Ended March 31,	
	2014	***2013***
CBLI Stand-alone:		
Cash, cash equivalents, and short-term investments, beginning of period	$ 7,957,302	$17,945,147
Cash, cash equivalents and short-term investments, end of period	12,021,569	13,333,966
Period increase/(decrease)	4,064,267	(4,611,181)
Less net proceeds from the sale of common stock	6,355,001	—
Net cash burn for the period	(2,290,734)	(4,611,181)
Number of months in period	3	3
Net monthly cash burn	$ (763,578)	$ (1,537,060)
Consolidated:		
Cash, cash equivalents, and short-term investments, beginning of period	$10,354,004	$28,286,027
Cash, cash equivalents and short-term investments, end of period	13,671,910	21,055,874
Period increase/(decrease)	3,317,906	(7,230,153)
Less net proceeds from the sale of common stock	6,355,001	—
Net cash burn for the period	(3,037,095)	(7,230,153)
Number of months in period	3	3
Net monthly cash burn	$ (1,012,365)	$ (2,410,051)