CLEVELAND BIOLABS INC
Form 8-K
February 22, 2016

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): February 22, 2016

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 and zip code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Conditions.

On February 22, 2016, Cleveland BioLabs, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2015. 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 2015 Financial Results and Development Progress", dated February 22, 2016

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: February 22, 2016 By: /s/ YAKOV KOGAN
Name: Yakov Kogan
Title: Chief Executive Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

CLEVELAND BIOLABS REPORTS 2015 FINANCIAL RESULTS AND DEVELOPMENT PROGRESS

Buffalo, NY - February 22, 2016 - Cleveland BioLabs, Inc. (NASDAQ:CBLI) today reported financial results and development progress for the fourth quarter and year ended December 31, 2015.

Cleveland BioLabs reported a net loss, excluding minority interests, of $(1.4) million for the fourth quarter of 2015, or $(0.13) per share, compared to net income of $11.3 million, or $3.95 per share, for the fourth quarter of 2014. Net loss, excluding minority interests, for full year 2015 was $(12.6) million, or $(1.79) per share, compared to a net income of $1.6 million, or $0.60 per share, for full year 2014. The 2014 periods reported net income due to a $14.2 million gain on the deconsolidation of the Company's joint venture, Incuron LLC. Excluding the gain on the deconsolidation of Incuron, net loss per share for the fourth quarter of 2014 was $(1.02) and net loss per share for full year 2014 was $(4.66).

As of December 31, 2015, the Company had $19.6 million in cash, cash equivalents and short-term investments, which, based on the Company’s current operational plan, is expected to fund the Company’s operating requirements beyond one year.

Yakov Kogan, Ph.D., MBA, Chief Executive Officer, stated, “The past year was one of significant momentum and accomplishment for CBLI. We strengthened our financial resources through the addition of a $25 million strategic investor and the award of $15.8 million in funding from the Department of Defense Congressionally Directed Medical Research Programs for continued development of entolimod’s biodefense indication. We streamlined our corporate structure with the sale of Incuron, while retaining a royalty on Incuron’s future success. We achieved several major milestones with our development programs, including the submission of a pre-Emergency Use Authorization (pre-EUA) dossier for entolimod as a radiation countermeasure and presentation of clinical oncology data for entolimod at the 2015 annual meeting of the American Society of Clinical Oncology. And, we commenced or continued clinical studies designed to further substantiate the potential of our Toll-like receptor agonists, entolimod, CBLB612 and Mobilan.”

“The pursuit of commercialization for entolimod as a radiation countermeasure remains our top priority,” continued Dr. Kogan. “We continue to work with the U.S. Food and Drug Administration to facilitate the review of our pre-EUA dossier. Products with pre-EUA status may be purchased by certain US government stakeholders for stockpiling in the event of a disaster and we believe achievement of this status may also increase interest from foreign governments. We recently initiated a regulatory process with the European Medicines Agency, which has granted entolimod orphan drug designation for the treatment of acute radiation syndrome, and we continue to evaluate other foreign markets.”

Other Recent Operational Highlights

- Studies elucidating immunotherapeutic mechanisms through which entolimod suppresses metastasis were published in Proceedings of the National Academy of Sciences of the United States of America (PNAS). The studies presented in the PNAS publication decipher the cascade of cell-signaling events that are triggered by entolimod activation of the TLR5 pathway in the liver. (http://www.pnas.org/content/early/2016/01/27/1521359113.full.pdf)
- Dosing commenced in a Phase 2 clinical study of the safety and tolerability of entolimod as a neo-adjuvant therapy in treatment-naïve patients with primary colorectal cancer who are recommended for surgery. This study is being conducted in the Russian Federation.

- A Phase 2 clinical study of CBLB612 as myelosuppressive prophylaxis in patients with breast cancer receiving doxorubicin-cyclophosphamide chemotherapy started dosing in the Russian Federation.
- Panacela Labs continued dosing in a Phase 1 study with Mobilan evaluating single injections administered directly into the prostate of patients with prostate cancer. This study is being conducted in the Russian Federation.

All of the studies being conducted in the Russian Federation are supported by development contracts with the Russian Federation Ministry of Industry and Trade, or MPT.

Further Financial Results

Revenue for the fourth quarter of 2015 was $1.3 million compared to $1.4 million for the fourth quarter of 2014. Revenue for full year 2015 was $2.7 million compared to $3.7 million for full year 2014. These decreases are primarily due to the completion of an Incuron research contract with the Skolkovo Foundation in 2014. Other offsetting variances include new revenue from recently awarded Department of Defense contracts, offset by reduced revenue from MPT contracts due largely to variations in the foreign currency exchange rate.

Research and development costs for the fourth quarter of 2015 were $1.9 million compared to $2.8 million for the fourth quarter of 2014. Research and development costs for full year 2015 decreased to $7.1 million compared to $9.7 million for full year 2014. These decreases primarily resulted from the deconsolidation of Incuron and nonrecurring drug production costs for Mobilan, both occurring in 2014. Somewhat offsetting were reductions in entolimod's biodefense program due to the completion and subsequent submission of the pre-EUA dossier in the second quarter of 2015, offset by increases in entolimod's oncology development largely due to the clinical activities commenced in the Russian Federation.

General and administrative costs for the fourth quarter of 2015 were $1.2 million compared to $2.0 million for the fourth quarter of 2014. General and administrative costs for full year 2015 decreased to $6.4 million compared to $8.5 million for full year 2014. Approximately 40% of this net decrease was attributable to the deconsolidation of Incuron, with the remainder primarily attributable to reductions in personnel and outside professional costs.

At December 31, 2015 the Company had approximately 11 million shares of common stock outstanding. In addition, the Company has 343,643 shares of common stock reserved for issuance pursuant to outstanding stock options with a weighted average exercise price of $46.60 and 2.2 million shares of common stock reserved for issuance pursuant to outstanding warrants exercisable at a weighted average price of $13.98.

About Cleveland BioLabs
Cleveland BioLabs, Inc. is an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. The company's proprietary platform of Toll-like immune receptor activators has applications in radiation mitigation, oncology immunotherapy, and vaccines. The company's most advanced product candidate is entolimod, which is being developed for a biodefense indication and as an immunotherapy for oncology and other indications. The company conducts business in the United States and in the Russian Federation through a wholly-owned subsidiary, BioLab 612, LLC and a joint venture with OJSC Rusnano, Panacela Labs, Inc. The company maintains strategic relationships with the Cleveland Clinic and Roswell Park Cancer Institute. 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 do not relate strictly to historical or current facts. Words and phrases such as "potential," "may," "future," "will," "plan," "anticipate," "believe," "intend" and similar expr are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding the company's future financial position, business strategy, new products, budgets, liquidity, cash flows,

projected costs, regulatory approvals or the impact of any laws or regulations applicable to the company, and plans and objectives of management for future operations. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the company, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements.

These factors include, among others, the risks inherent in the early stages of drug development and in conducting clinical trials; the company's plans and expectations with respect to future clinical trials and commercial scale-up activities; the company's ability to attract collaborators with development, regulatory and commercialization expertise and the financial risks related to those relationships; the company's ability to comply with its obligations under license agreements; the company's inability to obtain regulatory approval in a timely manner or at all; the commercialization of the company's product candidates, if approved; the company's plans to research, develop and commercialize its product candidates; future agreements with third parties in connection with the commercialization of any approved product; the size and growth potential of the markets for the company's product candidates, and its ability to serve those markets; the rate and degree of market acceptance of the company's product candidates; the company's history of operating losses and the potential for future losses, which may lead the company to not be able to continue as a going concern; regulatory developments in the United States and foreign countries; the performance of the company's third-party suppliers and manufacturers; and the success of competing therapies that are or may become available. 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.

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	$5,918,424	$3,103,969
Short-term investments	13,701,273	—
Accounts receivable	631,084	267,199
Other current assets	442,642	174,179
	20,693,423	3,545,347
Equipment, net	122,958	244,537
Restricted cash	37,663	1,699,759
Other long-term assets	26,560	56,131
Investment in Incuron, LLC	—	4,268,458
Total assets	$20,880,604	$9,814,232
LIABILITIES & STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$197,134	$1,057,743
Accrued expenses	1,584,826	1,804,456
Deferred revenue	11,892	156,317
Accrued warrant liability	4,048,900	862,074
Current portion of note payable	—	2,640,968
Current portion of capital lease obligation	—	7,522
	5,842,752	6,529,080
Long-term debt	—	1,499,050
Commitments and contingencies	—	—
Total liabilities	5,842,752	8,028,130
Stockholders' equity:		
Total Cleveland BioLabs, Inc. stockholders' deficit	9,888,182	(1,607,397)
Noncontrolling interest in stockholders' equity	5,149,670	3,393,499
Total stockholders' equity	15,037,852	1,786,102
Total liabilities and stockholders' equity	$20,880,604	$9,814,232

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	(unaudited)			
	Quarter ended December 31,		Year to date December 31,	
Revenues:	2015	2014	2015	2014
Grants and contracts	$1,269,433	$1,390,432	$2,708,225	$3,701,899
Operating expenses:				
Research and development	1,896,587	2,821,903	7,143,293	9,654,144
General and administrative	1,184,391	2,020,159	6,355,962	8,469,690
Total operating expenses	3,080,978	4,842,062	13,499,255	18,123,834
Loss from operations	(1,811,545)	(3,451,630)	(10,791,030)	(14,421,935)
Other income (expense):				
Interest and other income (expense)	261,665	(78,942)	(99,488)	(1,089,582)
Foreign exchange gain (loss)	(318,719)	(705,583)	(509,513)	(1,036,459)
Gain on deconsolidation of Incuron, LLC	—	14,206,555	—	14,206,555
Investment loss provision	(1,060,834)	—	(1,060,834)	—
Change in value of warrant liability	1,260,775	998,939	(221,915)	2,662,329
Equity in loss of Incuron, LLC	—	(285,542)	(362,137)	(285,542)
Total other income (expense)	142,887	14,135,427	(2,253,887)	14,457,301
Net income (loss)	(1,668,658)	10,683,797	(13,044,917)	35,366
Net loss attributable to noncontrolling interests	246,195	587,974	407,280	1,593,738
Net income (loss) attributable to Cleveland BioLabs, Inc.	$(1,422,463)	$11,271,771	$(12,637,637)	$1,629,104
Net income (loss) per share, basic and diluted	$(0.13)	$3.95	$(1.79)	$0.60
Weighted average number of shares basic and diluted	10,769,940	2,856,461	7,060,396	2,702,884

Non- GAAP Measures:
We define comparable net income (loss) available to common stockholders per share of common stock, basic and diluted as excluding the effect of the one-time gain on the deconsolidation of Incuron LLC and the one-time investment loss provision. 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 this adjusted earnings (loss) per share is relevant and useful information for the Company and our investors as it provides a simple method of comparing results of operations between periods, on a per share basis. A calculation of earnings (loss) per share is provided below:

Net income (loss) per share, basic and diluted, reported above	$(0.13)	$3.95	$(1.79)	$0.60
Investment loss provision	0.10	—	0.15	—
Gain on deconsolidation of Incuron, LLC	—	(4.97)	—	(5.26)
Comparable Net loss available to common stockholders per share of common stock, basic and diluted	$(0.03)	$(1.02)	$(1.64)	$(4.66)

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

	For the year ended December 31,	
	2015	2014
Cash flows used in operating activities	$(12,080,120)	$(14,455,187)
Cash flows used in investing activities	(10,276,623)	(1,786,744)
Cash flows provided by financing activities	24,935,624	10,590,030
Effect of exchange rate change on cash and cash equivalents	235,574	(1,292,595)
Increase (decrease) in cash and cash equivalents	2,814,455	(6,944,496)
Cash and cash equivalents at beginning of period	3,103,969	10,048,466
Cash and cash equivalents at end of period	$5,918,424	$3,103,969