

CLEVELAND BIOLABS INC
Form 10-Q
May 12, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2014

OR

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

For the transition period from _____ to _____

Commission file number 001-32954

CLEVELAND BIOLABS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE (State or other jurisdiction of	20-0077155 (I.R.S. Employer
incorporation or organization)	Identification No.)
73 High Street, Buffalo, New York (Address of principal executive offices)	14203 (Zip Code)
(Registrant's telephone number, including area code) (716) 849-6810	
(Former name, former address and former fiscal year, if changed since last report)	

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of April 30, 2014, there were 50,942,798 shares outstanding of registrant's common stock, par value \$0.005 per share.

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CLEVELAND BIOLABS INC. AND SUBSIDIARIES

10-Q

May [TBD], 2014

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In this report, except as otherwise stated or the context otherwise requires, the terms "Cleveland BioLabs" and "CBLI" refer to Cleveland BioLabs, Inc., but not its consolidated subsidiaries and the Company, "we," "us" and "our" refer to Cleveland BioLabs, Inc. together with its consolidated subsidiaries. Our common stock, par value \$0.005 per share, is referred to as "common stock."

Table of Contents**CLEVELAND BIOLABS, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS**

	March 31, 2014 (unaudited)	December 31, 2013
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 AND 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 notes payable	892,828	351,527
Current portion of capital lease obligation	71,350	83,634
Total current liabilities	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:		
Preferred stock, \$.005 par value; 10,000,000 shares authorized, 0 shares issued and outstanding as of March 31, 2014 and December 31, 2013, respectively		
Common stock, \$.005 par value; 160,000,000 shares authorized, 50,942,798 and 45,182,114 shares issued and outstanding as of March 31, 2014 and December 31, 2013, respectively	254,714	225,911
Additional paid-in capital	130,080,558	125,508,471
Accumulated other comprehensive income	117,324	307,339
Accumulated deficit	(137,150,038)	(135,564,666)

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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

See Notes to Consolidated Financial Statements

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

	For the Three Months 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

See Notes to Consolidated Financial Statements

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

	For the Three Months Ended March 31,	
	2014	2013
Net loss including noncontrolling interests	\$ (1,901,197)	\$ (10,787,148)
Other comprehensive loss		
Foreign currency translation adjustment	(291,466)	(157,447)
Comprehensive loss including noncontrolling interests	(2,192,663)	(10,944,595)
Comprehensive loss attributable to noncontrolling interests	417,276	1,088,080
Comprehensive loss attributable to Cleveland BioLabs, Inc.	\$ (1,775,387)	\$ (9,856,515)

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY
(UNAUDITED)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Noncontrolling Interests	Total
	Shares	Amount					
Balance at December 31, 2013	45,182,114	\$ 225,911	\$ 125,508,471	\$ 307,339	\$ (135,564,666)	\$ 11,103,923	\$ 1,580,978
Stock based compensation			342,240				342,240
Issuance of shares for compensation	22,978	115	15,510				15,625
Issuance of common stock, net of offering costs of \$540,382	5,737,706	28,688	6,430,930				6,459,618
Allocation of equity proceeds to fair value of warrants			(2,216,593)				(2,216,593)
Net loss					(1,585,372)	(315,825)	(1,901,197)
Foreign currency translation				(190,015)		(101,451)	(291,466)
Balance at March 31, 2014	50,942,798	\$ 254,714	\$ 130,080,558	\$ 117,324	\$ (137,150,038)	\$ 10,686,647	\$ 3,989,205

See Notes to Consolidated Financial Statements

Table of Contents**CLEVELAND BIOLABS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS****(UNAUDITED)**

	For the Three Months Ended March 31,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$ (1,901,197)	\$ (10,787,148)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	57,811	94,927
Amortization	91,929	
Loss on equipment disposal	24,685	
Noncash compensation	48,416	635,005
Warrant issuance costs	171,116	
Change in value of warrant liability	(2,087,558)	3,447,723
Changes in operating assets and liabilities:		
Accounts receivable	41,901	(435,284)
Other current assets	(54,818)	(74,125)
Other long-term assets	9,847	(22,619)
Accounts payable	(273,086)	(286,377)
Deferred revenue	108,127	(219,280)
Accrued expenses	929,518	643,876
Net cash used in operating activities	(2,833,309)	(7,003,302)
Cash flows from investing activities:		
Sale of short-term investments		1,315,175
Purchase of equipment	(10,805)	(20,054)
Net cash provided by (used in) investing activities	(10,805)	1,295,121
Cash flows from financing activities:		
Issuance of common stock, net of offering costs	6,355,001	
Repayment of capital lease obligation	(19,806)	(16,974)
Net cash 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
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	\$ 159,780	\$ 5,861
Supplemental schedule of noncash financing activities:		

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Noncash financing costs on common stock offering	\$	50,505	\$
Noncash warrant issuance costs	\$	15,993	\$

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Description of Business

Cleveland BioLabs, Inc., or CBLI, or the Company, is an innovative biopharmaceutical company seeking to develop first-in-class pharmaceuticals designed to address diseases with significant unmet medical need. Our lead product candidates are Entolimod, which we are developing as a radiation countermeasure and an oncology drug and Curaxin CBL0137, our lead oncology product candidate. We conduct business in the United States and in the Russian Federation through several legal entities, some of which are majority-owned in collaboration with financial partners.

CBLI was incorporated in Delaware in June 2003 and is headquartered in Buffalo, New York. CBLI has one wholly-owned operating subsidiary, BioLab 612, LLC, or BioLab 612, which began operations in 2012. CBLI has two majority-owned operating subsidiaries, Incuron, LLC, or Incuron, and Panacela Labs, Inc., or Panacela, which were formed in 2010 and 2011, respectively. Additionally, Panacela has a wholly-owned operating subsidiary, Panacela Labs, LLC.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements include the accounts of CBLI and its subsidiaries, BioLab 612, Incuron and Panacela. All significant intercompany balances and transactions have been eliminated in consolidation.

The unaudited consolidated financial statements included herein have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP, for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission, or the SEC. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2013, as filed with the SEC.

In the opinion of the Company's management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of March 31, 2014, along with its results of operations for the three month periods ended March 31, 2014 and 2013 and cash flows for the three month periods ended March 31, 2014 and 2013. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Recent Accounting Pronouncements

In March 2013, the FASB issued ASU No. 2013-05, Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity. ASU 2013-05 addresses the accounting for the cumulative translation adjustment when a parent either sells a part or all of its investment in a foreign entity or no longer holds a controlling financial interest in a subsidiary

or group of assets that is a nonprofit activity or a business within a foreign entity. ASU 2013-05 is effective prospectively for fiscal years and interim periods within those fiscal years beginning after December 15, 2013 and early adoption is permitted. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Of the \$13.4 million and \$10.0 million of cash and cash equivalents at March 31, 2014 and December 31, 2013, respectively, \$0.0 million and \$3.5 million, respectively, consisted of highly liquid investments with maturities of 90 days or less when purchased. These investments consist of commercial paper, short-term debt securities, time deposits and investments in money market funds with commercial banks and financial institutions. As of March 31, 2014, \$1.4 million of the Company's cash and cash equivalents was restricted to the use of its majority-owned subsidiaries, leaving \$12.0 million available for general use.

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Short-Term Investments

The Company's short-term investments are classified as held to maturity given the intent and ability to hold the investments to maturity. Accordingly, these investments are carried at amortized cost. Short-term investments classified as held-to-maturity consisted of certificates of deposit with maturity dates beyond three months and less than one year. As of March 31, 2014, all of the Company's short-term investments were restricted to use by its majority-owned subsidiaries.

Significant Customers and Accounts Receivable

Grant and contract revenue from the U.S. government accounted for 1.8% and 31.5% of total revenue for the three months ended March 31, 2014 and 2013, respectively. Grant and contract revenue received by the Company's subsidiaries from Russian government agencies accounted for 98.2% and 68.5% of total consolidated revenues for the three months ended March 31, 2014 and 2013, respectively. Although the Company anticipates ongoing U.S. and Russian government contract and grant revenue, there is no guarantee that these revenue streams will continue in the future.

Accounts receivable consist of amounts due under reimbursement contracts with certain government and foreign entities. The Company extends unsecured credit to customers under normal trade agreements, which generally require payment within 30 days.

Management estimates an allowance for doubtful accounts that is based upon management's review of delinquent accounts and an assessment of the Company's historical evidence of collections. There were no allowances for doubtful accounts as of March 31, 2014 and December 31, 2013, as the collection history from the Company's customers indicated that collection was probable.

Intellectual Property

Costs related to filing and pursuing patent applications are recognized as general and administrative expenses, or G&A expenses, as incurred, since the recoverability of such expenditures is uncertain. Upon marketing approval by the U.S. Food and Drug Administration, or FDA, or a respective foreign governing body, such costs will be capitalized and depreciated over the expected life of the related patent.

Accounting for Stock-Based Compensation

The 2006 Equity Incentive Plan, as amended, or the Plan, authorizes CBLI to grant (i) options to purchase common stock, (ii) restricted or unrestricted stock units, and (iii) stock appreciation rights, so long as the exercise or grant price of each are at least equal to the fair market value of the stock on the date of grant. As of March 31, 2014, an aggregate of 10.0 million shares of common stock were authorized for issuance under the Plan, of which a total of approximately 1.5 million shares of common stock remained available for future awards. A single participant cannot be awarded more than 400,000 shares annually. Awards granted under the Plan have a contractual life of no more than 10 years. The terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Plan are specified in an award document, and approved by the Company's compensation committee.

In June 2013, the Company's stockholders approved the 2013 Employee Stock Purchase Plan, or ESPP, which provides a means by which eligible employees of the Company and certain designated related corporations may be given an opportunity to purchase shares of Common Stock. As of March 31, 2014, there are 2.3 million shares of Common Stock reserved for purchase under the ESPP. The number of shares reserved for purchase under the ESPP

increases on January 1 of each calendar year by the lesser of (i) 10% of the total number of shares of Common Stock outstanding on December 31st of the preceding year, or (ii) 200,000 shares of Common Stock. The ESPP allows employees to use up to 15% of their compensation to purchase shares of Common Stock at an amount equal to 85% of the fair market value of the Company's Common Stock on the offering date or the purchase date, whichever is less.

The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted where the vesting period is based on length of service or performance, while a Monte Carlo simulation model is used for estimating the fair value of stock options with market-based vesting conditions. Set forth below are the assumptions used in valuing the stock options granted and a discussion of the Company's methodology for developing each of the assumptions used:

For the three months ended March 31,