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)

x **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	**20-0077155**
(State or other jurisdiction of	**(I.R.S. Employer**
incorporation or organization)	**Identification No.)**
73 High Street, Buffalo, New York	**14203**
(Address of principal executive offices)	**(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 x 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 x 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 x
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 x

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

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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.

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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)

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)

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY

(UNAUDITED)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income	Accumulated	Noncontrolling	
	Shares	Amount	Capital	(Loss)	Deficit	Interests	Total
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

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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:		

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,	
	2014	**2013**
Risk-free interest rate	1.59%	.93 - 1.00%
Expected dividend yield	0%	0%
Expected life	5 Years	5 - 6 Years
Expected volatility	74.21%	88.54 - 89.60%

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Risk-free interest rate means the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date the option is granted.

Expected dividend yield means the Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.

Expected life means the period of time that options granted are expected to remain outstanding, based wholly on the use of the simplified (safe harbor) method. The simplified method is used because the Company does not yet have adequate historical exercise information to estimate the expected life the options granted.

Expected volatility means a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (implied volatility) during a period. Expected volatility is based on the Company s historical volatility and incorporates the volatility of the common stock of comparable companies when the expected life of the option exceeds the Company s trading history.

Income Taxes

No income tax expense was recorded for the three months ended March 31, 2014 and 2013, as the Company does not expect to have taxable income for 2014 and did not have taxable income in 2013. A full valuation allowance has been recorded against the Company s deferred tax asset.

Earnings (Loss) per Share

Basic net income (loss) per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net income (loss) by the weighted average number of shares outstanding for the period. Diluted net income (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Diluted net loss per share is identical to basic net loss per share as potentially dilutive securities have been excluded from the calculation of diluted net loss per common share because the inclusion of such securities would be antidilutive.

The Company has excluded the following outstanding warrants and options from the calculation of diluted net loss per share because all such securities were antidilutive for the periods presented:

	As of March 31,	
Common Equivalent Securities	**2014**	**2013**
Warrants	16,444,083	10,377,995
Options	6,124,655	4,966,753
Total	22,568,738	15,344,748

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues for liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. For all periods presented, the Company is not a party to any pending material litigation that is estimable and probable of loss.

3. Fair Value of Financial Instruments

The Company measures and records warrant liabilities at fair value in the accompanying financial statements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value, includes:

Level 1 Observable inputs for identical assets or liabilities such as quoted prices in active markets;

Level 2 Inputs other than quoted prices in active markets that are either directly or indirectly observable; and

Level 3 Unobservable inputs in which little or no market data exists, which are therefore developed by the Company using estimates and assumptions that reflect those that a market participant would use.

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The following tables represent the Company s fair value hierarchy for its financial liabilities measured at fair value on a recurring basis as of March 31, 2014 and December 31, 2013:

	As of March 31, 2014			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Accrued warrant liability	$	$	$ 1,436,845	$ 1,436,845
Total liabilities	$	$	$ 1,436,845	$ 1,436,845

	As of December 31, 2013			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Accrued warrant liability	$	$	$ 1,241,311	$ 1,241,311
Compensatory stock options not yet issued			309,450	309,450
Total liabilities	$	$	$ 1,550,761	$ 1,550,761

The Company uses the Black-Scholes model to measure the accrued warrant liability and its accrual for compensatory stock options not yet issued. The following are the assumptions used to measure the accrued warrant liability at March 31, 2014 and December 31, 2013, which were determined in a manner consistent with that described for grants of options to purchase common stock as set forth in Note 2:

	March 31, 2014	December 31, 2013
Stock Price	$0.68	$1.17
Exercise Price	$1.22 - 5.00	$1.60 - 5.00
Term in years	0.46 - 4.80	0.59 - 1.91
Volatility	61.06 - 78.53%	42.52 - 76.03%
Annual rate of quarterly dividends	0%	0%
Discount rate- bond equivalent yield	.06 - 1.64%	.08 - .36%

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The following table sets forth a summary of changes in the fair value of the Company s Level 3 fair value measurements for the three months ended March 31, 2014 and 2013:

	Accrued Warrant Liability	Compensatory Stock Options Not Yet Issued
Balance, December 31, 2013	$ 1,241,311	$ 309,450
Issuances	2,283,092	
Total (gains) or losses, realized and unrealized, included in earnings (1)(2)	(2,087,558)	(21,055)
Settlements		(288,395)
Balance, March 31, 2014	$ 1,436,845	$
Balance, December 31, 2012	$ 4,105,659	$
Total (gains) or losses, realized and unrealized, included in earnings (1)	3,447,723	
Estimates and other changes in fair value		63,641
Balance, March 31, 2013	$ 7,553,382	$ 63,641

(1) Unrealized gains or losses related to the accrued warrant liability were included as change in value of accrued warrant liability. There were no realized gains or losses for the three months ended March 31, 2014 and 2013.
(2) Expenses recorded for compensatory stock options not yet issued are included in research and development expense and general and administrative expense.

As of March 31, 2014 and December 31, 2013, the Company had no assets or liabilities that were measured at fair value on a nonrecurring basis.

The Company considers the accrued warrant liability and compensatory stock options not yet issued to be Level 3 because some of the inputs into the measurements are neither directly or indirectly observable. Both the accrued warrant liability and compensatory stock options not yet issued use management s estimate for the expected term, which is based on the safe harbor method as historical exercise information over the term of each security is not readily available. Additionally, the number of compensatory options awarded involves an estimate of management s performance in relation to the targets set forth in the Company s Executive Compensation Plan. The following table summarizes the unobservable inputs into the fair value measurement for the accrued warrant liability as of March 31, 2014:

		March 31, 2014		
Description	**Fair Value**	**Valuation Technique**	**Unobservable Input**	**Range**
	$ 1,436,845	Black-scholes pricing model	Expected term - Years	0.46 - 4.80

Accrued warrant liability	

Management believes the value of both the accrued warrant liability and compensatory stock options is more sensitive to a change in the Company s stock price at the end of the respective reporting period as opposed to a change in one of the unobservable inputs described above.

The carrying amounts of the Company s short-term financial instruments, which include cash and cash equivalents, short-term investments, accounts receivable and accounts payable, approximate their fair values due to their short maturities.

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4. Stockholders Equity

On January 16, 2014, the Company completed a public offering of 5,737,706 shares of the Company s common stock at a price of $1.22 per share, resulting in net proceeds of approximately $6.4 million after deducting for placement agent fees and offering expenses. In connection with the offering, the Company issued Series A warrants for 2,868,853 shares of common stock and Series B warrants for 2,868,853 shares of common stock to the purchasers. Each Series A warrant has an exercise price of $1.22 per share, and will become exercisable six months following the date of issuance and expire five years from the date of issuance. Each Series B warrant has an exercise price of $1.22 per share, and will become exercisable six months following the date of issuance and expire 18 months from the date of issuance. In addition to the warrants issued to the purchasers, the Company also issued Series A warrants for an aggregate of 86,066 shares of common stock and Series B warrants for an aggregate of 86,066 shares of common stock to the placement agent as compensation for completing the offering. The warrants to the placement agent have the same terms, including exercise price, as the warrants issued to investors. The offering also triggered a reduction in the exercise price of 4,421,195 of the Company s warrants from $1.66 to $1.22.

The Series A and B warrants contain provisions that could require the Company to settle the warrants in cash, and accordingly, have been classified as a liability. The fair value of the Series A and B warrants amounted to $2,283,092 and was determined based on the following assumptions using the Black-Scholes valuation model:

	March 31, 2014
Stock Price	$1.23
Exercise Price	$1.22
Term in years	0.75 - 2.50
Volatility	43.06 - 79.86%
Annual rate of quarterly dividends	0%
Discount rate- bond equivalent yield	.09 - .58%

The Company has granted options to purchase shares of common stock. The following is a summary of option award activity during the three months ended March 31, 2014:

	Quarter Ended March 31, 2014			
	Total Stock Options Outstanding	Weighted Average Exercise Price per Share	Nonvested Stock Options	Weighted Average Grant Date Fair Value per Share
December 31, 2013	5,564,833	$ 4.14	594,479	$ 1.50
Granted	696,000	0.68		
Vested			(36,250)	4.82
Exercised				
Forfeited, Canceled	(136,178)	2.27	(86,250)	1.43
March 31, 2014	6,124,655	$ 3.79	471,979	$ 1.26

The following is a summary of outstanding stock options as of March 31, 2014:

	As of March 31, 2014	
	Stock Options Outstanding	Vested Stock Options
Quantity	6,124,655	5,652,676
Weighted-average exercise price	$ 3.79	$ 3.97
Weighted Average Remaining Contractual Term (in Years)	6.84	6.66
Intrinsic value	$ 232	$ 232

For the three months ended March 31, 2014 and 2013, the Company granted 696,000 and 60,000 stock options, respectively, with a weighted-average grant date fair value of $0.41 and $1.14, respectively. For the three months ended March 31, 2014 and 2013, the total fair value of options vested was $174,658 and $286,809, respectively.

As of March 31, 2014, total compensation cost not yet recognized related to unvested stock options was $271,586. The Company expects to recognize this cost over a weighted average period of approximately 1.05 years.

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5. Warrants

In connection with sales of the Company s common stock and the issuance of debt instruments, warrants were issued with exercise prices ranging from $1.22 to $5.00. The warrants expire between one and seven years from the date of grant, subject to the terms applicable in the agreement. As of March 31, 2014, the Company had warrants outstanding that are exercisable into 16,444,083 shares of common stock, with a weighted average exercise price of $2.07 per share.

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

This management s discussion and analysis of financial condition and results of operations and other portions of this filing contain forward-looking information that involves risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as anticipates, believes, could, estimates, expects, intends, may, plans, potential, predicts, projects, should, will, would and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, and because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not transpire. We discuss many of these risks in Item 1A under the heading Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2013 and in subsequent filings, including in Item 1A under the heading Risk Factors in this Quarterly Report on Form 10-Q. Factors that may cause such differences include, but are not limited to, availability and cost of financial resources, results of our research and development efforts and clinical trials, product demand, market acceptance and other factors discussed below and in our other SEC filings, including our Annual Report on Form 10-K for the year ended December 31, 2013. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this document. You should read this document with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we do not undertake any obligation to publicly update or revise any forward-looking statements contained in this report, whether as a result of new information, future events or otherwise. This management s discussion and analysis of financial condition and results of operations should be read in conjunction with our financial statements and the related notes included elsewhere in this filing and in our Annual Report on Form 10-K for the year ended December 31, 2013.

OVERVIEW

We are an innovative biopharmaceutical company seeking to develop first-in-class pharmaceuticals designed to address diseases with significant unmet medical need. Our programs are focused on the implementation of novel pharmacological approaches to control cell death. Our proprietary drug candidates act via unique mechanisms and targets to kill cancer and protect healthy cells. 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 also have an additional clinical stage program and multiple innovative projects in different stages of preclinical drug development.

See Part I, Item 1. Business in our Annual Report on Form 10-K for the year ended December 31, 2013, for more information on our product candidates.

Critical Accounting Policies and Significant Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of

America, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect our reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, income taxes, stock-based compensation, investments and in-process research and development. We based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates.

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2013. Other than as set forth below, our critical accounting policies and significant estimates have not changed substantially from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013.

Fair Value of Financial Instruments

We use the Black-Scholes model to determine the fair value of certain common stock warrants and stock options not yet issued on

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a recurring basis, and classify such warrants and options as Level 3 in the fair value hierarchy. The Black-Scholes model utilizes inputs consisting of: (i) the closing price of our common stock; (ii) the expected remaining life; (iii) the expected volatility using a weighted average of historical volatilities of CBLI and a group of comparable companies; and (iv) the risk-free market rate.

As of March 31, 2014, we held approximately $1.2 million in accrued expenses primarily related to warrants to purchase common stock, which we classified as Level 3.

Three Months Ended March 31, 2014 Compared to Three Months Ended March 31, 2013

Revenue

Revenue decreased from $1.4 million for the three months ended March 31, 2013 to $1.3 million for the three months ended March 31, 2014, representing a decrease of $0.1 million, or 7%. We have received revenues from the U.S. Department of Defense, or DoD; the Ministry of Industry and Trade of the Russian Federation, or MPT; and the Skolkovo Foundation, or Skolkovo. The revenues related to our contracts and grants and differences between the periods are set forth in the following table:

		Three Months Ended March 31,		
Funding Source	**Program**	**2014**	**2013**	**Variance**
DoD	MCS Contract	$ 23,390	$ 335,722	$ (312,332)
MPT	CBLB612 Pre-clinical (1)	180,211	258,163	(77,952)
MPT	CBLB502 Colorectal Cancer (1)	37,186		37,186
DoD	DTRA Contract		94,384	(94,384)
		240,787	688,269	(447,482)
Skolkovo	Curaxin research (1)	612,659	504,070	108,589
MPT	Xenomycins Pre-clinical (1)	28,605	175,133	(146,528)
MPT	Mobilan Pre-clinical (1)	452,203		452,203
		$ 1,334,254	$ 1,367,472	$ (33,218)

(1) The grants received from Russian government entities are denominated in Russian Rubles (RUB). The revenue above was calculated using average exchange rates for the periods presented.

We anticipate our revenue over the next year will continue to be derived mainly from government grants and contracts. We plan to submit or have submitted proposals for government grants and contracts to funding sources that have awarded us grants and contracts in the past, but there can be no assurance that we will receive future funding awards. The following table sets forth information regarding our currently active grants and contracts:

		As of March 31, 2014
Funding Source	**Program**	

		Total Award Value	Funded Award Value	Cumulative Revenue Recognized	Funded Backlog	Unfunded Backlog
MPT	CBLB612 Pre-clinical (1)	$ 4,132,272	$ 2,893,729	$ 2,134,351	$ 759,378	$ 1,238,543
MPT	Entolimod Colorectal Cancer (1)	4,282,603	3,167,354	974,685	2,192,669	1,115,249
		8,414,875	6,061,083	3,109,036	2,952,047	2,353,792
Skolkovo	Curaxin research (1)	4,630,842	4,630,842	4,250,204	380,638	
MPT	Xenomycins Pre-clinical (1)	4,360,048	3,281,227	2,188,395	1,092,832	1,078,821
MPT	Mobilan Pre-clinical (1)	4,291,070	3,175,821	1,389,702	1,786,119	1,115,249
		$ 21,696,835	$ 17,148,973	$ 10,937,337	$ 6,211,636	$ 4,547,862

(1) The contracts received from Russian government entities are denominated in Russian Rubles (RUB). The contract value above is calculated based on the cumulative revenue recognized to date plus our backlog valued at the March 31, 2014 exchange rate.

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Research and Development Expenses

Research and development, or R&D, expenses decreased from $5.3 million for the three months ended March 31, 2013 to $2.4 million for the three months ended March 31, 2014, representing a decrease of $2.9 million, or 55%. Approximately half, or $1.5 million, of this net decrease related to reduced payments to third-party vendors, spread relatively evenly between Entolimod as a radiation countermeasure, Curaxin compounds and Panacela compounds. $1.2 million relates to reduced compensation costs primarily attributable to reduced headcount associated with our transfer of personnel to Buffalo BioLabs, Inc. in the fourth quarter of 2013. Of the $1.2 million in reduced compensation costs, $1.0 million relates to cash compensation costs and $0.2 million relates to non-cash compensation costs. And, $0.2 million relates to reduced facilities and travel costs. The following table sets forth our R&D expenses by drug candidate:

	Three Months Ended March 31,		
	2014	2013	Variance
Entolimod for Biodefense Applications	$ 882,107	$ 2,315,129	$ (1,433,022)
CBLB612	135,719	214,441	(78,722)
Entolimod for Oncology Indications	197,675	210,687	(13,012)
	1,215,501	2,740,257	(1,524,756)
Curaxins	641,209	1,464,899	(823,690)
Panacela product candidates	583,063	1,126,459	(543,396)
Total research & development expenses	$ 2,439,773	$ 5,331,615	$ (2,891,842)

General and Administrative Expenses

General and administrative, or G&A, costs decreased from $3.5 million for the three months ended March 31, 2013 to $2.4 million for the three months ended March 31, 2014, representing a decrease of $1.1 million, or 31%. This net decrease was primarily due to a reduction of personnel, representing a reduction in compensation expense of $0.7 million. Of the $0.7 million in reduced compensation expense, $0.4 million relates to cash compensation costs and $0.3 million relates to non-cash compensation costs. Additionally, we realized reductions of $0.2 million each for business development and professional fees.

Other Income and Expenses

Other income (expense) increased from $3.3 million of other net expense for the three months ended March 31, 2013 to $1.6 million of other net income for the three months ended March 31, 2014, representing an income increase of $5.0 million, or 149%. $5.5 million of this net increase in income was primarily attributable to changes in the value of our warrant liability, offset by $0.3 million in interest expense associated with loans entered into in the later part of 2013 and $0.2 million in additional foreign exchange losses.

Liquidity and Capital Resources

We have incurred net losses of $137.2 million since inception through March 31, 2014. Historically, we have not generated, and do not expect to generate in the immediate future, revenue from sales of product candidates. Since our founding in 2003, we have funded our operations through a variety of means:

Through March 31, 2014, we have raised $114.2 million of net equity capital, including amounts received from the exercise of options and warrants. We have also received $5.8 million in net proceeds from the issuance of long-term debt instruments;

DoD and the Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services, or BARDA have funded grants and contracts totaling $44.6 million for the development of Entolimod as a radiation countermeasure;

Entities affiliated with the Russian Federation have awarded us contracts totaling $21.7 million, through a series of awards of over $4.0 million each. All awards are valued based on revenue recognized to date, with the remaining backlog valued at the March 31, 2014 exchange rate. These contracts include a requirement for us to contribute matching funds, which are satisfied with both the value of developed intellectual property at the time of award, incurred development expenses and future expenses. At March 31, 2014, $17.1 million of the awards were funded; $11.9 million was received, of which $1.1 million remains as deferred revenue. We expect to recognize the remaining funding in 2014 and 2015;

We have been awarded $4.0 million in grant and contracts not described above, all of which has been recognized at March 31, 2014;

We actively pursue all reasonable domestic and international sources of grant and contract funding for our drug pipeline;

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Incuron was formed to develop and commercialize our Curaxin product line, namely two compounds CBL0102 and CBL0137. BioProcess Capital Partners, or BCP, committed to contribute up to $16.8 million (based on the current dollar-ruble exchange rate) of funding as development milestones were accomplished. To date, Incuron has received $11.7 million of funding from BCP. BCP s remaining capital contribution of $5.1 million is due upon completion of certain developmental milestones, which the Company believes will occur in 2014; and

Panacela was formed to develop and commercialize five preclinical compounds. Open Joint Stock Company Rusnano contributed $9.0 million at formation and has options to contribute up to $17.0 million of additional funding. CBLI contributed $3.0 million plus intellectual property at formation and has an option to contribute additional capital based on agreed-upon terms.

At March 31, 2014, we had cash, cash equivalents and short-term investments of $13.7 million. Of that total, $1.7 million was restricted for the use of our majority-owned subsidiaries, leaving $12.0 million available for general use. Furthermore, Panacela and Biolab 612 had $2.7 million of restricted cash held for performance bonds in connection with their respective MPT grants, which are classified as long-term assets.

Operating Activities

Net cash used in operations decreased by $4.2 million to $2.8 million for the three months ended March 31, 2014 from $7.0 million for the three months ended March 31, 2013. After adjusting for non-cash items, the net loss decreased by $3.0 million, while changes in working capital provided cash and cash equivalents of $1.2 million between the periods.

Investing Activities

Net cash provided by investing activities was $0.0 million for the three months ended March 31, 2014, compared to net cash provided by investing activities of $1.3 million for the three months ended March 31, 2013, representing a decrease of $1.3 million between the periods. This net decrease was due to a decrease of $1.3 million related to the management of our cash and short-term investments.

Financing Activities

Cash flows provided by financing activities increased by $6.4 million for the three months ended March 31, 2014 as compared to the three months ended March 31, 2013. Cash flows provided by financing activities was $6.4 million for the three months ended March 31, 2014, wholly attributable to the net proceeds from CBLI s closing of an equity investment in January 2014.

Other

We have incurred cumulative net losses and expect to incur additional losses related to our research and development activities. We do not have commercial products and have limited capital resources. We will need additional funds to complete the development of our products. Our plans with regard to these matters may include seeking additional capital through a combination of government contracts, collaborative agreements, strategic alliances, research grants and future equity and debt financing. Although we continue to pursue these plans, there is no assurance that we will be successful in obtaining future financing on commercially reasonable terms or that we will be able to secure funding from anticipated government contracts and grants.

We believe that our existing funds combined with cash flows from existing government grants and contracts will be sufficient to fund our projected operating requirements into the first quarter of 2015, based upon current operating plans and spending assumptions, limited to existing contracts in place. The success of our company is dependent upon commercializing our research and development programs and our ability to obtain adequate future financing. There can be no assurance that we will be able to obtain future financing or, if obtained, what the terms of such future financing may be, or that any amount that we are able to obtain will be adequate to support our working capital requirements until we achieve profitable operations. If we are unable to raise adequate capital and/or achieve profitable operations, future operations might need to be scaled back or discontinued. The financial statements do not include any adjustments relating to the recoverability of the carrying amount of recorded assets and liabilities that might result from the outcome of these uncertainties.

Impact of Inflation

We believe that our results of operations are not dependent upon moderate changes in inflation rates.

Impact of Exchange Rate Fluctuations

From time-to-time, our operations are somewhat dependent upon changes in foreign currency exchange rates, however at March 31, 2014, our foreign currency obligations were not material.

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Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There has been no significant change in our exposure to market risk during the first three months of 2014. For a discussion of our exposure to market risk, refer to Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk, contained in our Annual Report on Form 10-K for the year ended December 31, 2013.

Item 4. Controls and Procedures

Effectiveness of Disclosure

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act as of March 31, 2014. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2014, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective to assure that information required to be declared by us in reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the periods specified in the SEC s rules and forms and (2) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) during the fiscal quarter ended March 31, 2014, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II Other Information

Item 1. Legal Proceedings

On February 20, 2014, Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd., two purchasers in the January 2014 sale of securities, brought suit in the U.S. District Court for the Southern District of New York against the Company in an action captioned Sabby Healthcare Volatility Master Fund, Ltd. v. Cleveland BioLabs, Inc., No. 14-cv-1055 (S.D.N.Y.). The plaintiffs allege that the Company misrepresented the state of its funding negotiations with BARDA during the period leading up to the sale of securities in January 2014, and as a result, the plaintiffs were harmed when the Company s stock price declined following the announcement that BARDA had terminated negotiations with the Company. The complaint asserts claims under Section 10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, as well as claims for fraudulent inducement, breach of contract, and indemnification. The plaintiffs seek $2 million, plus interest, attorney s fees, and litigation costs.

Item 1A. Risk Factors

We have marked with an asterisk those risk factors that reflect material changes from the risk factors previously discussed in our Form 10-K for the year ended December 31, 2013.

RISKS RELATED TO OUR FINANCIAL CONDITION AND NEED FOR ADDITIONAL CAPITAL

***We will require substantial additional financing in order to meet our business objectives.**

Since our inception, most of our resources have been dedicated to the pre-clinical and clinical development of our product candidates. In particular, we are currently conducting multiple clinical trials of our product candidates, each of which will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future developing our pre-clinical and clinical product candidates. These expenditures will include costs associated with research and development, conducting pre-clinical and clinical trials, obtaining regulatory approvals and products from third-party manufacturers, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts of capital necessary to successfully complete the development and commercialization of our product candidates.

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As of March 31, 2014, our cash, cash equivalents and short-term investments amounted to $13.7 million. We believe that our existing cash, cash equivalents, and marketable securities will allow us to fund our operating plan into the first quarter of 2015.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amounts of our total capital requirements. Our future capital requirements depend on many factors, including:

- the number and characteristics of the product candidates we pursue;