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;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting pre-clinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities for any of our product candidates that are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates and any products we successfully commercialize;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- whether we realize the full amount of any projected cost savings associated with our strategic restructuring;
- the occurrence of a breach or event of default under our loan agreement with Hercules or under any other agreements with third parties;
- the success of any pre-EUA submission we make with the FDA; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

In addition, it is possible that Hercules Technology II, L.P., or Hercules, could take the position that the decision of BARDA, to terminate negotiations of our proposal constitutes a material adverse effect under our loan and security

agreement with Hercules, under which we had $6.6 million in liability as of March 31, 2014, including a $550,000 end of term charge on the loan. Such determination by Hercules could trigger a repayment of all principal and interest due under the loan, as well as the prepayment charge under the loan, unless Hercules waives such event of default.

If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, or if we identify additional opportunities to do so, we may seek to sell additional equity or debt securities or obtain additional credit facilities. The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock or through additional credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of our common stock and could contain covenants that would restrict our operations. Furthermore, any funds raised through collaboration and licensing arrangements with third parties may require us to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. In any such event, our business prospects, financial condition and results of operations could be materially adversely affected.

We may require additional capital beyond our currently forecasted amounts and additional funds may not be available when we need them, on terms that are acceptable to us, or at all. In particular, the decline in the market price of our common stock could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. In addition, the variable rate clauses associated in many of our stock purchase agreements that prohibit certain types of capital raising activities for certain periods of time and pledge of assets in our loan and security agreement with Hercules may inhibit our ability to attract future investors and/or lenders. Additionally, our corporate structure, including the ownership of several of our product candidates in our non-wholly owned subsidiaries, may deter third parties from entering into collaboration and licensing arrangements with us. If we fail to raise sufficient additional financing, on terms and dates acceptable to us, we may not be able to continue our operations and the development of our product candidates, and may be required to reduce staff, reduce or eliminate research and development, slow the development of our product candidates, outsource or eliminate several business functions or shut down operations.

***We have a history of operating losses. We expect to continue to incur losses and may not continue as a going concern.**

We have incurred net losses of approximately $1.6 million and $137.2 million for the three months ended March 31, 2014 and since inception, respectively. We expect significant losses to continue for the next few years as we spend substantial sums on the continued research and development of our proprietary product candidates, and there is no certainty that we will ever become profitable as a result of these expenditures. As a result of losses that will continue throughout our development stage, we may exhaust our financial resources and be unable to complete the development of our product candidates.

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Our ability to become profitable depends primarily on the following factors:

- our ability to obtain adequate sources of continued financing;
- our ability to obtain approval for, and if approved, to successfully commercialize our product candidates;
- our ability to successfully enter into license, development or other partnership agreements with third-parties for the development and/or commercialization of one or more of our product candidates;
- our R&D efforts, including the timing and cost of clinical trials; and
- our ability to enter into favorable alliances with third-parties who can provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales, marketing and distribution.

Even if we successfully develop and market our product candidates, we may not generate sufficient or sustainable revenue to achieve or sustain profitability.

***We may be unable to service our existing debt due to lack of cash flow, which could lead to default.**

In September 2013, we entered into a loan and security agreement with Hercules Technology II, L.P., or Hercules, under which we borrowed $6.0 million. The current interest rate is 10.45%, with the initial 12 months of the facility requiring interest only payments and the following 30 months requiring interest and principal payments. The loan matures on January 1, 2017. Since entering into the agreement with Hercules, we have been making monthly interest-only payments to Hercules of approximately $54,000 per month and plan to continue making such payments until November 2014 when our payments will increase to approximately $228,000 per month, with a principal and interest payment of approximately $907,000 due in January 2017. As of March 31, 2014, the outstanding principal owed to Hercules was $6.0 million. Additionally, upon termination of the loan, we will also owe Hercules an end-of-term fee of $550,000. We granted Hercules a first priority security interest in substantially all of our assets, with the exception of our intellectual property, where the security interest is limited to proceeds of intellectual property.

If we do not make the required payments when due, either at maturity, or at applicable installment payment dates, or if we breach the agreement, default under the agreement by having a material adverse event happen to the business of the Company or become insolvent, Hercules could elect to declare all amounts outstanding together with all accrued and unpaid interest and penalties, to be immediately due and payable. In order to continue our planned operations and satisfy our debt obligations with Hercules, we will need to raise additional capital in the future. Additional capital may not be available on terms acceptable to us, or at all. Even if we were able to repay the full amount in cash, any such repayment could leave us with little or no working capital for our business. If we are unable to repay these amounts, Hercules will have a first claim on our assets pledged under the loan agreement. If Hercules should attempt to foreclose on the collateral, there may not be any assets remaining for distribution to shareholders after repayment in full of such secured indebtedness. Any default under the loan agreement and resulting foreclosure would have a material adverse effect on our financial condition and our ability to continue our operations.

Additionally, in September 2013, our majority owned subsidiary Panacela entered into a $1.5 million Convertible Loan Agreement with Rusnano, or the Rusnano Loan, and is required to pay all unpaid principal and interest under the loan in September 2015. The loan may be converted into shares of Panacela stock at any time at Rusnano s option or will automatically convert upon certain financing events. In the event Panacela defaults on the loan and such default is not cured, Rusnano shall have the right to exercise a Warrant to purchase shares of Cleveland BioLabs common stock equal to 69.2% of the outstanding amount remaining unpaid under the Rusnano Loan at the time of exercise, divided by the exercise price of $1.694 per share.

Our ability to use our net operating loss carryforwards may be limited.

As of December 31, 2013, we had federal net operating loss carryforwards, or NOLs, of $109.9 million to offset future taxable income, which begin to expire if not utilized by 2023. Under the provisions of the Internal Revenue Code, substantial changes in our ownership, in certain circumstances, will limit the amount of NOLs that can be utilized annually in the future to offset taxable income. In particular, section 382 of the Internal Revenue Code imposed limitations on a company s ability to use NOLs if a company experiences a more than 50% ownership change over a three-year period. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to utilize our NOLs fully. A full valuation allowance has been recorded against our deferred tax assets, including the net operating loss carryforwards, as we believe it is more likely than not we will be unable to realize the benefit of these assets.

RISKS RELATED TO PRODUCT DEVELOPMENT

We may not be able to successfully and timely develop our products.

Our product candidates range from ones currently in the research stage to ones currently in the clinical stage of development and all require further testing to determine their technical and commercial viability. Our success will depend on our ability to achieve scientific, clinical and technological advances and to translate such advances into reliable, commercially competitive products on a timely basis. In addition, the success of our subsidiaries will depend on their ability to meet developmental milestones in a timely manner or to fulfill certain other development requirements under contractual agreements, which are pre-requisites to their

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receipt of additional funding from their non-controlling interest holders or the government agency funding their government contracts. Products that we may develop are not likely to be commercially available for several years. The proposed development schedules for our products may be affected by a variety of factors, including, among others, technological difficulties, proprietary technology of others, the government approval process, the availability of funds and changes in government regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects and the unproven technology involved, we may not be able to complete successfully the development or marketing of any products.

We may fail to develop and commercialize some or all of our products successfully or in a timely manner because:

- pre-clinical study or clinical trial results may show the product to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;

- we fail to receive the necessary regulatory approvals or there is a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or a pre-EUA, NDA or BLA preparation, discussions with the FDA, an FDA request for additional pre-clinical or clinical data or unexpected safety or manufacturing issues;

- they fail to conform to a changing standard of care for the diseases they seek to treat;

- they are less effective or more expensive than current or alternative treatment methods;

- of manufacturing costs, pricing or reimbursement issues, or other factors that make the product not economically feasible; or

- proprietary rights of others and their competing products and technologies may prevent our product from being commercialized.

Our collaborative relationships with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return.

We anticipate substantial reliance upon strategic collaborations for marketing and commercialization of our product candidates and we may rely even more on strategic collaborations for R&D of our product candidates. Our business depends on our ability to sell drugs to both government agencies and to the general pharmaceutical market. Offering Entolimod for its biodefense indication use to government agencies may require us to develop new sales, marketing or distribution capabilities beyond those already existing in the Company and we may not be successful in selling Entolimod for its biodefense indication use in the United States or in foreign countries despite our efforts. Selling oncology drugs will require a more significant infrastructure. We plan to sell oncology drugs through strategic partnerships with pharmaceutical companies. If we are unable to establish or manage such strategic collaborations on

terms favorable to us in the future, our revenue and drug development may be limited. To date, we have not entered into any strategic collaboration with a third party capable of providing these services and we can make no guarantee that we will be able to enter into a strategic collaboration in the future. In addition, we have not yet marketed or sold any of our product candidates or entered into successful collaborations for these services in order to ultimately commercialize our product candidates. We also rely on third-party collaborations with our manufacturers. Manufacturers producing our product candidates must follow current Good Manufacturing Practice, or cGMP, regulations enforced by the FDA and foreign equivalents.

Establishing strategic collaborations is difficult and time-consuming. Our discussion with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our product candidates or the generation of sales revenue. In addition, to the extent that we enter into collaborative arrangements, our drug revenues are likely to be lower than if we directly marketed and sold any drugs that we may develop.

We will not be able to commercialize our product candidates if our pre-clinical development efforts are not successful, our clinical trials do not demonstrate safety or our clinical trials or animal studies do not demonstrate efficacy.

Before obtaining required regulatory approvals for the commercial sale of any of our product candidates, we must conduct extensive pre-clinical testing and clinical trials to demonstrate that our product candidates are safe and clinical or animal trials to demonstrate the efficacy of our product candidates. Pre-clinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful and interim results of a clinical trial or animal efficacy study does not necessarily predict final results. In addition, we must outsource our clinical trials and a majority of our animal studies required to obtain regulatory approval of our products. We are not certain that we will successfully or promptly finalize agreements for the conduct of these studies. Delay in finalizing such agreements would delay the commencement of our pre-clinical and clinical studies, such as animal efficacy studies for Entolimod s biodefense indication and clinical trials of Entolimod, CBL0102 and CBL0137 for oncology indications. In addition, we are seeking FDA agreement on the scope and design of our pivotal animal efficacy and human safety program for Entolimod s biodefense indication. Delay in agreement with the FDA on this program will delay conduct of the pivotal animal efficacy and human safety studies.

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Agreements with contract research organizations, or CROs, and study investigators, for clinical or animal testing and with other third parties for data management services place substantial responsibilities on these parties, which could result in delays in, or termination of, our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with Good Clinical Practices or our pivotal animal studies fail to comply with Good Laboratory Practices we may be unable to use the data generated at those sites. In these studies, if contracted CROs or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or for other reasons, our clinical or animal studies may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for or successfully commercialize our product candidates.

Our clinical trial operations will be subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we or they may receive warning letters or other correspondence detailing deficiencies and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions that we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be the subject of an enforcement action, the government may refuse to approve our marketing applications or allow us to manufacture or market our products or we may be criminally prosecuted.

In addition, a failure of one or more of our clinical trials or animal studies can occur at any stage of testing and such failure could have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations. We may experience numerous unforeseen events during, or as a result of, pre-clinical testing and the clinical trial or animal study process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- Regulators or institutional review boards, or IRB, may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site or an institutional animal care and use committee, or IACUC, may not authorize us to commence an animal study at a prospective study site;

- We may decide, or regulators may require us, to conduct additional pre-clinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our pre-clinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;

- We might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable safety risks;

- Regulators or IRBs may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or if it is believed that the clinical trials present an unacceptable safety risk to the patients enrolled in our clinical trials;

- The cost of our clinical trials or animal studies could escalate and become cost prohibitive;

Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;

We may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials or certain animals used in our animal studies or facilities conducting our studies may not be available at the time that we plan to initiate a study;

The effects of our product candidates may not be the desired effects, may include undesirable side effects, or the product candidates may have other unexpected characteristics; and

Our collaborators that conduct our clinical or pivotal animal studies could go out of business and not be available for FDA inspection when we submit our product for approval.

Even if we or our collaborators complete our animal studies and clinical trials and receive regulatory approval, it is possible that a product may be found to be ineffective or unsafe due to conditions or facts that arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such product from the market. To the extent that our success will depend on any regulatory approvals from government authorities outside of the United States that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist.

***Our majority-owned subsidiaries have significant non-controlling interest holders and, as such, are not operated solely for our benefit.**

As of March 31, 2014, we owned 59.2% of the equity interests in Incuron and 54.6% of the equity interests in Panacela. Additionally, we anticipate that Incuron will receive their last funding tranche from BioProcess Capital Partners in 2014 and that

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following such investment our ownership interest in Incuron will fall below 50% if we do not invest $3 million of additional funds. Although these subsidiaries are currently majority-owned by us and are consolidated in our results, they have significant non-controlling interest holders, each of which are funds regulated by the Russian Federation government. As such, we share ownership and management of our subsidiaries with one or more parties who may not have the same goals, strategies, priorities, or resources as we do.

In each of our majority-owned subsidiaries, both we and our co-owners have certain rights in respect of such subsidiaries. Our majority-owned subsidiaries provide the right to each party to designate certain of the board members and certain decisions in respect of these subsidiaries may not be made without a supermajority vote of the equity holders or the consent of all of the equity holders. The right to transfer ownership interests in our majority-owned subsidiaries is restricted by provisions such as rights of first refusal and tag along and drag along rights. In addition, the use of funds and other matters are subject to monitoring and oversight by both groups of equity holders. Furthermore, we are required to pay more attention to our relationship with our co-owners as well as with the subsidiaries, and if a co-owner changes, our relationship may be materially adversely affected. These various restrictions may lead to additional organizational formalities as well as time-consuming procedures for sharing information and making decisions. In addition, the benefits from a successful joint venture are shared among the co-owners, so that we would not receive all the benefits from our successful joint ventures.

The co-owners of our majority-owned subsidiaries are required to make additional payments to the subsidiaries to finance their operations. Such additional contributions are dependent on the satisfaction of various developmental milestones by our majority-owned subsidiaries, which may not be achieved within set time periods, and if such contributions or investments are not achieved, may result in a material adverse effect in our business, financial condition and results of operations.

If parties on whom we rely to manufacture our product candidates do not manufacture them in satisfactory quality, in a timely manner, in sufficient quantities or at an acceptable cost, clinical development and commercialization of our product candidates could be delayed.

We do not own or operate manufacturing facilities. Consequently, we rely on third parties as sole suppliers of our product candidates. We do not expect to establish our own manufacturing facilities and we will continue to rely on third-party manufacturers to produce supplies for pre-clinical, clinical and pivotal animal studies and for commercial quantities of any products or product candidates that we market or may supply to our collaborators. Our dependence on third parties for the manufacture of our product candidates may adversely affect our ability to develop and commercialize any product candidates on a timely and competitive basis.

To date, our product candidates have only been manufactured in quantities sufficient for pre-clinical studies and initial clinical trials. We rely on a single collaborator for production of each of our product candidates. For a variety of reasons, dependence on any single manufacturer may adversely affect our ability to develop and commercialize our product candidates in a timely and competitive basis. In addition, our current contractual arrangements alone may not be sufficient to guarantee that we will be able to procure the needed supplies as we complete clinical development and/or enter commercialization.

Additionally, in connection with our application for commercial approvals and if any product candidate is approved by the FDA or other regulatory agencies for commercial sale, we will need to procure commercial quantities from qualified third-party manufacturers. We may not be able to contract for increased manufacturing capacity for any of our product candidates in a timely or economic manner or at all. A significant scale-up in manufacturing may require additional validation studies and commensurate financial investments by the contract manufacturers. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial

launch of that product candidate may be delayed or there may be a shortage of supply, which could limit our sales and could initiate regulatory intervention to minimize the public health risk.

Other risks associated with our reliance on contract manufacturers include the following:

- Contract manufacturers may encounter difficulties in achieving volume production, quality control and quality assurance and also may experience shortages in qualified personnel and obtaining active ingredients for our product candidates;

- If, for any circumstance, we are required to change manufacturers, we could be faced with significant monetary and lost opportunity costs with switching manufacturers. Furthermore, such change may take a significant amount of time. The FDA and foreign regulatory agencies must approve these manufacturers in advance. This requires prior approval of regulatory submissions as well as successful completion of pre-approval inspections to ensure compliance with FDA and foreign regulations and standards;

- Contract manufacturers are subject to ongoing periodic, unannounced inspection by the FDA and state and foreign agencies or their designees to ensure strict compliance with cGMP and other governmental regulations and corresponding foreign standards. We do not have control over compliance by our contract manufacturers with these regulations and standards. Our contract manufacturers may not be able to comply with cGMP and other FDA requirements or other regulatory requirements outside the United States. Failure of contract manufacturers to comply with applicable regulations could result in delays, suspensions or withdrawal of approvals, seizures or recalls of product candidates and operating restrictions, any of which could significantly and adversely affect our business; and

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Contract manufacturers may breach the manufacturing agreements that we have with them because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient to us.

Changes to the manufacturing process during the conduct of clinical trials or after marketing approval also require regulatory submissions and the demonstration to the FDA or other regulatory authorities that the product manufactured under the new conditions complies with cGMP requirements. These requirements especially apply to moving manufacturing functions to another facility. In each phase of investigation, sufficient information about changes in the manufacturing process must be submitted to the regulatory authorities and may require prior approval before implementation with the potential of substantial delay or the inability to implement the requested changes.

RISKS RELATING TO REGULATORY APPROVAL

We may not be able to obtain regulatory approval in a timely manner or at all and the results of clinical trials may not be favorable.

The testing, marketing and manufacturing of any product for use in the United States will require approval from the FDA. We cannot predict with any certainty the amount of time necessary to obtain FDA approval and whether any such approval will ultimately be granted. Pre-clinical studies and clinical trials may reveal that one or more products are ineffective or unsafe, in which event, further development of such products could be seriously delayed, terminated or rendered more expensive. Moreover, obtaining approval for certain products may require testing on human subjects of substances whose effects on humans are not fully understood or documented.

In addition, we expect to rely on an FDA regulation known as the Animal Rule to obtain approval for Entolimod s biodefense indication. The Animal Rule permits the use of animal efficacy studies together with human clinical safety trials to support an application for marketing approval of products when human efficacy studies are neither ethical nor feasible. These regulations are relatively new and we have limited experience in the application of these rules to the product candidates that we are developing. As such, we cannot predict the time required for them to confirm the relevant rules, or the scope thereof. Additionally, we may submit an application with the FDA for pre- EUA, so that Entolimod may be used in an emergency situation. If and when we provide the FDA with the data to support a pre-EUA for Entolimod in the event of a radiation emergency we cannot guarantee that the FDA will review the data in a timely manner, or that, when the data is reviewed, that the FDA will accept the data. The FDA may decide that our data are insufficient for pre-EUA or BLA approval and require additional pre-clinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. If we are not successful in completing the development, licensure and commercialization of Entolimod for its biodefense indication use, or if we are significantly delayed in doing so, our business will be materially harmed.

The receipt of FDA approval may be delayed for reasons other than the results of pre-clinical studies and clinical trials. For example, in 2011, the IND application for Entolimod s biodefense indication was transferred within the FDA from the Division of Biologic Oncology Products, or DBOP, to the Division of Medical Imaging Products, or DMIP. As a result of this transfer, we requested and participated in nine meetings with DMIP during 2011-2013 to review the product mechanisms of action, safety profile and preliminary estimation of an effective human dose. DMIP has agreed on the scope and design of the proposed pivotal animal efficacy program and has acknowledged that specific cytokines do play an important role in Entolimod s mechanism of action and, as such, can be used as biomarkers for animal-to-human dose-conversion. DMIP has also provided advice on the design of the remaining program needed for BLA submission. However, we are still in the process of reaching an agreement with FDA on the certain elements of the design of our remaining clinical studies for Entolimod. There can be no guarantee that we will reach a satisfactory agreement in a timely manner, or at all, or that DMIP may request any additional information related to our pre-clinical or clinical programs.

Delays in obtaining FDA or any other necessary regulatory approvals of any proposed product or the failure to receive such approvals would have an adverse effect on our ability to develop such product, the product s potential commercial success and/or on our business, prospects, financial condition and results of operations.

Failure to obtain regulatory approval in international jurisdictions could prevent us from marketing our products abroad.

We intend to market our product candidates, including specifically the product candidates being developed by our subsidiaries, in the United States, the Russian Federation and other countries and regulatory jurisdictions. In order to market our product candidates in the United States, Russia and other jurisdictions, we must obtain separate regulatory approvals in each of these countries and territories. The procedures and requirements for obtaining marketing approval vary among countries and regulatory jurisdictions and can involve additional clinical trials or other tests. In addition, we do not have in-house experience and expertise regarding the procedures and requirements for filing for and obtaining marketing approval for drugs in countries outside of the United States, Europe and Japan and may need to engage and rely upon expertise of third parties when we file for marketing

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approval in countries outside of the United States, Europe and Japan. Also, the time required to obtain approval in markets outside of the United States may differ from that required to obtain FDA approval, while still including all of the risks associated with obtaining FDA approval. We may not be able to obtain all of the desirable or necessary regulatory approvals on a timely basis, if at all. Approval by a regulatory authority in a particular country or regulatory jurisdiction, such as the FDA in the United States or the Roszdravnadzor in Russia, does not ensure approval by a regulatory authority in another country.

We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any or all of the countries or regulatory jurisdictions in which we desire to market our product candidates. At this time, other countries do not have an equivalent to the Animal Rule and, as a result, such countries do not have established criteria for review and approval for this type of product outside their normal review process. Specifically, because such other countries do not have an equivalent to the Animal Rule, we may not be able to file for or receive regulatory approvals for Entolimod s biodefense indication outside the United States based on our animal efficacy and human safety data.

The Fast Track designation for Entolimod may not actually lead to a faster development or regulatory review or approval process.

We have obtained a Fast Track designation from the FDA for Entolimod s biodefense indication. However, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw our Fast Track designation if the FDA believes that the designation is no longer supported by data from our clinical development program. Our Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the FDA s expedited review procedures or that any application that we may submit to the FDA for regulatory approval will be accepted for filing or ultimately approved.

Any pre-EUA submission we make to the FDA may not be successful and even if such submission is successful it may not accelerate BLA approval of Entolimod or result in any purchase by the U.S. government for this product.

In 2014, we plan to meet with the FDA regarding human dose-conversion of Entolimod and, if appropriate after such meeting, submit a pre-EUA in order to inform and expedite the FDA s issuance of an EUA, should one become necessary in the event of an emergency. The FDA does not have review deadlines with respect to pre-EUA submissions and, therefore, the timing of any approval of a pre-EUA submission is uncertain. If we submit a pre-EUA, the FDA may decide not to accept the data or decide that our data are insufficient for pre-EUA and require additional pre-clinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. An acceptance of our pre-EUA submission does not guarantee, and may not accelerate, BLA approval of Entolimod as a radiation countermeasure. Further, even if our pre-EUA submission is authorized, there is no guarantee that such authorization will lead to procurement by the U.S. or other governments or any additional development funding. If we are not successful in partnering Entolimod or completing the development, licensure and commercialization of Entolimod for its biodefense indication use, or if we are significantly delayed in doing so, our business may be materially harmed.

Even if our drug candidates obtain regulatory approval, we will be subject to on-going government regulation.

Even if our drug candidates obtain regulatory approval, our products will be subject to continuing regulation by the FDA, including record keeping requirements, submitting periodic reports to the FDA, reporting of any adverse experiences with the product and complying with Risk Evaluation and Mitigation Strategies and drug sampling and distribution requirements. In addition, updated safety and efficacy information must be maintained and provided to the

FDA. We or our collaborative partners, if any, must comply with requirements concerning advertising and promotional labeling, including the prohibition against promoting and non-FDA approved or off-label indications or products. Failure to comply with these requirements could result in significant enforcement action by the FDA, including warning letters, orders to pull the promotional materials and substantial fines.

After FDA approval of a product, the discovery of problems with a product or its class, or the failure to comply with requirements may result in restrictions on a product, manufacturer, or holder of an approved marketing application. These include withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay or prevent further marketing. Newly discovered or developed safety or effectiveness data, including from other products in a therapeutic class, may require changes to a product s approved labeling, including the addition of new warnings and contraindications. Also, the FDA requires post-market clinical testing of products approved under the Animal Rule at the time of a declared emergency and may require post-market clinical testing of other products. They may also require surveillance to monitor the product s safety or efficacy to evaluate long-term effects. It is also possible that rare but serious adverse events not seen in our drug candidates may be identified after marketing approval. This could result in withdrawal of our product from the market.

Compliance with post-marketing regulations may be time-consuming and costly and could delay or prevent us from generating revenue from the commercialization of our drug candidates.

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If physicians and patients do not accept and use our drugs, we will not achieve sufficient product revenues and our business will suffer.

Even if we gain marketing approval of our drug candidates, government purchasers, physicians and/or patients may not accept and use them. Acceptance and use of these products may depend on a number of factors including:

- Perceptions by members of the government healthcare community, including physicians, about the safety and effectiveness of our drugs;
- Published studies demonstrating the safety and effectiveness of our drugs;
- Adequate reimbursement for our products from payors; and
- Effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of our drugs, if approved for marketing, to gain acceptance in the market would harm our business and could require us to seek additional financing.

RISKS RELATED TO OUR DEPENDENCE ON U.S. GOVERNMENT CONTRACTS AND GRANTS

***If we are unable to procure additional government funding, we may not be able to fund future R&D and implement technological improvements, which would materially harm our financial conditions and operating results.**

Grant and contract revenue from the U.S. government accounted for 1.8% and 31.5% of our revenue for the three months ended March 31, 2014 and 2013, respectively.

These revenues have funded some of our personnel and other R&D and General and Administrative costs and expenses. It is possible that we may not choose to apply for or, if we do apply, be able to procure new grants and contracts that provide sufficient funding, or any funding at all. In addition, the finalization of new contracts and grants may require a significant time from the initial request and negotiations for such contracts and grants are subject to a significant amount of uncertainty.

For example, in May 2011, we announced that we had concluded advanced stages of contract negotiation with BARDA for the funding of certain development activities relating to Entolimod s biodefense indication in our 2010 proposal to BARDA. BARDA indicated that further contract-related negotiations would require clarification of the development path for Entolimod s biodefense indication with the FDA, which is in the process of actively reviewing our IND application for Entolimod. BARDA indicated that we might resubmit an updated proposal upon confirmation from the FDA that they do not have any objections to us proceeding with our development plan as a result of this review. We received a confirmatory letter from the FDA in late 2011 and submitted a white paper to BARDA under its currently open Broad Agency Announcement, or the BAA. In April 2012, we announced that BARDA had declined to invite the Company to submit a full proposal pursuant to the white paper submitted. After further discussions with both the FDA and BARDA, we announced in October 2012, that the Company had submitted a proposal to BARDA under the BAA for the remaining development steps needed for FDA licensure of Entolimod as a

medical radiation countermeasure. In January 2014, we announced that BARDA had terminated negotiations of our proposal due to lack of availability of funds. If and when we do submit additional funding proposals to BARDA or other U.S. or foreign government agencies there is no assurance that such agencies will make a positive decision with regard to funding our proposal(s) or award a contract (if one is awarded) in a timely manner.

If we are unable to obtain sufficient grants and contracts on a timely basis or if our existing grants and contracts are not funded, our ability to fund future R&D would be diminished, which would negatively impact our ability to compete in our industry and could materially and adversely affect our business, financial condition and results of operations.

Our future business may be harmed as a result of the government contracting process as it involves risks not present in the commercial marketplace.

We expect that a significant portion of the business that we will seek in the near future will be under government contracts or subcontracts, both U.S. and foreign, which may be awarded through competitive bidding. Competitive bidding for government contracts presents a number of risks that are not typically present in the commercial contracting process, which may include:

- The need to devote substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- The need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;
- The risk that the government will issue a request for proposal to which we would not be eligible to respond;
- The risk that third parties may submit protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal;
- The expenses that we might incur and the delays that we might suffer if our competitors protest or challenge contract awards made to us pursuant to competitive bidding and the risk that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in termination, reduction or modification of the awarded contract; and

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The risk that review of our proposal or award of a contract or an option to an existing contract could be significantly delayed for reasons including, but not limited to, the need for us to resubmit our proposal or limitations on available funds due to government budget cuts.

The U.S. government may choose to award future contracts for the supply of medical radiation countermeasures to our competitors instead of to us. If we are unable to win particular contracts, or if the government chooses not to fully exercise all options under contracts awarded to us, we may not be able to operate in the market for products that are provided under those contracts for a number of years. If we are unable to consistently win new contract awards and have the options under our existing contracts exercised over an extended period, or if we fail to anticipate all of the costs and resources that will be required to secure such contract awards, our growth strategy and our business, financial condition and operating results could be materially adversely affected.

The market for U.S. and other government funding is highly competitive.

Our biodefense product candidate, Entolimod, faces significant competition for U.S. government funding for both development and procurement of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. In addition, we may not be able to compete effectively if our products and product candidates do not satisfy procurement requirements of the U.S. government with respect to biodefense products. Our opportunities to succeed in this industry could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than any products that we may develop.

U.S. government agencies have special contracting requirements, which create additional risks.

We have historically entered into contracts with various U.S. government agencies. Due to these contracts with government agencies, we are subject to various federal contract requirements. Future sales to U.S. government agencies will depend, in part, on our ability to meet these requirements, certain of which we may not be able to satisfy.

U.S. government contracts typically contain unfavorable termination provisions and are subject to audit by the government at its sole discretion even after the end of the period of performance under the contract, which subjects us to additional risks. These risks include the ability of the U.S. government to unilaterally:

Suspend or prevent us for a set period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations;

Terminate our existing contracts;

Reduce the scope and value of our existing contracts;

Audit and object to our contract-related costs and fees, including allocated indirect costs;

Control and potentially prohibit the export of our products; and

Change certain terms and conditions in our contracts.

Pursuant to our government contracts, we are generally permitted to retain title to any patentable invention or discovery made while performing the contract. However, the U.S. government is generally entitled to receive a non-exclusive, non-transferable, irrevocable, paid-up license to the subject inventions throughout the world. In addition, our government contracts generally provide that the U.S. government retains unlimited rights in the technical data produced under such government contract.

Our business could be adversely affected by a negative audit by the U.S. government.

As a U.S. government contractor, we may become subject to periodic audits and reviews by U.S. government agencies such as the Defense Contract Audit Agency, or the DCAA. These agencies review a contractor s performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. The DCAA also reviews the adequacy of, and a contractor s compliance with, its internal control systems and policies, including the contractor s purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, which such costs already reimbursed must be refunded.

Based on the results of these audits, the U.S. government may adjust our contract-related costs and fees, which have already been paid to us, including allocated indirect costs. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer

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serious harm to our reputation if allegations of impropriety were made against us. In addition, under U.S. government purchasing regulations, some of our costs, including most financing costs, amortization of intangible assets, portions of our R&D costs and some marketing expenses, may not be reimbursable or allowed under our contracts. Further, as a U.S. government contractor, we may become subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities to which purely private sector companies are not.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

We rely upon licensed patents to protect our technology. We may be unable to obtain or protect such intellectual property rights and we may be liable for infringing upon the intellectual property rights of others.

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies and the proprietary technology of others with which we have entered into licensing agreements. We have entered into five separate exclusive license agreements to license our product candidates that are not owned by us and some product candidates are covered by up to three separate license agreements. Pursuant to these license agreements we maintain patents and patent applications covering our product candidates. We do not know whether any of these patent applications that are still in the approval process will ultimately result in the issuance of a patent with respect to the technology owned by us or licensed to us. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the United States Patent and Trademark Office use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others.

Our technology may be found in the future to infringe upon the rights of others or be infringed upon by others. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties patent rights. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief, which could effectively block our ability to further develop, commercialize and sell products. In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our products so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology and the technology exclusively licensed by us or developed with our collaborative partners. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

Moreover, the cost to us of any litigation or other proceeding relating to our patents and other intellectual property rights, even if resolved in our favor, could be substantial and the litigation would divert our management s efforts and our resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If we fail to comply with our obligations under our license agreement with third parties, we could lose our ability to develop our product candidates.

The manufacture and sale of any products developed by us may involve the use of processes, products or information, the rights to certain of which are owned by others. Although we have obtained exclusive licenses for our product

candidates from Cleveland Clinic Foundation, Roswell Park Cancer Institute and Children s Cancer Institute Australia with regard to the use of patent applications as described above and certain processes, products and information of others, these licenses could be terminated or expire during critical periods and we may not be able to obtain licenses for other rights that may be important to us, or, if obtained, such licenses may not be obtained on commercially reasonable terms. Furthermore, some of our product candidates require the use of technology licensed from multiple third parties, each of which is necessary for the development of such product candidates. If we are unable to maintain and/or obtain licenses, we may have to develop alternatives to avoid infringing upon the patents of others, potentially causing increased costs and delays in product development and introduction or precluding the development, manufacture, or sale of planned products. Additionally, the patents underlying any licenses may not be valid and enforceable. To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical.

Our current exclusive licenses impose various development, royalty, diligence, record keeping, insurance and other obligations on us. If we breach any of these obligations and do not cure such breaches within the relevant cure period, the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology.

In addition, while we cannot currently determine the dollar amount of the royalty and other payments we will be required to make in the future under the license agreements, if any, the amounts may be significant. The dollar amount of our future payment obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any.

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If we are not able to protect and control our unpatented trade secrets, know-how and other technology, we may suffer competitive harm.

We also rely on a combination of trade secrets, know-how, technology and nondisclosure and other contractual agreements and technical measures to protect our rights in the technology. However, trade secrets are difficult to protect and we rely on third parties to develop our products and thus must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements will typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. If any trade secret, know-how or other technology not protected by a patent or intellectual property right were disclosed to, or independently developed by, a competitor, our business, financial condition and results of operations could be materially adversely affected.

RISKS RELATING TO OUR INDUSTRY AND OTHER EXTERNAL FACTORS

The biopharmaceutical market in which we compete is highly competitive.

The biopharmaceutical industry is characterized by rapid and significant technological change. Our success will depend on our ability to develop and apply our technologies in the design and development of our product candidates and to establish and maintain a market for our product candidates. In addition, there are many companies, both public and private, including major pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions engaged in developing pharmaceutical and biotechnology products. Many of these companies have substantially greater financial, technical, research and development resources and human resources than us. Competitors may develop products or other technologies that are more effective than those that are being developed by us or may obtain FDA or other governmental approvals for products more rapidly than us. If we commence commercial sales of products, we still must compete in the manufacturing and marketing of such products, areas in which we have no experience.

Our growth could be limited if we are unable to attract and retain key personnel and consultants.

We have limited experience in filing and prosecuting regulatory applications to obtain marketing approval from the FDA or other regulatory authorities. The loss of services of one or more of our key employees or consultants could have a negative impact on our business or our ability to expand our research, development and clinical programs. We depend on our scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial and marketing personnel, particularly as we expand our activities in clinical trials, the regulatory approval process, external partner solicitations and sales and manufacturing. We routinely enter into consulting agreements with our scientific and clinical collaborators and advisors, opinion leaders and heads of academic departments in the ordinary course of our business. We also enter into contractual agreements with physicians and institutions who recruit patients into our clinical trials on our behalf in the ordinary course of our business. In addition, as a result of our 2013 corporate restructuring and workforce reductions, we may face additional challenges in retaining our existing senior management and key employees and recruiting new

employees to join our company, as our business needs change. We face significant competition for this type of personnel and for employees from other companies, research and academic institutions, government entities and other organizations. We cannot predict our success in hiring or retaining the personnel we require for continued growth.

We may be subject to damages resulting from claims that we, our employees, or our consultants have wrongfully used or disclosed alleged trade secrets of their former employers,

We engage as employees and consultants individuals who were previously employed at other biotechnology or pharmaceutical companies, including at competitors or potential competitors. Although no claims against us are currently pending, we may become subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and distract management.

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We may incur substantial liabilities from any product liability and other claims if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if the product candidates are sold commercially. An individual may bring a product liability claim against us if one of the product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

Decreased demand for our product candidates;

Injury to our reputation;

Withdrawal of clinical trial participants;

Costs of related litigation;

Diversion of our management s time and attention;

Substantial monetary awards to patients or other claimants;

Loss of revenues;

The inability to commercialize product candidates; and

Increased difficulty in raising required additional funds in the private and public capital markets.

We currently have product liability insurance and intend to expand such coverage from coverage for clinical trials to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage that will be adequate to satisfy any liability that may arise.

From time to time, we may also become subject to litigation, such as stockholder derivative claims or securities fraud claims, which could involve our directors and officers as defendants. We currently have director and officer, or D&O, insurance to cover such risk exposure for our directors and officers. Our bylaws require us to indemnify our current and past directors and officers from reasonable expenses related to the defense of any action arising from their service to us. Our certificate of incorporation and by-laws include provisions to indemnify the directors and officers to the fullest extent permitted by the Delaware General Corporation Law, including circumstances under which indemnification is otherwise discretionary. If our D&O insurance is insufficient to cover all such expenses for all

directors and officers, we would be obligated to cover any shortfall, which may be substantial. Such expenditure could have a material adverse effect on our results of operation, financial condition and liquidity. Further, if D&O insurance becomes prohibitively expensive to maintain in the future, we may be unable to renew such insurance on economic terms or unable renew such insurance at all. The lack of D&O insurance may make it difficult for us to retain and attract talented and skilled directors and officers to serve our company, which could adversely affect our business.

We have been named as a defendant in a lawsuit that could result in substantial costs and divert management s attention.

We have been named as a defendant in a lawsuit initiated earlier this year that generally alleges we misrepresented the state of our funding negotiations with BARDA during the period leading up to the sale of our common stock and warrants in January 2014, and as a result, the plaintiffs were harmed when our stock price declined following the announcement that BARDA had terminated negotiations with us. 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. Any conclusion of these matters in a manner adverse to us would have a material adverse effect on our financial condition and business. For example, we could incur substantial costs not covered by our directors and officers liability insurance, suffer a significant adverse impact on our reputation and divert management s attention and resources from other priorities, including the execution of business plans and strategies that are important to our ability to grow our business, any of which could have a material adverse effect on our business. In addition, any of these matters could require payments that are not covered by our available directors and officers liability insurance, which could have a material adverse effect on our operating results or financial condition. Additional similar lawsuits might be filed.

Our former laboratories used certain chemical and biological agents and compounds that may be deemed hazardous and we were subject to various safety and environmental laws and regulations. Our prior compliance with these laws and regulations may result in significant costs, which could materially reduce our ability to become profitable.

Until late 2013, we had laboratories that used hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. As appropriate, we stored these materials and wastes resulting from their use at our laboratory facility pending their ultimate use or disposal. We contracted with a third party to properly dispose of these materials and wastes. We were subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. We may incur significant costs if we unknowingly failed to comply with environmental laws and regulations.

Political or social factors may delay or impair our ability to market our products.

Entolimod is being developed to treat radiation sickness, which is a disease that may be caused by terrorist acts. The political and social responses to terrorism have been highly charged and unpredictable. Political or social pressures may delay or cause resistance to bringing our products to market or limit pricing of our products, which would harm our business. Changes to favorable laws, such as the Project BioShield Act, could have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations.

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We hope to receive funding from U.S. or foreign government agencies for the development of Entolimod and our products. Changes in government budgets and agendas, however, have previously resulted in termination of our contract negotiations and may, in the future, result in future funding being decreased and de-prioritized, government contracts contain provisions that permit cancellation in the event that funds are unavailable to the government agency. Furthermore, we cannot be certain of the timing of any future funding and substantial delays or cancellations of funding could result from protests or challenges from third parties. If the U.S. government fails to continue to adequately fund R&D programs, we may be unable to generate sufficient revenues to continue development of Entolimod or continuation of our other operations. Similarly, if our pre-EUA submission for Entolimod is authorized by the FDA or we develop another product candidate that is approved by the FDA, but the U.S. government does not place sufficient orders for this product, our future business may be harmed.

Failure to comply with the United States Foreign Corrupt Practices Act and similar foreign laws could subject us to penalties and other adverse consequences.

We are required to comply with the United States Foreign Corrupt Practices Act, or FCPA, which prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business. Foreign companies, including some that may compete with us, are not subject to these prohibitions. Furthermore, foreign jurisdictions in which we operate may have laws that are similar to the FCPA to which we are or may become subject. This may place us at a significant competitive disadvantage. Corruption, extortion, bribery, pay-offs, theft and other fraudulent practices may occur from time to time in the foreign markets where we conduct business. Although we inform our personnel that such practices are illegal, we can make no assurance that our employees or other agents will not engage in illegal conduct for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA and similar foreign anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, such anti-bribery laws present particular challenges in the biotech or pharmaceutical industry, because, in many countries, hospitals are operated by the government and doctors and other hospital employees may be considered foreign officials.

Our business is subject to changing regulations for corporate governance and public disclosure that has increased both our costs and the risk of noncompliance.

Each year, under Section 404 of the Sarbanes-Oxley Act, we are required to evaluate our internal controls systems in order to allow management to report on our internal controls as required by and to permit our independent registered public accounting firm to attest to our internal controls. As a result, we have incurred and will continue to incur additional expenses and divert our management s time to comply with these regulations. In addition, if we cannot continue to comply with the requirements of Section 404 in a timely manner, we might be subject to sanctions or investigation by regulatory and quasi-governmental authorities, such as the SEC, the Public Company Accounting Oversight Board, or The NASDAQ Stock Market. Any such action could adversely affect our financial results and the market price of our common stock.

In addition, stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business.

RISKS RELATING TO OUR SECURITIES

***The price of our common stock has been and could remain volatile, which may in turn expose us to securities litigation.**

The market price of our common stock has historically experienced and may continue to experience significant volatility. From first quarter 2013 through first quarter 2014, the market price of our common stock, which is listed on the NASDAQ Capital Market, fluctuated from a high of $2.28 per share in the first quarter of 2013 to a low of $0.63 in the first quarter of 2014. Additionally, since December 2013 our stock has further fluctuated to a low of $0.63 per share. The listing of our common stock on the NASDAQ Capital Market does not assure that a meaningful, consistent and liquid trading market will exist, and in recent years, the market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility in addition to volatility caused by the occurrence of industry and company specific events. Factors that could cause fluctuations include, but are not limited to, the following:

Our progress in developing and commercializing our products;

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Price and volume fluctuations in the overall stock market from time to time;

Fluctuations in stock market prices and trading volumes of similar companies;

Actual or anticipated changes in our earnings or fluctuations in our operating results or in the expectations of securities analysts;

General economic conditions and trends;

Major catastrophic events;

Sales of large blocks of our stock;

Departures of key personnel;

Changes in the regulatory status of our product candidates, including results of our pre-clinical studies and clinical trials;

Status of contract and funding negotiations relating to our product candidates;

Events affecting our collaborators;

Announcements of new products or technologies, commercial relationships or other events by us or our competitors;

Regulatory developments in the U.S. and other countries;

Failure of our common stock to be listed or quoted on the NASDAQ Capital Market, other national market system or any national stock exchange;

Changes in accounting principles; and

Discussion of us or our stock price by the financial and scientific press and in online investor communities.

As a result of the volatility of our stock price, we could be subject to securities litigation, which could result in substantial costs and divert management s attention and company resources from our business.

***Issuance of additional equity may adversely affect the market price of our stock.**

We are currently authorized to issue 160,000,000 shares of common stock and 10,000,000 of preferred stock. As of March 31, 2014, 50,942,798 shares of our common stock were issued and outstanding and we had issued warrants to purchase 16,444,083 shares and had granted 6,124,655 options. To the extent the shares of common stock are issued or options and warrants are exercised, holders of our common stock will experience dilution.

In the event of any future issuances of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution. Furthermore, our outstanding warrants contain provisions that, in certain circumstances, could result in the number of shares of common stock issuable upon the exercise of such warrants to increase and/or the exercise price of such warrants to decrease.

Moreover, our board of directors is authorized to issue preferred stock without any action on the part of our stockholders. Our board of directors also has the power, without stockholder approval, to set the terms of any such preferred stock that may be issued, including voting rights, conversion rights, dividend rights, preferences over our common stock with respect to dividends or if we liquidate, dissolve or wind up our business and other terms. If we issue preferred stock in the future that has preference over our common stock with respect to the payment of dividends or upon our liquidation, dissolution or winding up, or if we issue preferred stock with voting rights that dilute the voting power of our common stock, the market price of our common stock could decrease. Any provision permitting the conversion of any such preferred stock into our common stock could result in significant dilution to the holders of our common stock.

We also consider from time to time various strategic alternatives that could involve issuances of additional shares of common stock or shares of preferred stock, including but not limited to acquisitions and business combinations.

We have no plans to pay dividends on our common stock and investors may not receive funds without selling their common stock.

We have not declared or paid any cash dividends on our common stock, nor do we expect to pay any cash dividends on our common stock for the foreseeable future. We currently intend to retain any additional future earnings to finance our operations and growth and, therefore, we have no plans to pay cash dividends on our common stock at this time. Any future determination to pay cash dividends on our common stock will be at the discretion of our board of directors and will be dependent on our earnings, financial condition, operating results, capital requirements, any contractual restrictions, regulatory and other restrictions on the payment of dividends by our subsidiaries to us and other factors that our board of directors deems relevant.

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Accordingly, investors may have to sell some or all of their common stock in order to generate cash from your investment. Investors may not receive a gain on their investment when they sell our common stock and may lose the entire amount of their investment.

Provisions in our charter documents and Delaware law may inhibit a takeover or impact operational control of our company, which could adversely affect the value of our common stock.

Our certificate of incorporation and bylaws, as well as Delaware corporate law, contain provisions that could delay or prevent a change of control or changes in our management that a stockholder might consider favorable. These provisions include, among others, prohibiting stockholder action by written consent, advance notice for raising business or making nominations at meetings of stockholders and the issuance of preferred stock with rights that may be senior to those of our common stock without stockholder approval. These provisions would apply even if a takeover offer may be considered beneficial by some of our stockholders. If a change of control or change in management is delayed or prevented, the market price of our common stock could decline.

RISKS RELATED TO CONDUCTING BUSINESS IN THE RUSSIAN FEDERATION

Political, economic and governmental instability in Russia could materially adversely affect our operations and financial results.

Political and economic relations between Russia and the United States, two of the jurisdictions in which we operate, are complex. Political, ethnic, religious, historical and other differences have, on occasion, given rise to tensions. The current situation in Ukraine and Crimea along with the response of the Russian and United States governments to this situation, have the potential to materially adversely affect our operations in Russia. In connection with the current situation in Ukraine, the United States has ordered sanctions against Russian and Crimean officials. While we do not anticipate that the current sanctions will materially affect our business, if further sanctions are ordered by the United States or other international interests, such sanction may materially adversely affect out operations in Russia.

These current events may negatively affect the Russian economy and have negatively affected the value of the Russian ruble relative to the U.S. dollar. Continuing fluctuations in the rates at which the U.S. dollar are exchanged into Russian rubles may result in both foreign currency transaction and translation losses. We are subject to exchange rate fluctuations as (i) CBLI exchanges dollar-denominated funds into ruble-denominated funds in order to conduct operations of our Russian-based subsidiary BioLab 612, (ii) Panacela, Incuron and BioLab 612 use their ruble-denominated funds to pay for services under dollar-denominated contracts, including payments to CBLI for services we provide to our subsidiaries, and (iii) the US dollar equivalent of ruble denominated assets and liabilities fluctuate from period-to-period causing us to record foreign currency translation adjustments which are reflected as a change in other comprehensive income (loss). As the dollar strengthens or weakens relative to the ruble, our ruble-denominated revenue and expenses decline or increase respectively, when translated into U.S. Dollars for financial reporting purposes. Should exchange rates in effect at the time of this filing as compared to early 2014 and 2013, continue throughout the year, we expect the exchange rates to reduce our revenues and expenses in 2014 compared to 2013, and we would also record other comprehensive losses on our ruble denominated assets and liabilities when translated into the US dollar. Additionally, the purchasing power of US dollar denominated services is reduced, such as those being provided in the US for Incuron s Phase 2 trial of the intravenous application of CBL0137.

Even before the current events mentioned above, and since the early 1990s, Russia has sought to transform from a one-party state with a centrally planned economy to a democracy with a market economy. As a result of the sweeping nature of various reforms and the failure of some of them, the political system of Russia remains vulnerable to popular dissatisfaction, including demands for autonomy from particular regional and ethnic groups. Current and future

changes in the Russian government, major policy shifts or lack of consensus between various branches of the government and powerful economic groups could disrupt or reverse economic and regulatory reforms. Furthermore, the Russian economy is vulnerable to market downturns and economic slowdowns elsewhere in the world, and has experienced periods of considerable instability. Although the Russian economy showed positive trends until 2008, including annual increases in the gross domestic product, a relatively stable currency, strong domestic demand, rising real wages and a reduced rate of inflation, these trends were interrupted by the global financial crisis in late 2008, in which Russia experienced adverse economic and financial effects including a substantial decrease in the growth rate of gross domestic product, depreciation of local currency and a decline in domestic and international demand for its products and services. Economic instability in Russia could materially adversely affect our business, financial condition and results of operations.

Emerging markets, such as Russia, are subject to greater risks than more developed markets and financial turmoil in Russia could disrupt our business.

Investors in emerging markets, such as Russia, should be aware that these markets are subject to greater risks than more developed markets, including significant economic risks. For example, the Russian economy has periodically experienced high rates of inflation. According to The World Bank and Bloomberg, the annual inflation rate in Russia, as measured by the consumer price index, was 8.4% in 2011 and 5.1% in 2012. Periods of higher inflation may slow economic growth. Inflation also is likely to increase some of our costs and expenses including the costs for our subsidiaries to conduct business operations, including any outsourced product testing costs.

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Prospective investors in our common stock should note that emerging markets are subject to rapid change and that the information set out in this Annual Report on Form 10-K about our operations in Russia may become outdated relatively quickly.

The legal system in Russia can create an uncertain environment for business activity, which could materially adversely affect our business and operations in Russia.

The legal framework to support a market economy remains new and in flux in Russia and, as a result, its legal system can be characterized by: inconsistencies between and among laws and governmental, ministerial and local regulations, orders, decisions, resolutions and other acts; gaps in the regulatory structure resulting from the delay in adoption or absence of implementing regulations; selective enforcement of laws or regulations, sometimes in ways that have been perceived as being motivated by political or financial considerations; limited judicial and administrative guidance on interpreting legislation; relatively limited experience of judges and courts in interpreting recent commercial legislation; a perceived lack of judicial and prosecutorial independence from political, social and commercial forces; inadequate court system resources; a high degree of discretion on the part of the judiciary and governmental authorities; and underdeveloped bankruptcy procedures that are subject to abuse.

In addition, as is true of civil law systems generally, judicial precedents generally have no binding effect on subsequent decisions. Not all legislation and court decisions in Russia are readily available to the public or organized in a manner that facilitates understanding. Enforcement of court orders can in practice be very difficult. All of these factors make judicial decisions difficult to predict and effective redress uncertain. Additionally, court claims and governmental prosecutions may be used in furtherance of what some perceive to be political or commercial aims.

In February 2014, a new law came into force amending the Russian Constitution and merging the Higher Arbitrary court with the Higher Court, creating a new Higher Court. As of the date of this report, the new Higher Court is in the process of being established. We cannot predict the effect of this merger on judicial practice and the Russian judicial system.

The untested nature of much of recent legislation in Russia and the rapid evolution of its legal system may result in ambiguities, inconsistencies and anomalies in the application and interpretation of laws and regulations. Any of these factors may affect our ability to enforce our rights under our contracts or to defend ourselves against claims by others, or result in our being subject to unpredictable requirements. These uncertainties also extend to property rights and the expropriation or nationalization of any of our entities, their assets or portions thereof, potentially without adequate compensation, could materially adversely affect our business, financial condition and results of operations.

Changes in the tax system in Russia or the arbitrary or unforeseen application of existing rules could materially adversely affect our financial condition and results of operations.

There have been significant changes to the taxation system in Russia in recent years as the authorities have gradually replaced legislation regulating the application of major taxes such as corporate income tax, value added tax, corporate property tax and other taxes with new legislation. Tax authorities in Russia have also been aggressive in their interpretation of tax laws and their many ambiguities, as well as in their enforcement and collection activities. Technical violations of contradictory laws and regulations, many of which are relatively new and have not been subject to extensive application or interpretation, can lead to penalties. High-profile companies can be particularly vulnerable to aggressive application of unclear requirements. Many companies must negotiate their tax bills with tax inspectors who may demand higher taxes than applicable law appears to provide. Our Russian subsidiaries tax liabilities may become greater than the estimated amount that they have expensed to date and paid or accrued on the balance sheets, particularly if the tax benefits currently received in Russia are changed or removed. Any additional tax

liability, as well as any unforeseen changes in tax laws, could materially adversely affect our future results of operations, financial condition or cash flows in a particular period.

In October 2006, the Supreme Arbitration Court of Russia issued a ruling that introduced the concept of an unjustified tax benefit, which is a benefit that may be disallowed for tax purposes. Specific examples cited by the court include benefits obtained under transactions lacking a business purpose (*i.e.*, when the only purpose of a deal or structure is to derive tax benefits). The tax authorities have actively sought to apply this concept when challenging tax positions taken by taxpayers. Although the intention of the ruling was to combat tax abuse, in practice there is no assurance that the tax authorities will not seek to apply this concept in a broader sense than may have been intended by the court. In addition, the tax authorities and the courts have indicated a willingness to interpret broadly the application of criminal responsibility for tax violations.

The tax systems in Russia impose additional burdens and costs on our operations there and complicate our tax planning and related business decisions. For example, the tax environment in Russia has historically been complicated by contradictions in Russian tax law and tax laws are unclear in areas such as the deductibility of certain expenses. This uncertainty could result in a greater than expected tax burden and potentially exposes us to significant fines and penalties and enforcement measures, despite our best efforts at compliance. These factors raise the risk of a sudden imposition of arbitrary or onerous taxes on our operations in these countries. This could materially adversely affect our financial condition and results of operations.

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Selective or arbitrary government action may have an adverse effect on our business and the value of our common stock.

Government authorities have a high degree of discretion in Russia and have at times exercised their discretion selectively or arbitrarily, without hearing or prior notice, and sometimes in a manner that is influenced by political or commercial considerations. The government also has the power, in certain circumstances, to interfere with the performance of, nullify or terminate contracts. Selective or arbitrary actions have included withdrawal of licenses, sudden and unexpected tax audits, criminal prosecutions and civil actions. Federal and local government entities have also used common defects in documentation as pretexts for court claims and other demands to invalidate and/or to void transactions, apparently for political purposes. We cannot assure you that regulators, judicial authorities or third parties will not challenge our compliance with applicable laws, decrees and regulations in Russia. Selective or arbitrary government action could have a material adverse effect on our business and on the value of our common stock.

Shareholder liability under Russian legislation could cause us to become liable for the obligations of our subsidiaries.

The Russian Civil Code and the Law on Limited Liability Companies generally provide that shareholders in a Russian limited liability company are not liable for the obligations of the company and bear only the risk of loss of their investment. This may not be the case, however, when one person, an effective parent, is capable of determining decisions made by another, an effective subsidiary. The effective parent bears joint and several responsibilities for transactions concluded by the effective subsidiary in carrying out these decisions in certain circumstances.

In addition, a parent is secondarily liable for an effective subsidiary s debts if an effective subsidiary becomes insolvent or bankrupt as a result of the action or inaction of the parent. This is the case no matter how the parent s capability to determine decisions of the effective subsidiary arises. For example, this liability could arise through ownership of voting securities or by contract. In these instances, other shareholders of the effective subsidiary may claim compensation for the effective subsidiary s losses from the parent that caused the effective subsidiary to act or fail to act, knowing that such action or inaction would result in losses. Accordingly, in CBLI s position as a parent, it could be liable in some cases for the debts of its effective subsidiaries. Although the total indebtedness of CBLI s effective subsidiaries in Russia is currently immaterial, it is possible that CBLI could face material liability in this regard in the future, which could materially adversely affect our business and our results of operations.

Our majority-owned Russian subsidiaries can be forced into liquidation on the basis of formal noncompliance with certain legal requirements.

Our subsidiaries operate in Russia primarily through Incuron, BioLab 612, and the wholly-owned Russian subsidiary of Panacela, all of which were organized under the laws of the Russian Federation. Certain provisions of Russian law may allow a court to order the liquidation of a locally organized legal entity on the basis of its formal noncompliance with certain requirements during formation, reorganization or during its operations. Additionally, Russian corporate law allows the government to liquidate a company if its net assets fall below a certain threshold. Similarly, there have also been cases in Russia in which formal deficiencies in the establishment process of a legal entity or noncompliance with provisions of law have been used by courts as a basis for liquidation of a legal entity. Weaknesses in the legal systems of Russia create an uncertain legal environment, which makes the decisions of a court or a governmental authority difficult, if not impossible, to predict. If involuntary liquidation of either of the aforementioned entities were to occur, such liquidation could materially adversely affect our financial condition and results of operations.

Crime and corruption could disrupt our ability to conduct our business.

Political and economic changes in Russia in recent years have resulted in significant dislocations of authority. The local and international press has reported the existence of significant organized criminal activity, particularly in large metropolitan centers. In addition, the local and international press has reported high levels of corruption, including the bribing of officials for the purpose of initiating investigations by government agencies. Press reports have also described instances in which state officials have engaged in selective investigations and prosecutions to further the interests of the state and individual officials, as well as private businesses, including competitors and corporate raiders. Corruption in Russia is pervasive and, in some cases, is worsening. The government in Russia has recently pursued a campaign against corruption. However, there is no assurance that such laws or other laws enacted elsewhere will be applied with any effectiveness by the local authorities and the continuing effects of corruption, money laundering and other criminal activity could have a negative effect on the Russian economy and could materially adversely affect our business in Russia.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

In January 2014, in connection with our public offering, we issued to the placement agent and its affiliates warrants to purchase an aggregate of 172,132 shares of our common stock with an exercise price of $1.22 per share. The Company issued the warrants in

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reliance on the exemption from registration provided for under Section 4(2) of the Securities Act of 1933, as amended (the Securities Act). The Company relied on the exemption from registration provided for under Section 4(2) of the Securities Act based in part on the representations made by the placement agent, including the representations with respect to the placement agent s investment intent with respect to the warrants and the underlying shares of common stock. The placement agent had adequate access, through its relationship with us, to information about us.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

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Item 6. Exhibits

(a) The following exhibits are included as part of this report:

Exhibit Number	Description of Document
4.1	Form of Series A/B Warrant to Purchase Common Stock (Incorporated by reference to Form 8-K filed on January 15, 2014)
10.1	Letter Agreement, dated January 9, 2014, by and among Cleveland BioLabs, Inc. and H.C. Wainwright & Co., LLC (Incorporated by reference to Form 8-K filed on January 15, 2014)
10.2	Securities Purchase Agreement, dated January 14, 2014, by and among Cleveland BioLabs, Inc. and the Purchasers set forth therein (Incorporated by reference to Form 8-K filed on January 15, 2014)
31.1	Rule 13a-14(a)/15d-14(a) Certification of Yakov Kogan.
31.2	Rule 13a-14(a)/15d-14(a) Certification of C. Neil Lyons.
32.1	Certification pursuant to 18 U.S.C. Section 1350.
101.1	The following information from CBLI s Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of March 31, 2014 and December 31, 2013; (ii) Consolidated Statements of Operations for the Three Months Ended March 31, 2014 and 2013; (iii) Consolidated Statements of Comprehensive Loss for the Three Months Ended March 31, 2014 and 2013; (iv) Consolidated Statements of Cash Flows for the Three Months ended March 31, 2014 and 2013; (v) Consolidated Statements of Stockholders Equity for the Three Months Ended March 31, 2014; and (vi) Notes to Consolidated Financial Statements.*

* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

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Signatures

In accordance with 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 thereunto duly authorized.

CLEVELAND BIOLABS, INC.

Dated: May 12, 2014

By: /s/ YAKOV KOGAN
Yakov Kogan

Chief Executive Officer

(Principal Executive Officer)

Dated: May 12, 2014

By: /s/ C. NEIL LYONS
C. Neil Lyons

Chief Financial Officer

(Principal Financial Officer)