CLEVELAND BIOLABS INC
Form 10-Q
August 09, 2013

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2013

OR

o 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 incorporation or organization)	(I.R.S. Employer 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 July 31, 2013, there were 45,020,989 shares outstanding of registrant's common stock, par value $0.005 per share.

CLEVELAND BIOLABS INC. AND SUBSIDIARIES
10-Q
August 9, 2013

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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.”

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	June 30, 2013 (unaudited)	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$13,245,397	$ 25,652,083
Short-term investments	305,726	2,633,944
Accounts receivable	1,172,444	41,896
Other current assets	730,074	1,078,040
Total current assets	15,453,641	29,405,963
Equipment, net	880,326	986,553
Restricted cash	1,465,214	1,577,920
Other long-term assets	54,033	39,597
Total assets	$17,853,214	$ 32,010,033
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,194,219	$ 1,523,875
Accrued expenses	3,021,424	2,410,592
Deferred revenue	2,450,569	3,314,918
Accrued warrant liability	4,757,770	4,105,659
Current portion of capital lease obligation	77,886	71,679
Total current liabilities	11,501,868	11,426,723
Noncurrent portion of capital lease obligation	50,827	97,602
Commitments and contingencies	-	-
Total liabilities	11,552,695	11,524,325
Stockholders' equity:		
Preferred stock, $.005 par value; 10,000,000 shares authorized, 0 shares issued and outstanding as of June 30, 2013 and December 31, 2012, respectively	-	-
Common stock, $.005 par value; 160,000,000 shares authorized, 44,970,989 shares issued and outstanding as of June 30, 2013; 80,000,000 shares authorized, 44,730,445 shares issued and outstanding as of December 31, 2012	224,855	223,653
Additional paid-in capital	124,792,077	123,864,830
Accumulated other comprehensive income	288,467	546,473
Accumulated deficit	(131,108,223)	(118,301,789)
Total Cleveland BioLabs, Inc. stockholders' (deficit) equity	(5,802,824)	6,333,167
Noncontrolling interest in stockholders' equity	12,103,343	14,152,541
Total stockholders' equity	6,300,519	20,485,708

Total liabilities and stockholders' equity	$17,853,214	$ 32,010,033

See Notes to Consolidated Financial Statements

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2013	2012	2013	2012
Revenues:				
Grants and contracts	$ 1,613,262	$ 258,237	$ 2,980,734	$ 1,189,634
Operating expenses:				
Research and development	5,373,029	6,093,275	10,704,644	12,079,076
General and administrative	3,016,851	3,326,686	6,500,223	5,754,157
Total operating expenses	8,389,880	9,419,961	17,204,867	17,833,233
Loss from operations	(6,776,618)	(9,161,724)	(14,224,133)	(16,643,599)
Other income (expense):				
Interest and other income	47,809	70,252	127,765	125,893
Foreign exchange gain (loss)	46,776	641,332	74,910	(51,084)
Change in value of warrant liability	2,795,612	2,543,270	(652,111)	4,263,026
Total other income (expense)	2,890,197	3,254,854	(449,436)	4,337,835
Net loss	(3,886,421)	(5,906,870)	(14,673,569)	(12,305,764)
Net loss attributable to noncontrolling interests	844,310	828,186	1,867,135	1,839,934
Net loss attributable to Cleveland BioLabs, Inc.	$ (3,042,111)	$ (5,078,684)	$ (12,806,434)	$ (10,465,830)
Net loss available to common stockholders per share of common stock, basic and diluted	$ (0.07)	$ (0.14)	$ (0.29)	$ (0.29)
Weighted average number of shares used in calculating net loss per share, basic and diluted	44,948,591	35,745,675	44,887,920	35,701,619

See Notes to Consolidated Financial Statements

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2013	2012	2013	2012
Net income/(loss) including noncontrolling interests	$ (3,886,421)	$ (5,906,870)	$ (14,673,569)	$ (12,305,764)
Other comprehensive income (loss)				
Foreign currency translation adjustment	(282,622)	(668,874)	(440,069)	65,764
Comprehensive income/(loss) including noncontrolling interests	(4,169,043)	(6,575,744)	(15,113,638)	(12,240,000)
Comprehensive loss attributable to noncontrolling interests	961,118	1,122,633	2,049,198	1,815,293
Comprehensive income/(loss) attributable to Cleveland BioLabs, Inc.	$ (3,207,925)	$ (5,453,111)	$ (13,064,440)	$ (10,424,707)

See Notes to Consolidated Financial Statements

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 January 1, 2013	44,730,445	$223,653	$123,864,830	$546,473	$(118,301,789)	$14,152,541	$20,485,70
Stock based compensation	230,863	1,154	914,903				916,057
Exercise of options	9,681	48	12,344				12,392
Net loss					(12,806,434)	(1,867,135)	(14,673,5
Foreign currency translation				(258,006)		(182,063)	(440,069
Balance at June 30, 2013	44,970,989	$224,855	$124,792,077	$288,467	$(131,108,223)	$12,103,343	$6,300,519

See Notes to Consolidated Financial Statements

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

	For the Six Months Ended June 30,	
	2013	2012
Cash flows from operating activities:		
Net income (loss)	$ (14,673,569)	$ (12,305,764)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	189,840	257,641
Unrealized loss on short-term investments	-	12,801
Noncash compensation	1,122,857	1,222,552
Change in value of warrant liability	652,111	(4,263,026)
Changes in operating assets and liabilities:		
Accounts receivable	(1,155,910)	1,701,736
Other current assets	303,845	(494,131)
Other long-term assets	(16,801)	(2,592)
Accounts payable	(322,004)	(234,314)
Deferred revenue	(661,811)	-
Accrued expenses	437,647	1,935,580
Net cash used in operating activities	(14,123,795)	(12,169,517)
Cash flows from investing activities:		
Purchase of short-term investments	-	(4,973,524)
Sale of short-term investments	2,256,834	1,347,181
Purchase of equipment	(85,800)	(116,355)
Net cash provided by (used in) investing activities	2,171,034	(3,742,698)
Cash flows from financing activities:		
Noncontrolling interest capital contribution to Incuron, LLC	-	5,893,557
Exercise of options	12,392	1,425
Repayment of capital lease obligation	(40,568)	(20,221)
Net cash provided by (used in) financing activities	(28,176)	5,874,761
Effect of exchange rate change on cash and equivalents	(425,749)	394,545
Decrease in cash and cash equivalents	(12,406,686)	(9,642,909)
Cash and cash equivalents at beginning of period	25,652,083	22,872,589
Cash and cash equivalents at end of period	$ 13,245,397	$ 13,229,680
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 12,714	$ 10,226
Supplemental schedule of noncash financing activities:		
Equipment acquired through lease financing	$ -	$ 221,690

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. (“CBLI”) is a clinical-stage biotechnology company with a focus on oncology drug development. Since inception, CBLI has pursued the research, development and commercialization of products that have the potential to treat cancer, reduce death from total body irradiation and counteract the toxic effects of radio- and chemotherapies for oncology patients.

CBLI is incorporated under the laws of the State of Delaware and is headquartered in Buffalo, New York. CBLI has one wholly-owned operating subsidiary, BioLab 612, LLC (“BioLab 612”), which began operations in 2012. CBLI also has two majority-owned operating subsidiaries, Incuron, LLC (“Incuron”) and Panacela Labs, Inc. (“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, collectively referred to herein as the “Company.” All significant intercompany balances and transactions have been eliminated in consolidation.

The unaudited consolidated financial statements included herein have been prepared in accordance with U.S. generally accepted accounting principles 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 ("SEC"). Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles 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, 2012, as filed with the SEC, as amended.

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 June 30, 2013, along with its results of operations for the three and six month periods ended June 30, 2013 and 2012 and cash flows for the six month periods ended June 30, 2013 and 2012. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (“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 $13.2 million and $25.7 million of cash and cash equivalents at June 30, 2013 and December 31, 2012, respectively, $4.4 million and $13.0 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 June 30, 2013, $4.4 million of the Company's cash and cash equivalents was restricted to the use of its majority-owned subsidiaries, leaving $8.8 million available for general use.

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 June 30, 2013, all of the Company’s short-term investments were restricted to the use of its majority-owned subsidiaries.

Significant Customers and Accounts Receivable

Grant and contract revenue from the United States government accounted for 37.7% and 34.8% of total revenue for the three and six months ended June 30, 2013, respectively, and 100.0% of total revenue for both the three and six months ended June 30, 2012.

Grant and contract revenue received by subsidiaries from Russian government agencies accounted for 62.3% and 65.2% of total revenues for the three and six months ended June 30, 2013, respectively, and 0% for both the three and six months ended June 30, 2012.

Although the Company anticipates ongoing federal 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 June 30, 2013 and December 31, 2012, 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 (“G&A expenses”) as incurred, since the recoverability of such expenditures is uncertain. Upon marketability approval by the U.S. Food and Drug Administration (“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 (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 June 30, 2013, an aggregate of 10.0 million shares of common stock were authorized for issuance under the Plan, of which a total of approximately 2.1 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 (“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 June 30, 2013, there are 2,100,000 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 six months ended June 30,	
	2013	2012
Risk-free interest rate	0.02 - 1.92%	0.75 - 1.49%
Expected dividend yield	0%	0%
Expected life (Years)	5 - 7.3	5 - 6
Expected volatility	80.71 - 89.66%	86.58 - 92.24%

"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 and six months ended June 30, 2013 and 2012, as the Company does not expect to have taxable income for 2013 and did not have taxable income in 2012. 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 June 30,	
Common Equivalent Securities	2013	2012
Warrants	10,377,995	6,065,495
Options	5,683,944	4,716,012
Total	16,061,939	10,781,507

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 or other material legal proceedings.

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.

The following tables represent the Company's fair value hierarchy for its financial liabilities measured at fair value on a recurring basis as of June 30, 2013 and December 31, 2012:

	As of June 30, 2013			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Compensatory stock options not yet issued (1)	$-	$-	$63,838	$63,838
Accrued warrant liability	-	-	4,757,770	4,757,770
Total liabilities	$-	$-	$4,821,608	$4,821,608

	As of December 31, 2012			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Accrued warrant liability	$-	$-	$4,105,659	$4,105,659
Total liabilities	$-	$-	$4,105,659	$4,105,659

(1) Included in accrued expenses in the accompanying consolidated balance sheets.

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 June 30, 2013 and December 31, 2012, which were determined in a manner consistent with that described for grants of options to purchase common stock as set forth in Note 2:

	June 30, 2013	December 31, 2012
Stock Price	$1.58	$1.33
Exercise Price	$1.60 - 5.00	$1.60 - 5.00
Term in years	0.84 - 2.16	1.09 - 2.41
Volatility	68.47 - 87.18%	82.75 - 95.91%
Annual rate of quarterly dividends	0%	0%
Discount rate- bond equivalent yield	.13 - .40%	.17 - .29%

The following are the assumptions used to measure the compensatory stock options not yet issued at June 30, 2013:

	June 30, 2013	
Stock price	$ 1.58	
Term in years	5	
Volatility	80.80	%
Annual rate of quarterly dividends	0	%
Discount rate - bond equivalent yield	1.41	%

The following table sets forth a summary of changes in the fair value of the Company's Level 3 fair value measurements for the six months ended June 30, 2013 and 2012:

	Three months ended June 30, 2013		Six months ended June 30, 2013	
	Accrued Warrant Liability	Compensatory Stock Options Not Yet Issued	Accrued Warrant Liability	Compensatory Stock Options Not Yet Issued
Beginning balance	$ 7,553,382	$ 63,641	$ 4,105,659	$ -
Total (gains) or losses, realized and unrealized, included in earnings (1)	(2,795,612)	-	652,111	-
Estimates and other changes in fair value (2)	-	197	-	63,838
Settlements	-	-	-	-
Balance, June 30, 2013	$ 4,757,770	$ 63,838	$ 4,757,770	$ 63,838

	Three months ended June 30, 2012		Six months ended June 30, 2012	
	Accrued Warrant Liability	Compensatory Stock Options Not Yet Issued	Accrued Warrant Liability	Compensatory Stock Options Not Yet Issued
Beginning balance	$ 5,566,203	$ 85,000	$ 7,285,959	$ 378,750
Total (gains) or losses, realized and unrealized, included in earnings (1)	(2,543,270)	-	(4,263,026)	51,823
Estimates and other changes in fair value (2)	-	29,617	-	114,617
Settlements	-	-	-	(430,573)
Balance, June 30, 2012	$ 3,022,933	$ 114,617	$ 3,022,933	$ 114,617

(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 and six month periods ended June 30, 2013 and 2012.

(2) Expenses recorded for compensatory stock options not yet issued are included in research & development expense and general and administrative expense.

As of June 30, 2013 and December 31, 2012, 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 measurements:

	June 30, 2013			
Description	Fair Value	Valuation Technique	Unobservable Input	Estimate/ Range
Compensatory stock options not yet issued	$ 63,838	Black-scholes pricing model	Expected term	5
			Quantity of options	62,500
Accrued warrant liability	4,757,770	Black-scholes pricing model	Expected term	0.84 - 2.16
	$ 4,821,608			

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.

4. Stockholders' Equity

The Company has granted options to purchase shares of common stock and shares of restricted stock. The following is a summary of option award activity during the six months ended June 30, 2013:

	Six months ended June 30, 2013			
	Total Stock Options Outstanding	Weighted Average Exercise Price per Share	Nonvested Stock Options	Weighted Average Grant Date Fair Value per Share
December 31, 2012	5,016,916	$ 4.54	404,500	$ 2.30
Granted	863,604	1.68	863,604	1.22
Vested	-	-	(389,750)	1.75
Exercised	(9,681)	1.28	-	-
Forfeited, Canceled	(186,895)	2.63	(121,250)	0.94
June 30, 2013	5,683,944	$ 4.18	757,104	$ 1.56

The following is a summary of outstanding stock options as of June 30, 2013:

	As of June 30, 2013	
	Stock Options Outstanding	Vested Stock Options
Quantity	5,683,944	4,926,840
Weighted-average exercise price	$4.18	$ 4.49
Weighted Average Remaining Contractual Term (in Years)	7.24	6.90
Intrinsic value	$146,762	$ 129,358

For the six months ended June 30, 2013 and 2012, the Company granted 863,604 and 639,500 stock options, respectively, with a weighted-average grant date fair value of $1.22 and $1.61, respectively. For the six months ended June 30, 2013 and 2012, the total fair value of options vested was $681,599 and $996,698, respectively. The total intrinsic value of options exercised for the six months ended June 30, 2013 and 2012 was $5,736 and $1,500, respectively.

As of June 30, 2013, total compensation cost not yet recognized related to nonvested stock options was $785,099. The Company expects to recognize this cost over a weighted average period of approximately 1 year.

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5. Warrants

In connection with sales of the Company's common stock, warrants were issued with exercise prices ranging from $1.60 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 June 30, 2013, the Company had warrants outstanding that are exercisable into 10,377,995 shares of common stock, with a weighted average exercise price of $2.76 per share. There was no warrant activity during six months ended June 30, 2013.

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," "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, 2012, as amended, 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, 2012, as amended. 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, 2012, as amended.

OVERVIEW

We are a clinical-stage biotechnology company with a focus on oncology drug development whose lead drug candidate, Entolimod, is being developed for dual indications: under an FDA regulation commonly referred to as the "Animal Rule" as a radiation countermeasure; and under the FDA's traditional drug approval pathway as a targeted cancer therapeutic. Since our inception, we have pursued the research, development and commercialization of products that have the potential to treat cancer, reduce death from total body irradiation and counteract the side effects of radio- and chemotherapies for oncology patients. Presently, nine product candidates are under development directly by us and our majority-owned subsidiaries.

See "Part I, Item 1. Business" in our Annual Report on Form 10-K for the year ended December 31, 2012, as amended, 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 ("U.S. 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, 2012, as amended. 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, 2012, as amended.

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 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 June 30, 2013, we held approximately $4.8 million in accrued expenses primarily related to warrants to purchase common stock, which we classified as Level 3.

Three Months Ended June 30, 2013 Compared to Three Months Ended June 30, 2012

Revenue

Revenue increased from $0.3 million for the three months ended June 30, 2012 to $1.6 million for the three months ended June 30, 2013, representing an increase of $1.3 million, or 525%. This increase was primarily related to an increase of $1.0 million related to our Russian grants and contracts and $0.3 million from our contracts with the U.S. Department of Defense ("DoD"). The revenues related to our contracts and grants and differences between the periods are set forth in the following table:

Funding Source	Program	Three Months Ended June 30, 2013	2012	Variance
DoD	CBMS-MITS Contract	$ 335,722	$ 183,111	$ 152,611
Russian Federation Ministry of Industry & Trade	CBLB612 Pre-clinical (1)	404,626	-	404,626
DoD	DTRA Contract	272,272	75,126	197,146
		1,012,620	258,237	754,383
Skolkovo Foundation	Curaxin research (1)	401,043	-	401,043
Russian Federation Ministry of Industry & Trade	Xenomycins Pre-clinical (1)	199,599	-	199,599
		$ 1,613,262	$ 258,237	$ 1,355,025

(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 June 30, 2013		
Funding Source	Program	Total Award Value	Funded Award Value	Cumulative Revenue Recognized	Funded Backlog
DoD	CBMS-MITS Contract (1)	$ 48,322,695	$ 6,933,761	$ 6,093,392	$ 840,369
Russian Federation Ministry of Industry & Trade	CBLB612 Pre-clinical (2)	4,326,147	2,974,837	1,551,475	1,423,362
DoD	DTRA Contract (3)	2,359,548	2,035,452	1,959,221	76,231
		55,008,390	11,944,050	9,604,088	2,339,962
Russian Federation Ministry of Industry & Trade	Xenomycins Pre-clinical (2)	4,560,523	3,383,477	1,323,996	2,059,481
Skolkovo Foundation	Curaxin research (2)	4,704,411	4,704,411	2,482,578	2,221,833

$ 64,273,323	$ 20,031,937	$ 13,410,662	$ 6,621,275

(1) Includes a $30 million conditional purchase option for 37,500 doses of Entolimod as a radiation countermeasure, exercisable upon approval.
(2) 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 June 30, 2013 exchange rate.
(3) On July 10, 2013, we received $324,096 of funding from DTRA, making the contract fully funded. This funding is not reflected in the funded award value as of June 30, 2013.

Research and Development Expenses

Research and development ("R&D") expenses decreased from $6.1 million for the three months ended June 30, 2012 to $5.4 million for the three months ended June 30, 2013, representing a decrease of $0.7 million, or 12%. This net decrease primarily reflected decreases of $0.9 million for Entolimod for Biodefense applications as we worked towards the completion of a pivotal non-human primate ("NHP") study during the three months ended June 30, 2012, $0.8 million related to a decline in the pace of development of preclinical assets at Panacela, and a $0.1 million decline related to Entolimod for Oncology applications. We are in the process of amending the protocol for Entolimod's Phase 1 oncology trial being conducted at Roswell Park Cancer Institute ("RPCI"), with the objective of accelerating and enhancing the trial to better capture the immunostimulatory properties of Entolimod. These decreases were partially offset by increases of $0.8 million in costs related to our Curaxin compounds due to our recently initiated clinical trial in the U.S. and our ongoing clinical trial in Russia, both for the CBL0137 drug candidate, and $0.3M to prepare CBLB612's dossier of information for an investigational new drug application ("IND") filing in Russia. The following table sets forth our R&D expenses by drug candidate:

	Three Months Ended June 30,		
	2013	2012	Variance
Entolimod for Biodefense Applications	$ 2,735,190	$ 3,610,619	$(875,429)
CBLB612	573,572	272,904	300,668
Entolimod for Oncology Applications	40,144	200,781	(160,637)
	3,348,906	4,084,304	(735,398)
Curaxins	1,231,592	408,996	822,596
Panacela product candidates	792,532	1,599,975	(807,443)
Total R&D expenses	$ 5,373,029	$ 6,093,275	$(720,246)

General and Administrative Expenses

General and administrative costs decreased from $3.3 million for the three months ended June 30, 2012 to $3.0 million for the three months ended June 30, 2013, representing a decrease of $0.3 million, or 9%. This net decrease was due to decreases of $0.4 million in business development costs and $0.3 million in stock based compensation. These decreases were partially offset by increases of $0.2 million related to our Russian-based subsidiaries including BioLabs 612 which was not operational in 2012 and $0.2 million in corporate legal and intellectual property fees.

Other Income and Expenses

Other income decreased from $3.3 million for the three months ended June 30, 2012 to $2.9 million for the three months ended June 30, 2013, representing a decrease of $0.4 million, or 11%. This net decrease was primarily attributable to a decrease in foreign exchange gains of $0.6 million, which was the result of a foreign exchange gain recorded for the three months ended June 30, 2012, and a decrease of $0.1 million in interest and other income. These decreases were partially offset by a $0.3 million increase in the change in the value of our warrant liability for the three months ended June 30, 2013 as compared to June 30, 2012, primarily driven by the change in the fair market value of our stock price.

Six Months Ended June 30, 2013 Compared to Six Months Ended June 30, 2012

Revenue

Revenue increased from $1.2 million for the six months ended June 30, 2012 to $3.0 million for the six months ended June 30, 2013, representing an increase of $1.8 million, or 151%. This increase was primarily related to an increase of $1.9 million related to our Russian grants and contracts. The increase was partially offset by a decrease of $0.1 million from our contracts with the DoD. The revenues related to our contracts and grants and differences between the periods are set forth in the following table:

Funding Source	Program	Six Months Ended June 30, 2013	2012	Variance
DoD	CBMS-MITS Contract	$ 671,444	$ 1,062,945	$ (391,501)
Russian Federation Ministry of Industry & Trade	CBLB612 Pre-clinical (1)	662,789	-	662,789
DoD	DTRA Contract	366,656	126,689	239,967
		1,700,889	1,189,634	511,255
Skolkovo Foundation	Curaxin research (1)	905,113	-	905,113
Russian Federation Ministry of Industry & Trade	Xenomycins Pre-clinical (1)	374,732	-	374,732
		$ 2,980,734	$ 1,189,634	$ 1,791,100

(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.

Research and Development Expenses

R&D expenses decreased from $12.1 million for the six months ended June 30, 2012 to $10.7 million for the six months ended June 30, 2013, representing a decrease of $1.4 million, or 11%. This decrease primarily reflected decreases of $2.4 million for Entolimod for Biodefense applications as we worked towards the completion of a pivotal NHP study during the six months ended June 30, 2012, $0.3 million related to our Panacela product candidates and $0.1 million related to Entolimod for Oncology applications. These decreases were partially offset by increases of $1.2 million in costs related to Curaxin compounds due to our recently initiated clinical trial in the U.S. and our ongoing clinical trial in Russia, both for the CBL0137 drug candidate, and $0.2 million to prepare CBLB612's dossier of information for an IND filing in Russia. The following table sets forth our R&D expenses by drug candidate:

	Six Months Ended June 30, 2013	2012	Variance
Entolimod for Biodefense Applications	$5,050,319	$7,417,587	$(2,367,268)
CBLB612	788,013	559,653	228,360
Entolimod for Oncology Applications	250,830	396,983	(146,153)
	6,089,162	8,374,223	(2,285,061)
Curaxins	2,696,491	1,439,299	1,257,192
Panacela product candidates	1,918,990	2,265,554	(346,564)
Total R&D expenses	$10,704,644	$12,079,076	$(1,374,432)

General and Administrative Expenses

General and administrative costs increased from $5.8 million for the six months ended June 30, 2012 to $6.5 million for the six months ended June 30, 2013, representing an increase of $0.7 million, or 13%. This increase was primarily attributable to increases of $0.4 million related to our Russian-based subsidiaries including BioLabs 612 which was not operational in 2012 and $0.3 million in corporate legal and intellectual property fees.

Other Income and Expenses

Other income (expense) decreased from $4.3 million of other income for the six months ended June 30, 2012 to $0.5 million of other expense for the six months ended June 30, 2013, representing a decrease of $4.8 million, or 110%.

The change in the value of our warrant liability decreased by $4.9 million for the six months ended June 30, 2013 as compared to June 30, 2012, primarily driven by the change in the fair market value of our stock. This decrease was partially offset by an increase in foreign exchange gains of $0.1 million for the six months ended June 30, 2013 as compared to the six months ended June 30, 2012.

Liquidity and Capital Resources

We have incurred net losses of $131.1 million since inception through June 30, 2013. Historically, we have not generated, and do not expect to generate, revenue from sales of product candidates in the immediate future. Since our founding in 2003, we have funded our operations through a variety of means:

- Since our inception in 2003, we have raised $107.7 million of net equity capital, including amounts received from the exercise of options and warrants.
- The U.S. Department of Defense and Department of Health and Human Services awarded grants and contracts totaling $85.9 million for the development of Entolimod as a radiation countermeasure, including a $30 million purchase option for 37,500 doses, which is exercisable upon FDA approval. Of the total amount awarded, we earned $43.3 million through June 30, 2013 and expect to earn $1.2 million during the remainder of 2013. Additionally, we submitted a proposal to Biomedical Advanced Research and Development Agency ("BARDA") for the continued development of Entolimod as a radiation countermeasure. If awarded in full, this contract could fund all remaining work necessary to complete development of Entolimod as a radiation countermeasure and allow us to file a Biologic License Application ("BLA") with the FDA. There can be no assurance that the proposal for the BARDA funding will be granted, and if granted, when such award will be made.
- Entities affiliated with the Russian Federation have awarded us contracts totaling $13.6 million, including awards for the development of Curaxins ($4.7 million), CBLB612 ($4.3 million) and Xenomycins ($4.6 million). All awards are valued based on revenue recognized to date, with the remaining backlog valued at the June 30, 2013 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 and future expenses. At June 30, 2013, $11.1 million of the awards were funded; $7.3 million was received, of which $2.5 million remains as deferred revenue. We expect to recognize the remaining funding in 2013 and 2014.
- We have been awarded $4.0 million in grant and contracts not described above, all of which has been recognized at June 30, 2013.
- We actively pursue all reasonable domestic and international sources of grant and contract funding for our drug pipeline.
- Incuron was formed to develop and commercialize our Curaxin product line, namely two compounds CBL0102 and CBL0137. BioProcess Capital Partners ("BCP") committed to contribute up to $17.2 million (based on the current 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 $5.5 million is due upon completion of certain developmental milestones which the Company believes will occur in 2013.
- Panacela was formed to develop and commercialize five preclinical compounds. Open Joint Stock Company "Rusnano" contributed $9.0 million at formation and has commitments to contribute up to $17 million of additional funding as development milestones are accomplished. CBLI contributed $3.0 million plus intellectual property at formation and has options to contribute additional capital based on agreed-upon terms.

At June 30, 2013, we had cash, cash equivalents and short-term investments of $13.6 million. Of that total, $4.8 million was restricted for the use of our majority-owned subsidiaries, leaving $8.8 million available for general use. Additionally, at June 30, 2013, we had accounts receivable of $1.2 million, of which $1.0 million was due to us and the balance of $0.2 million to our majority-owned subsidiaries. Furthermore, Panacela had $1.5 million of restricted cash as a performance bond in connection with the Xenomycin grant, which is classified as a long-term asset.

Operating Activities

Net cash used in operations increased by $1.9 million to $14.1 million for the six months ended June 30, 2013 from $12.2 million for the six months ended June 30, 2012. After adjusting for non-cash items, the net loss decreased by $2.4 million, while changes in working capital used cash and cash equivalents of $4.3 million between the periods.

Investing Activities

Net cash provided by investing activities was $2.2 million for the six months ended June 30, 2013, compared to net cash used in investing activities of $3.7 million for the six months ended June 30, 2012, representing an increase of $5.9 million between the periods. This fluctuation was caused by the sale of $2.3 million of short-term investments for the six months ended June 30, 2013, as compared to the net purchase of $3.6 million of short-term investments for the six months ended June 30, 2012.

Financing Activities

Net cash provided by financing activities decreased from $5.9 million for the six months ended June 30, 2012 to $0.0 million for the six months ending June 30, 2013, which was primarily attributable to a capital contribution by BCP to Incuron during the quarter ended June 30, 2012.

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 2014, 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 June 30, 2013, our foreign currency obligations were not material.

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 six months of 2013. 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, 2012, as amended.

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 June 30, 2013. 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 June 30, 2013, 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 June 30, 2013, 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

As of June 30, 2013, we were not a party to any litigation or other legal proceeding.

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, 2012, as amended.

RISKS RELATED TO OUR FINANCIAL CONDITION AND NEED FOR ADDITIONAL CAPITAL

* 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 $12.8 million and $131.1 million for the six months ended June 30, 2013 and since inception, respectively. We expect significant losses to continue for the next few years as we spend substantial additional sums on the continued R&D 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.

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, Entolimod;
our ability to bring to market other proprietary drugs that are progressing through our development process;
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 will require substantial additional financing in order to meet our business objectives.

We are and will continue to be dependent on our ability to raise money through the issuance of additional equity or debt securities, or by entering into other financial arrangements, including relationships with corporate and other partners, in order to cover our operational costs, including the costs of product development and clinical testing.

Depending upon market conditions and subject to limitations imposed by the terms of our outstanding securities and contractual obligations, we may not be successful in raising sufficient additional capital for our long-term requirements. In addition, 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. Our internal sources of liquidity may prove to be insufficient, and in such case, we may not be able to successfully obtain financing on favorable terms, or at all. If we fail to raise sufficient additional financing and 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 R&D, slow the development of our product candidates, outsource or eliminate several business functions or shut down operations. Even if we are successful in raising such additional financing, we may not be able to successfully complete pre-clinical studies or clinical trials, development, and marketing of all, or of any, of our product candidates. Additionally, funds raised through debt financing would require us to make periodic payments of interest and principal and might impose restrictive covenants on the conduct of our business. 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.

Our R&D expenses are subject to uncertainty.

We are highly dependent on the success of our R&D efforts and, ultimately, upon regulatory approval and market acceptance of our products under development. Our ability to complete our R&D on schedule is, however, subject to a number of risks and uncertainties. Because we expect to expend substantial resources on R&D, our success depends in large part on the results as well as the costs of our R&D. R&D expenditures are uncertain and subject to much fluctuation. Factors affecting our R&D expenses include, but are not limited to:

the number and outcome of pre-clinical studies and clinical trials we are planning to conduct; for example, our R&D expenses may increase based on the number of pivotal animal studies and clinical trials that we may be required to conduct;
the number of products entering into development from late-stage research; for example, there is no guarantee that internal research efforts will succeed in generating sufficient data for us to make a positive development decision or that an external drug candidate will be available on terms acceptable to us and some promising product candidates may not yield sufficiently positive pre-clinical results to meet our stringent development criteria;
in-licensing activities, including the timing and amount of related development funding or milestone payments; for example, we may enter into agreements requiring us to pay a significant up-front fee for the purchase of in-process R&D that we may record as R&D expense; or
future levels of revenue; R&D expenses as a percentage of future potential revenues can fluctuate with the changes in future levels of revenue and lower revenues can lead to less spending on R&D efforts.

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

As of December 31, 2012, we had federal net operating loss carryforwards, or NOLs, of $94.1 million to offset future taxable income, which 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.

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 and technological advances and to translate such advances into reliable, commercially competitive products on a timely basis. In addition, the success or our subsidiaries will depend on their ability to meet developmental milestones in a timely manner, which are pre-requisites to their receipt of additional funding from the respective non-controlling interest holders. 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 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 an 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 other product candidates. Our business depends on our ability to sell drugs to both government agencies and to the general pharmaceutical market. Offering our product candidates for non-medical applications to government agencies does not require us to develop new sales, marketing or distribution capabilities beyond those already existing in the company. Selling oncology and anti-infective drugs, however, requires a more significant infrastructure. We plan to sell oncology and anti-infective 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 collaborations with third parties capable of providing these services. 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 ("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 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 for biodefense applications and clinical trials of Entolimod, CBL0102 and CBL0137 for oncology applications. In addition, we are seeking FDA agreement on the scope and design of our pivotal animal efficacy and human safety program for Entolimod for biodefense applications. Delay in agreement with the FDA on this program will delay conduct of the pivotal animal efficacy and human safety studies.

Agreements with contract research organizations ("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 ("GLP"), 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 Entolimod or other product candidates.

Our clinical trial operations are 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 (“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 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; and
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.

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 U.S. 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 June 30, 2013, we owned 59.2% of the equity interests in Incuron and 54.6% of the equity interests in Panacela. Although these subsidiaries are 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 subsidiary, and if a co-owner changes, our relationship may be materially adversely affected.

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. In the case of Panacela, we are required to meet the milestones within set time periods. As of June 30, 2013, Incuron and Panacela were potentially entitled to $5.5 million and $17 million of future milestone-based payments, respectively (in the case of Incuron, based on an exchange rate of $32.709 Rubles/USD as of June 30, 2013). The financing of our future subsidiaries may also be dependent on the satisfaction of similar milestones. The failure to satisfy the contractual requirements that we have with our co-owners in respect of obtaining additional financing from them may result in a material adverse effect in our business, financial condition

and results of operations.

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. Our future subsidiaries may also have significant non-controlling interest holders and the agreements with our co-owners may contain terms similar to those described above.

* 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 clinical supplies and 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 clinical trials. We rely on one collaborator to produce Entolimod, one collaborator to produce CBL0102, one collaborator to produce CBL0137, one collaborator to produce CBLB612 and one collaborator to produce Mobilan, and we do not have any collaborative manufacturing agreements for our other product candidates. For a variety of reasons, dependence on any single manufacturer may adversely affect our ability to develop and commercialize our product candidates on 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 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 U.S. 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.

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 U.S. 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 for biodefense applications. The Animal Rule permits the use of animal efficacy studies together with human clinical safety and immunogenicity 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. In fact, to date no new pharmaceuticals have been approved under the Animal Rule. As such the FDA is setting rule-making precedent given our advanced stage of development and, consequently, we cannot predict the time required for them to confirm the relevant rules, or the scope thereof. The FDA may decide that our data are insufficient for 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 biodefense applications, 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 for biodefense applications was transferred within the FDA from the Division of Biologic Oncology Products ("DBOP") to the Division of Medical Imaging Products ("DMIP"). As a result of this transfer, we requested and participated in seven additional meetings with DMIP during 2011-2012 to review the product mechanisms of action, safety profile and preliminary estimation of an effective human dose. While (i) DMIP has agreed on the scope and design of the proposed pivotal animal efficacy program, 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, and (ii) gave advice on the design of the remaining clinical program, 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 preclinical 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 U.S., the Russian Federation and other countries and regulatory jurisdictions. In order to market our product candidates in the U.S., 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 U.S.and Europe and may need to engage and rely upon expertise of third parties when we file for marketing approval in countries outside of the U.S.and Europe. Also, the time required to obtain approval in markets outside of the U.S. 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 U.S. 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 for biodefense applications outside the U.S. 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 for biodefense applications. 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.

Even if our drug candidates obtain regulatory approval, we will be subject to ongoing 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 may require post-market testing and surveillance to monitor the product's safety or efficacy, including additional clinical studies, known as Phase 4 trials, 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.

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, physicians and 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 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 lose our funding from R&D contracts and grants, or 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 United States government accounted for 34.8% and 100% of our revenue for the six months ended June 30, 2013 and 2012, respectively.

These revenues have funded some of our personnel and other R&D and General and Administrative costs and expenses. However, it is possible that awards that have been granted will not be funded in their entirety or that the funding will be delayed. It is also the case that we may not be able to procure new grants and contracts that provide sufficient funding, or 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, on May 31, 2011, we announced that we had concluded advanced stages of contract negotiation with BARDA for the funding of certain development activities relating to Entolimod for biodefense applications in our 2010 proposal to BARDA. BARDA indicated that further contract-related negotiations will require clarification of the development path for Entolimod for biodefense applications with the FDA, which is in the process of actively reviewing our IND application for Entolimod. BARDA indicated that we may 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 (the “BAA”). On April 4, 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 on October 18, 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. However, as with any federal contract proposal, there is no assurance that BARDA will make a positive decision with regard to funding our proposal. Additionally, there is no assurance that BARDA will review our proposal 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
- 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.

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

We have entered into contracts with various U.S. government agencies. For the near future, substantially all of our revenue may be derived from government contracts and grants. In contracting with government agencies, we will be 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 and modification by the government at its sole discretion, 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.

Furthermore, in most government contracts, including those awarded to us, much of the award amounts are not provided to the recipient until the underlying contract options are exercised. Such options may be exercised at the option of the government and, as a result, there is no guarantee that the government will exercise such options. If the U.S. government chooses not to exercise the options under the contracts it has with us, we will not be able to realize the full value of the awarded contracts, which may result in a material and adverse effect on our business, financial condition and results of operations.

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 (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, 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 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 the Cleveland Clinic Foundation ("CCF"), Roswell Park Cancer Institute ("RPCI") and Children's Cancer Institute Australia ("CCIA") 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.

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.

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 government 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.

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. Notwithstanding these arrangements, 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.

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, which could involve our directors and officers as defendants. We currently have 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.

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

We use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. As appropriate, we store these materials and wastes resulting from their use at our laboratory facility pending their ultimate use or disposal. We contract with a third party to properly dispose of these materials and wastes. We are 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 to comply with environmental laws and regulations adopted in the future.

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

Entolimod for biodefense applications is being developed to treat a disease 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.

We hope to continue receiving funding from the DoD and other government agencies for the development of Entolimod. Changes in government budgets and agendas, however, may 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 operations. Similarly, if we develop a 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 U.S. 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.

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 2012 through second quarter 2013, the market price of our common stock, which is listed on the NASDAQ Capital Market, fluctuated from a high of $4.06 per share in the first quarter of 2012 to a low of $1.15 in the second quarter of 2012. 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;
- 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 CCF, RPCI or our other 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 June 30, 2013, we had 44,970,989 shares of our common stock and no shares of our preferred stock issued and outstanding and warrants exercisable into 10,377,995 shares and 5,683,944 options outstanding. 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 common stock, including but not limited to acquisitions and business combinations, but do not currently have any definitive plans to enter into any of these transactions.

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.

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 your 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

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

Future deterioration in the international economic situation may cause financial instability in Russia and could adversely affect our business.

The Russian economy is vulnerable to market downturns and economic slowdowns elsewhere in the world, has experienced periods of considerable instability and has been subject to abrupt downturns. 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. More recently, the negative trends of the global economy and volatility in the financial markets, partially due to the recent debt crisis in Europe, have resulted in a decreased growth outlook for those countries dependent on Western Europe for trade. The Russian government has taken certain anti-crisis measures including using the “stabilization fund” and hard currency reserves to soften the impact of the global economic downturn on the Russian economy and support the value of the Russian

ruble. Should global economic conditions deteriorate significantly, it is possible that the Russian economy could continue to decline in the near future. Further economic instability in Russia where we operate through our consolidated subsidiaries and any future deterioration in the international economic situation could materially adversely affect our business, financial condition and results of operations.

Inflation in Russia and government efforts to combat inflation may contribute significantly to economic uncertainty in Russia and could materially adversely affect our financial condition and results of operations.

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 6.9% in 2010, 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.

* Political and governmental instability in Russia could materially adversely affect our business and operations in these countries.

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. Since the breakup of the U.S.S.R. in 1991, the political and economic situation in Russia has generally become more stable. However, there is still a risk of significant changes to the political and economic environment, potential changes in the direction of the reforms or reversal of the reforms. 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. Any disruption or reversal of reform policies could lead to political or governmental instability or the occurrence of conflicts among powerful economic groups, which could materially adversely affect our business and operations in Russia. Additionally, changes in governmental policies and objectives could affect our ability to apply for and/or receive non-dilutive grants from the Russian Government, such as the grants that we have received from Russian Federation Ministry of Industry & Trade and the Skolkovo Foundation totaling $13.6 million (based on current exchange rates).

A deterioration in political and economic relations between Russia and the United States could materially adversely affect our business and operations in Russia and generally.

Political and economic relations between Russia and the United States are complex. Political, ethnic, religious, historical and other differences have, on occasion, given rise to tensions. The emergence of new or escalated tensions could further exacerbate tensions between Russia and the United States and/or the European Union (EU) where we have manufacturing or other partners, which may have a negative effect on their economy. Any of the foregoing circumstances could materially adversely affect our business and operations in Russia and generally.

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.

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 (VAT), 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.

We may be exposed to liability for actions taken by our subsidiaries.

Under the laws of Russia, we may be jointly and severally liable for obligations of our subsidiaries. We may also incur secondary liability and, in certain cases, liability to creditors for obligations of our subsidiaries in certain instances involving bankruptcy or insolvency. This type of liability could result in significant obligations and could materially adversely affect our financial condition and results of operations.

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

Our majority-owned and wholly-owned subsidiaries operate in Russia primarily through Incuron, Panacela Labs, LLC and BioLab 612, 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

The Company issued 50,000 shares of the Company’s common stock on March 29, 2013 and an additional 50,000 shares of the Company’s common stock on June 27, 2013 to a consultant in exchange for consulting services provided by such consultant to the Company. The issuances of such shares were exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended. The purchaser had access to sufficient information regarding the Company so as to make an informed investment decision. More specifically, the Company had a reasonable basis to believe that the purchaser was an "accredited investor" and otherwise had the requisite sophistication to make an investment in the Company’s securities.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

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

Exhibit Number	Description of Document
3.1	Certificate of Amendment to the Restated Certificate of Incorporation, filed with the Secretary of State of Delaware on June 20, 2013.
10.1	Employment Agreement made as of April 4, 2013 and effective as of April 1, 2013 by and between Cleveland BioLabs, Inc. and Jean Viallet (Incorporated by reference to Form 8-K filed on April 9, 2013).
10.2	Cleveland Biolabs, Inc. 2013 Employee Stock Purchase Plan (Incorporated by reference to Form 8-K filed on June 20, 2013).
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 June 30, 2013, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of June 30, 2013 and December 31, 2012; (ii) Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2013 and 2012; (iii) Consolidated Statements of Comprehensive Loss for the Three and Six Months Ended June 30, 2013 and 2012; (iv) Consolidated Statements of Cash Flows for the Six Months ended June 30, 2013 and 2012; (v) Consolidated Statements of Stockholders' Equity for the Six Months Ended June 30, 2013; 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.

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: August 9, 2013	By:	/s/ YAKOV KOGAN Yakov Kogan Chief Executive Officer (Principal Executive Officer)
Dated: August 9, 2013	By:	/s/ C. NEIL LYONS C. Neil Lyons Chief Financial Officer (Principal Financial Officer)