CLEVELAND BIOLABS INC
Form 10-Q
November 09, 2012

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

OR

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

For the transition period from ____ to ____

Commission file number 001-32954

CLEVELAND BIOLABS, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	20-0077155
(State or other jurisdiction of 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 October 31, 2012, there were 43,435,309 shares outstanding of registrant's common stock, par value $0.005 per share.

CLEVELAND BIOLABS INC. AND SUBSIDIARIES
10-Q
11/9/2012

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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

	September 30, 2012 (unaudited)	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,188,573	$ 22,872,589
Short-term investments	6,954,820	5,520,000
Accounts receivable	82,035	1,740,629
Other current assets	1,321,196	876,889
Total current assets	20,546,624	31,010,107
Equipment, net	1,084,290	1,084,204
Other long-term assets	35,431	32,490
Total assets	$ 21,666,345	$ 32,126,801
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 440,520	$ 909,144
Accrued expenses	3,613,069	1,686,202
Deferred revenue	3,844,428	-
Accrued warrant liability	7,446,708	7,285,959
Current portion of capital lease obligation	69,172	-
Total current liabilities	15,413,897	9,881,305
Noncurrent portion of capital lease obligation	116,490	-
Commitments and contingencies	-	-
Total liabilities	15,530,387	9,881,305
Stockholders' equity:		
Preferred stock, $.005 par value; 10,000,000 shares authorized, 0 shares issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	-	-
Common stock, $.005 par value; 80,000,000 shares authorized, 35,934,809 and 35,612,192 shares issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	179,674	178,061
Additional paid-in capital	111,904,529	108,865,645
Accumulated other comprehensive income	463,661	84,613
Accumulated deficit	(121,411,313)	(100,067,647)
Total Cleveland BioLabs, Inc. stockholders' equity	(8,863,449)	9,060,672
Noncontrolling interest in stockholders' equity	14,999,407	13,184,824
Total stockholders' equity	6,135,958	22,245,496

Total liabilities and stockholders' equity	$	21,666,345	$	32,126,801

See Notes to Consolidated Financial Statements

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

	Three Months ended September 30,		Nine Months ended September 30,	
	2012	2011	2012	2011
Revenues:				
Grants and contracts	$ 219,575	$ 3,801,267	$ 1,409,209	$ 6,844,298
Operating expenses:				
Research and development	4,841,324	6,522,904	16,920,400	17,441,031
General and administrative	3,219,792	4,239,687	8,973,949	8,104,340
Total operating expenses	8,061,116	10,762,591	25,894,349	25,545,371
Loss from operations	(7,841,541)	(6,961,324)	(24,485,140)	(18,701,073)
Other income (expense):				
Interest and other income	228,580	52,776	354,473	158,106
Foreign exchange gain (loss)	(278,940)	36,555	(330,024)	(45,257)
Change in value of warrant liability	(4,423,775)	3,993,439	(160,749)	21,094,452
Total other income (expense)	(4,474,135)	4,082,770	(136,300)	21,207,301
Net income (loss)	(12,315,676)	(2,878,554)	(24,621,440)	2,506,228
Net loss attributable to noncontrolling interests	1,437,840	187,213	3,277,774	671,596
Net income (loss) attributable to Cleveland BioLabs, Inc.	$ (10,877,836)	$ (2,691,341)	$ (21,343,666)	$ 3,177,824
Net income (loss) available to common stockholders per share of common stock, basic	$ (0.30)	$ (0.08)	$ (0.60)	$ 0.10
Net income (loss) available to common stockholders per share of common stock, diluted	$ (0.30)	$ (0.08)	$ (0.60)	$ 0.09
Weighted average number of shares used in calculating net income (loss) per share, basic	35,879,245	35,447,032	35,761,260	31,553,562
Weighted average number of shares used in calculating net income (loss) per share, diluted	35,879,245	35,447,032	35,761,260	36,802,952

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME/(LOSS)
(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net income/(loss) including noncontrolling interests	$ (12,315,676)	$ (2,878,554)	$ (24,621,440)	$ 2,506,228
Other comprehensive income (loss)				
Foreign currency translation adjustment	593,124	(320,005)	658,888	(72,562)
Comprehensive income/(loss) including noncontrolling interests	(11,722,552)	(3,198,559)	(23,962,552)	2,433,666
Comprehensive loss attributable to noncontrolling interests	1,182,641	264,650	2,997,934	692,845
Comprehensive income/(loss) attributable to Cleveland BioLabs, Inc.	$ (10,539,911)	$ (2,933,909)	$ (20,964,618)	$ 3,126,511

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2012
(UNAUDITED)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interest	Total
Balance at January 1, 2012	35,612,192	$178,061	$108,865,645	$ 84,613	$(100,067,647)	$13,184,824	$22,245,496
Stock based compensation	321,867	1,609	1,956,423	-	-	-	1,958,032
Exercise of options	750	4	1,421	-	-	-	1,425
Noncontrolling interest capital contribution to Incuron, LLC	-	-	1,081,040	-	-	4,812,517	5,893,557
Net loss	-	-	-	-	(21,343,666)	(3,277,774)	(24,621,440)
Foreign currency translation	-	-	-	379,048	-	279,840	658,888
Balance at September 30, 2012	35,934,809	$179,674	$111,904,529	$ 463,661	$(121,411,313)	$14,999,407	$6,135,958

See Notes to Consolidated Financial Statements

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

	For the Nine Months Ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net income (loss)	$ (24,621,440)	$ 2,506,228
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	376,814	324,950
Amortization	-	13,147
Unrealized gain on short-term investments	138,910	-
Noncash compensation	2,272,020	3,063,477
Warrant issuance costs	-	150,827
Change in value of warrant liability	160,749	(21,094,452)
Patent costs	-	1,481,318
Changes in operating assets and liabilities:		
Accounts receivable	1,695,870	4,969,584
Other current assets	(435,305)	57,763
Other long-term assets	(2,554)	(890)
Accounts payable	(471,635)	65,753
Deferred revenue	3,821,991	(2,317,218)
Accrued expenses	1,609,369	170,055
Net cash used in operating activities	(15,455,211)	(10,609,458)
Cash flows from investing activities:		
Purchase of short-term investments	(4,898,314)	-
Sale of short-term investments	3,560,812	407,842
Issuance of note to Panacela Labs, LLC	-	(300,000)
Purchase of equipment	(154,742)	(508,128)
Investment in patents	-	(322,544)
Net cash used in investing activities	(1,492,244)	(722,830)
Cash flows from financing activities:		
Issuance of common stock, net of offering costs	-	21,946,801
Noncontrolling interest capital contribution to Incuron, LLC	5,893,557	2,340,374
Exercise of options	1,425	527,134
Repayment of capital lease obligation	(36,029)	-
Exercise of warrants	-	949,793
Net cash provided by financing activities	5,858,953	25,764,102
Effect of exchange rate change on cash and equivalents	404,486	(90,314)
Increase (decrease) in cash and cash equivalents	(10,684,016)	14,341,500
Cash and cash equivalents at beginning of period	22,872,589	10,918,537
Cash and cash equivalents at end of period	$ 12,188,573	$ 25,260,037
Supplemental disclosure of cash flow information:		

Cash paid during the period for interest	$ 17,253	$ -
Supplemental schedule of noncash financing activities:		
Equipment acquired through lease financing	$ 221,690	$ -
Conversion of warrant liability to equity upon warrant exercise	$ -	$ 995,428
Noncash financing costs on common stock offering	$ -	$ 207,905
Noncash warrant issuance costs	$ -	$ 19,361

See Notes to Consolidated Financial Statements

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, prevent and treat acute radiation syndrome and counteract the toxic effects of radio and chemotherapies for oncology patients.

CBLI was incorporated under the laws of the State of Delaware on June 5, 2003 and is headquartered in Buffalo, New York. CBLI has one wholly-owned subsidiary, BioLab 612, LLC (“BioLab 612”), which began operations in 2012. CBLI also has two majority-owned subsidiaries, Incuron, LLC (“Incuron”) and Panacela Labs Inc. (“Panacela”), which were formed in 2010 and 2011, respectively. Additionally, Panacela has a wholly-owned subsidiary, Panacela Labs, LLC.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying unaudited consolidated financial statements include the accounts of CBLI and its subsidiaries, Incuron, Panacela, and BioLab 612, 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 (“U.S. GAAP”) for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the SEC.

In the opinion of the Company’s management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of September 30, 2012, results of operations for the three and nine month periods ended September 30, 2012 and 2011, and cash flows for the nine month periods ended September 30, 2012 and 2011. 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 U.S. 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

Cash equivalents are highly liquid investments with a maturity of 90 days or less at the date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions. As of September 30, 2012, $8,106,250 of the Company's cash was restricted to the use of its majority-owned subsidiaries.

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 September 30, 2012, 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 approximately 23% and 88% of total revenue for the three and nine month periods ending September 30, 2012, respectively. Grant and contract revenue accounted for 39.3% and 66.1% of total revenue for the three and nine month periods ending September 30, 2011, respectively. Although the Company anticipates ongoing federal government contract and grant revenue, there is no guarantee that this revenue stream will continue in the future.

Accounts receivable consist of amounts due under reimbursement contracts with the federal government and related parties. 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 September 30, 2012 and December 31, 2011, 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 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.

Deferred Revenue

Deferred revenue represents cash received under cost reimbursable grants and contracts in excess of the revenue recognizable through the end of the respective financial reporting period. The revenue associated with these advances will be recognized in future periods as the applicable costs are incurred.

Line of Credit

CBLI has a working capital line of credit that is fully secured by cash equivalents and short-term investments. The working capital line of credit carries an interest rate equal to the prime rate, has a borrowing limit of $600,000, and expires on May 31, 2013. At September 30, 2012 and December 31, 2011, there were no outstanding borrowings under this credit facility.

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. At the 2012 annual meeting of stockholders, an amendment to increase the maximum number of shares of common stock reserved for issuance under the Plan was approved, and as of September 30, 2012, an aggregate of 10.0 million shares of common stock were authorized for issuance under the Plan, of which a total of approximately 3.2 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.

The Company estimates the fair value of all grants using the closing market price of CBLI’s common stock on the day of the grant. The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted. 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 nine months ended September 30,	
	2012	2011
Risk-free interest rate	0.71 - 1.49 %	1.46 - 2.75 %
Expected dividend yield	0 %	0 %
Expected life - Years	5 - 6	5 - 6
Expected volatility	86.58 - 92.24 %	84.23 - 89.55 %

“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” of zero is based on the fact that the Company has not historically paid 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 solely 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” is 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. Effective January 1, 2012, expected volatility is based on the historical volatility of the Company's common stock. Prior to that date, expected volatility was based on both the historical volatility of the Company's common stock and the volatility of the common stock of comparable companies when the expected life of the option exceeded the Company’s trading history.

Income Taxes

No income tax expenses were recorded for the three and nine months ended September 30, 2012 and 2011, as the Company does not expect to have taxable income for 2012 and did not have taxable income in 2011. A full valuation allowance has been recorded against the Company’s deferred tax asset.

Net Income (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.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net Income (Loss) Available to Common Shareholders	$ (10,877,836)	$ (2,691,341)	$ (21,343,666)	$ 3,177,824
Weighted Average Number of Common Shares Outstanding	35,879,245	35,447,032	35,761,260	31,553,562
Adjustments for Dilutive Securities:				
- Stock Options	-	-	-	684,765
- Warrants	-	-	-	4,564,625

Adjusted Weighted Average Number of Common Shares Outstanding	35,879,245	35,447,032	35,761,260	36,802,952
Basic Earnings/(Loss) Per Share	$ (0.30)	$ (0.08)	$ (0.60)	$ 0.10
Diluted Earnings/(Loss) Per Share	$ (0.30)	$ (0.08)	$ (0.60)	$ 0.09

Net loss per share of common stock for the three and nine month periods ended September 30, 2012 and the three month period ended September 30, 2011, are based on the weighted-average number of shares of common stock outstanding during such periods. Basic and diluted loss per share are identical for these periods as potentially dilutive securities have been excluded from the calculation of diluted net loss per share of common stock because their inclusion would be antidilutive. The potentially dilutive securities, which consisted of shares of common stock reserved for the exercise of outstanding options and warrants, amounted to 10,881,507 shares as of September 30, 2012.

Net income per share of common stock for the nine month period ended September 30, 2011 excluded stock options to purchase 1,086,199 shares of common stock and warrants to purchase 225,000 shares of common stock as their inclusion would be anti-dilutive. These securities are considered anti-dilutive as their exercise prices exceeded the average market price of the Company's common stock during the respective periods.

Reclassifications

Certain amounts presented in the prior year financial statements have been reclassified to conform to the current year presentation.

Recently Issued Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2011-04, Fair Value Measurement (Topic 820) ("ASU 2011-04"), which contains amendments to achieve common fair value measurement and disclosures in U.S. GAAP and International Financial Reporting Standards. ASU 2011-04 explains how to measure fair value for financial reporting. The guidance does not require fair value measurements in addition to those already required or permitted by other Topics. This ASU was effective for the Company beginning January 1, 2012. The adoption of ASU 2011-04 did not have a material effect on the Company's consolidated results of operations, financial position or liquidity, but did require expanded disclosures as set forth in Note 3, Fair Value of Financial Instruments.

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income ("ASU 2011-05"). This guidance is intended to increase the prominence of other comprehensive income in financial statements by presenting it in either a single statement or two-statement approach. This ASU was effective for the Company beginning January 1, 2012. The adoption of ASU 2011-05 did not have a material effect on the Company's consolidated results of operations, financial position or liquidity. The Company elected to present comprehensive income (loss) in two separate but consecutive statements as part of the consolidated financial statements included in this Quarterly Report on Form 10-Q.

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 cash equivalents and 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, or 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, include:

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 assets and liabilities measured at fair value on a recurring basis as of September 30, 2012 and December 31, 2011:

	As of September 30, 2012			
	Level 1	Level 2	Level 3	Total
Assets:				
Investment in money market funds (1)	$3,310,772	$-	$-	$3,310,772
Total assets	$3,310,772	$-	$-	$3,310,772
Liabilities:				
Compensatory stock options not yet issued (2)	$-	$-	$284,325	$284,325
Accrued warrant liability	-	-	7,446,708	7,446,708
Total liabilities	$-	$-	$7,731,033	$7,731,033

	As of December 31, 2011			
	Level 1	Level 2	Level 3	Total
Assets:				
Investment in money market funds (1)	$16,326,888	$-	$-	$16,326,888
Total assets	$16,326,888	$-	$-	$16,326,888
Liabilities:				
Compensatory stock options not yet issued (2)	$-	$-	$378,750	$378,750
Accrued warrant liability	-	-	7,285,959	7,285,959
Total liabilities	$-	$-	$7,664,709	$7,664,709

(1) Included in cash and cash equivalents in the accompanying consolidated balance sheets.
(2) 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 September 30, 2012 and December 31, 2011, which were determined in a manner consistent with that described for grants of options to purchase common stock as set forth in Note 2:

	September 30, 2012	December 31, 2011
Stock Price	$ 2.68	$ 2.86
Exercise Price	$ 1.60- 5.00	$ 1.60- 5.00
Term in years	1.21- 1.86	1.58- 2.23
Volatility	86.85- 98.53%	66.68- 71.55%
Annual rate of quarterly dividends	0%	0%
Discount rate- bond equivalent yield	0.18- 0.22%	0.20- 0.28%

The following are the assumptions used to measure the compensatory stock options not yet issued at September 30, 2012 and December 31, 2011:

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	September 30, 2012	December 31, 2011
Stock Price	$ 2.68	$ 2.86
Term in years	5.25	5
Volatility	90.73%	92.75%
Expected dividend yield	0%	0%
Risk-free interest rate	0.73%	0.83%

The following table sets forth a summary of changes in the fair value of the Company's Level 3 fair value measurements for the three and nine months ended September 30, 2012 and 2011:

	Three months ended September 30, 2012		Nine months ended September 30, 2012	
	Accrued Warrant Liability	Compensatory Stock Options Not Yet Issued	Accrued Warrant Liability	Compensatory Stock Options Not Yet Issued
Beginning Balance	$ 3,022,933	$ 114,617	$ 7,285,959	$ 378,750
Total (gains) or losses, realized and unrealized, included in earnings (1)(2)	4,423,775	-	160,749	51,823
Issuances	-	169,708	-	284,325
Settlements	-	-	-	(430,573)
Balance, September 30, 2012	$ 7,446,708	$ 284,325	$ 7,446,708	$ 284,325

	Three months ended September 30, 2011		Nine months ended September 30, 2011	
	Accrued Warrant Liability	Compensatory Stock Options Not Yet Issued	Accrued Warrant Liability	Compensatory Stock Options Not Yet Issued
Beginning Balance	$ 10,006,733	$ -	$ 25,350,733	$ 2,992,180
Total (gains) or losses, realized and unrealized, included in earnings (1)(2)	(3,993,439)	-	(21,094,452)	(17,953)
Issuances		-	2,752,441	-
Settlements		-	(995,428)	(2,974,227)
Balance, September 30, 2011	$ 6,013,294	$ -	$ 6,013,294	$ -
Amount of total gains or losses for the period included in earnings as change in value of warrant liability attributable to the change in unrealized gains or losses relating to liabilities recorded at the reporting date:				
September 30, 2012	$ 4,423,775	$ -	$ 160,749	$ -
September 30, 2011	$ (3,993,439)	$ -	$ (21,060,938)	$ -

(1) Realized and unrealized gains or losses related to the accrued warrant liability were included as change in value of accrued warrant liability.
(2) Realized gains or losses related to compensatory stock options were included in research and development expense and general and administrative expense.

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis, as documented above, from those measured at fair value on a nonrecurring basis. As of September 30, 2012 and December 31, 2011, 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:

		September 30, 2012		
Description	Fair Value	Valuation Technique	Unobservable Input	Range
Compensatory stock options not yet issued - years	$ 284,325	Black-Scholes pricing model	Expected term	5
			Quantity of options	200,000
Accrued warrant liability - years	7,446,708	Black-Scholes pricing model	Expected term	1.21 - 1.86
	$ 7,731,033			

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, 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 has granted restricted stock units under the Plan.

The following is a summary of option award activity under the Plan during the nine months ended September 30, 2012:

	Nine Months Ended September 30,			
	Total Stock Options Outstanding	Weighted Average Exercise Price per Share	Nonvested Stock Options	Weighted Average Grant Date Fair Value per Share
December 31, 2011	4,117,979	$ 5.21	356,100	$ 3.38
Granted	739,500	2.21	739,500	1.53
Vested	-	-	(600,750)	2.08
Exercised	(750)	1.90	-	
Forfeited, Canceled	(40,717)	6.14	(3,750)	2.20
September 30, 2012	4,816,012	4.74	491,100	2.20

The following is a summary of outstanding stock options under the Plan as of September 30, 2012:

	As of September 30, 2012	
	Stock Options Outstanding	Exercisable Stock Options
Quantity	4,816,012	4,324,912

Weighted-average exercise price	$ 4.74	$ 4.93
Weighted Average Remaining Contractual Term (in Years)	7.42	7.21
Intrinsic value	$ 715,652	$ 407,802

For the nine months ended September 30, 2012 and 2011, the Company granted 739,500 and 1,410,159 stock options, respectively, with a weighted-average grant date fair value of $1.53 and $4.10, respectively. For the nine months ended September 30, 2012 and 2011, the total fair value of options vested was $1,246,720 and $5,275,406, respectively. The total intrinsic value of options exercised for the nine months ended September 30, 2012 and 2011 was $1,500 and $709,557, respectively.

As of September 30, 2012, total compensation cost not yet recognized related to nonvested stock options was $578,700. The Company expects to recognize this cost over a weighted average period of 0.61 years.

5. Warrants

As of September 30, 2012, the Company had outstanding warrants with exercise prices ranging from $1.60 to $5.00 and expiration dates between March 2015 and June 2016. The following is a summary of warrant activity for the nine months ended September 30, 2012:

	Number of Warrants	Weighted Average Exercise Price	Number of Common Shares Exerciseable Into
Outstanding at December 31, 2011	10,121,219	$ 3.76	12,564,193
Forfeited, Canceled	(4,055,724)	5.07	(6,498,698)
Outstanding at September 30, 2012	6,065,495	2.89	6,065,495

6. Noncontrolling Interests

On May 31, 2012, Bioprocess Capital Ventures, the noncontrolling interest holder in Incuron, contributed approximately 194.0 million Russian rubles (approximately $5.9 million) to Incuron, which increased its ownership percentage to 40.78% and decreased CBLI's ownership percentage to 59.22%.

The effect of the changes in CBLI's ownership interest in Incuron on CBLI's equity is shown on the consolidated statement of stockholders' equity.

7. Subsequent Events

On October 19, 2012, CBLI priced an underwritten public offering of 7,500,000 units at a price to the public of $2.00 per unit, resulting in gross proceeds of $15.0 million. Each unit consisted of one share of common stock and one warrant to purchase 0.5 shares of common stock at an exercise price of $3.00 per whole share. The offering closed on October 24, 2012. Subsequent to the closing, the underwriters exercised their over-allotment option to purchase 1,025,000 additional shares of common stock and additional warrants to purchase 562,500 shares of common stock, which resulted in additional gross proceeds of $2.1 million.

Upon completion of the transaction described above, the exercise price of CBLI's warrants issued in March 2010 decreased from $4.00 to $2.00 per share.

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

This management's discussion and analysis of financial condition and results of operations and other portions of this filing contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking information. 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, 2011. See also the Risk Factors discussed under Item 1A of such Annual Report. 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, 2011.

OVERVIEW

We are a clinical-stage biotechnology company with a focus on oncology drug development. Our lead drug candidate, EntolimodTM1 is being developed for dual indications for biodefense application as a radiation countermeasure under a U.S. Food and Drug Administration (“FDA”) regulation commonly referred to as the “Animal Rule”, and as a cancer treatment and an oncologic supportive care therapy under the FDA’s traditional drug approval pathway. We anticipate that Entolimod, upon licensure as a radiation countermeasure, will be sold to the U.S. government for the national stockpile and other defense-related purposes, allied foreign governments and the nuclear energy industry, and upon licensure as a cancer treatment, will be sold to the public through traditional distribution channels.

Since our inception, we have pursued the research, development and commercialization of products that have the potential to treat cancer, prevent and treat acute radiation syndrome and counteract the toxic effects of radio and chemotherapies for oncology patients. Presently, we have nine product candidates in our pipeline that are being developed directly by us, our wholly-owned subsidiary BioLab 612, LLC (“BioLab 612”), and our majority-owned subsidiaries, Incuron, LLC (“Incuron”) and Panacela Labs, Inc. (“Panacela2”).

In addition to Entolimod, our product pipeline includes: CBLB612, an inducer and mobilizer of hematopoietic stem cells; the Curaxin line of cancer treatment candidates being developed by Incuron, and specifically includes CBL0102, a nonproprietary molecule originally used to combat the effects of malaria, which we have identified as having cancer treatment properties, and CBL0137, a new, proprietary molecule that leverages similar mechanisms of action in combating cancer; and five preclinical product candidates being developed by Panacela (Revercom, Mobilan, Arkil, and Antimycon for cancer treatment or oncology applications and Xenomycins for anti-infective applications).

See “Item 1. Business” in our Annual Report on Form 10-K for the year ended December 31, 2011 for more information on our product candidates.

Recent Developments

On October 2, 2012, we, along with Incuron, LLC, our joint venture with Bioprocess Capital Ventures, announced that CBL0102 had been granted orphan drug status by the FDA for treatment of hepatocellular carcinoma.

On October 4, 2012, we announced that we received a $770,442 increase under our existing contract, initially awarded to us on January 10, 2011, with the Defense Threat Reduction Agency (“DTRA”) of the United States Department of Defense (“DoD”).

On October 10, 2012, we announced that the first patient was dosed in a Phase I trial of the oral formulation of CBL0137 in subjects with advanced solid tumors that are resistant or refractory to standard of care treatment. The trial is being conducted in the Russian Federation.

On October 18, 2012, we announced that we had submitted a proposal to the Biomedical Advanced Research and Development Authority ("BARDA") of the Department of Health and Human Services ("HHS") for funding of the remaining development steps needed for FDA licensure of CBLB502 as a medical radiation countermeasure. The scope of the proposal is based on feedback recently received from the FDA regarding the pivotal animal efficacy and clinical programs and animal-to-human dose conversion. The new proposal is also intended to address the points noted by BARDA in connection with our previous CBLB502 proposal. There can be no assurance that BARDA will fund the proposal.

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1 Entolimod is a pending trademark for the Company's drug product formerly known as CBLB502 owned by Cleveland BioLabs, Inc.
2 Panacela is a pending trademark owned by Panacela Labs, Inc.

On October 19, 2012, CBLI priced an underwritten public offering (the "Offering") of 7,500,000 units at a price to the public of $2.00 per unit, resulting in gross proceeds of $15.0 million. Each unit consisted of one share of common stock and one warrant to purchase 0.5 shares of common stock at an exercise price of $3.00 per whole share. The offering closed on October 24, 2012. Subsequent to the closing, the underwriters exercised their over-allotment option to purchase 1,025,000 additional shares of common stock and additional warrants to purchase 562,500 shares of common stock, which resulted in additional gross proceeds of $2.1 million.

Upon completion of the Offering, the exercise price of CBLI's warrants issued in March 2010 decreased from $4.00 to $2.00 per share.

On October 25, 2012, we announced that DoD's Chemical Biological and Medical Systems ("CBMS") Medical Identification and Treatment Systems ("MITS") refocused approximately $1.5 million of existing contract funding to support critical path studies on non-human primates.

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, 2011. 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, 2011.

Fair Value of Financial Instruments

We use the Black-Scholes model to determine the fair value of certain common stock warrants on a recurring basis and classify such warrants 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 of the warrants; (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 September 30, 2012, we held approximately $3.3 million in money market funds, which we classified as Level 1, and held approximately $7.7 million in accrued expenses primarily related to warrants to purchase common stock, which we classified as Level 3.

Three Months Ended September 30, 2012 Compared to Three Months Ended September 30, 2011

Revenue

Revenue decreased from approximately $3.8 million for the three months ended September 30, 2011 to approximately $0.2 million for the three months ended September 30, 2012, representing a decrease of approximately $3.6 million, or 94%. This net decrease was primarily related to revenue recognized during the three months ended September 30, 2011 for the remaining amounts due under the NY State/Roswell Park Cancer Institute ("RPCI") Sponsored Research Agreement, which accounted for approximately $2.3 million of the decrease. The remaining reduction was related to decreases in research sponsored by the DoD - CBMS and the DoD - DTRA, which accounted for approximately $1.4 million of the decrease. These reductions were partially offset by an increase of approximately $0.2 million from research and development sponsored by the Russian Federation Ministry of Industry & Trade and the Skolkovo Foundation. 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 September 30, 2012	2011	Variance
DoD - CBMS	CBMS-MITS Contract	$ 50,885	$ 1,195,017	$ (1,144,132)
DoD - DTRA	DTRA Contract	-	297,458	(297,458)
NY State/RPCI	Sponsored Research Agreement	-	2,308,792	(2,308,792)
Russian Federation Ministry of Indusry & Trade	612 Research & Development	88,752	-	88,752
		139,637	3,801,267	(3,661,630)
Skolkovo Foundation	Curaxin Research & Development	79,938	-	79,938
		$ 219,575	$ 3,801,267	$ (3,581,692)

Research and Development Expenses

Research and development expenses decreased from approximately $6.5 million for the three months ended September 30, 2011 to approximately $4.8 million for the three months ended September 30, 2012, representing a decrease of approximately $1.7 million, or 26%. This decrease primarily reflected a reduction of approximately $3.2 million in expenses related to our development of Entolimod for Biodefense applications and a reduction of $0.4 million from decreased expenses related to CBLB612, Entolimod for Oncology applications, and general R&D spending. These decreases were partially offset by an increase of approximately $1.9 million in research and development related to our Panacela Compounds and Curaxins. Our research and development expenses and the changes between the periods are set forth in the following table:

	Three months ended September 30, 2012	2011	Variance
Entolimod for Biodefense Applications	$ 2,369,959	$ 5,549,454	$(3,179,495)
Entolimod for Oncology Applications	91,633	111,086	(19,453)
CBLB612	178,736	243,168	(64,432)
General	-	332,144	(332,144)
	2,640,328	6,235,852	(3,595,524)
Curaxins	665,654	287,052	378,602
Panacela Compounds	1,535,342	-	1,535,342
Total research & development expenses	$ 4,841,324	$ 6,522,904	$(1,681,580)

General and Administrative Expenses

General and administrative costs decreased from approximately $4.2 million for the three months ended September 30, 2011 to approximately $3.2 million for the three months ended September 30, 2012. This represents a decrease of approximately $1.0 million, or 32%. The decrease was primarily attributable to a non-cash charge of approximately $1.2 million incurred during the period ended September 30, 2011 related to a change in estimates for patents costs. Other significant variances between periods included a $0.4 million increase in general and administrative costs associated with subsidiaries that were not active in the same period in 2011, a $0.4 million increase in business development expenses, a $0.1 million increase in miscellaneous general and administrative costs and a $0.7 million

decrease in professional fees.

Other Income and Expenses

Other income decreased from income of approximately $4.1 million for the three months ended September 30, 2011 to a net expense of approximately $4.5 million for the three months ended September 30, 2012, representing a change of approximately $8.5 million. This change was primarily attributable to the periodic fair valuation of the Company's warrant liability which generated non-cash expense of approximately $4.4 million for the three months ended September 30, 2012 as compared to non-cash income of approximately $4.0 million for the three months ended September 30, 2011, resulting in a total difference of approximately $8.4 million between the periods. There was also a decrease of approximately $0.3 million of foreign exchange losses between the periods. These decreases were partially offset by an increase in interest and other income between the periods of approximately $0.2 million.

Nine Months Ended September 30, 2012 Compared to Nine Months Ended September 30, 2011

Revenue

Revenue decreased from approximately $6.8 million for the nine months ended September 30, 2011 to approximately $1.4 million for the nine months ended September 30, 2012, representing a decrease of approximately $5.4 million, or 79%. This decrease was primarily related to decreases in research sponsored by the DoD - CBMS, DoD - DTRA, BARDA, and the NY State/RPCI Sponsored Research Agreement. The revenues related to our contracts and the differences between the periods are set forth in the following table:

Funding Source	Program	Nine months ended September 30, 2012	2011	Variance
DoD - CBMS	CBMS-MITS Contract	$ 1,113,830	$ 3,116,869	$ (2,003,039)
DoD - DTRA	DTRA Contract	126,689	1,172,463	(1,045,774)
HHS	BARDA Contract	-	237,748	(237,748)
NY State/RPCI	Sponsored Research Agreement	-	2,317,218	(2,317,218)
Russian Federation Ministry of Indusry & Trade	612 Research & Development	88,752	-	88,752
		1,329,271	6,844,298	(5,515,027)
Skolkovo Foundation	Curaxin Research & Development	79,938	-	79,938
		$ 1,409,209	$ 6,844,298	$ (5,435,089)

Research and Development Expenses

Research and development expenses decreased from approximately $17.4 million for the nine months ended September 30, 2011 to approximately $16.9 million for the nine months ended September 30, 2012, representing a decrease of approximately $0.5 million, or 3%. This decrease was primarily due to reductions in spending on Entolimod for Biodefense applications and a reduction in general research, which aggregated to a reduction of $5.3 million between the two periods. This reduction was partially offset by cost increases of approximately $4.8 million, of which approximately $3.8 million related to activities associated with our Panacela Compounds. We also experienced an increase of approximately $0.4 million in research and development expenses for Entolimod for oncology applications, as we began our Advanced Cancer Trial at RPCI, approximately $0.5 million for CBLB612 development, and approximately $0.2 million for Curaxin development. Our research and development expenses and the changes between the periods are set forth in the following table:

	Nine months ended September 30, 2012	2011	Variance
Entolimod for Biodefense Applications	$ 9,787,546	$ 14,463,477	$ (4,675,931)
Entolimod for Oncology Applications	488,616	133,857	354,759
CBLB612	738,389	253,684	484,705
General	-	657,467	(657,467)
	11,014,551	15,508,485	(4,493,934)
Curaxins	2,104,953	1,932,546	172,407
Panacela Compounds	3,800,896	-	3,800,896

Total research & development expenses	$ 16,920,400	$ 17,441,031	$(520,631)

General and Administrative Expenses

General and administrative costs increased from approximately $8.1 million for the nine months ended September 30, 2011 to approximately $9.0 million for the nine months ended September 30, 2012. This represents an increase of approximately $0.9 million, or 11%. Significant variances between periods included a $1.1 million increase in general and administrative costs associated with subsidiaries that were not active in the same period in 2011, a $1.0 million increase in business development expenses, a $0.4 million increase in miscellaneous general and administrative costs, a $0.2 million increase in personnel costs, a $0.6 million decrease in professional fees, and a non-cash charge of approximately $1.2 million incurred during the period ended September 30, 2011 related to a change in estimates for patents costs.

Other Income and Expenses

Other income decreased from income of approximately $21.2 million for the nine months ended September 30, 2011 to a net expense of approximately $0.1 million for the nine months ended September 30, 2012, representing a change of approximately $21.3 million. This change was primarily attributable to the periodic fair valuation of the Company's warrant liability which generated non-cash expense of approximately $0.2 million for the nine months ended September 30, 2012 as compared to non-cash income of approximately $21.1 million for the nine months ended September 30, 2011, for a total decrease of approximately $21.3 million between the periods.

Liquidity and Capital Resources

At September 30, 2012, we had approximately $12.2 million in cash and cash equivalents (of which $8.1 million was restricted to the use of our subsidiaries) and $7.0 million in short-term investments (all of which was restricted to the use of our subsidiaries) for a combined total of available financial resources of approximately $19.2 million. As described in “Recent Developments” above, we received approximately $15.7 million in net proceeds (including the proceeds from the exercise of the underwriters’ overallotment option), after deducting underwriting discounts and commissions and deal-related expenses. Including the estimated net proceeds from the Offering along with the $19.2 million of total financial resources as of September 30, 2012, our financial resources as of September 30, 2012 would have been approximately $34.9 million.

As discussed in “Recent Developments” above, we are also in active discussions with BARDA and DoD for continued funding of our research and development of Entolimod for biodefense applications. In addition, we actively respond to all other contract and grant award possibilities we believe appropriate, both domestic and international, such as the recently announced grant we received for the development of CBLB612 from the Ministry of Industry and Trade in the Russian Federation for approximately $4.0 million; however, there can be no assurance that any of these contracts or grant award applications will result in funding.

Operating Activities

Net cash used in operations increased from approximately $10.6 million for the nine months ended September 30, 2011 to approximately $15.5 million for the nine months ended September 30, 2012, representing an increase of approximately $4.9 million, or 46%. After adjusting for non-cash items, the net loss increased by approximately $8.1 million between the periods, while changes in working capital items provided cash and cash equivalents of approximately $3.2 million.

Investing Activities

Net cash used in investing activities increased from approximately $0.7 million during the nine months ended September 30, 2011 to approximately $1.5 million during the nine months ended September 30, 2012, representing an increase of approximately $0.8 million, or 106%. For the nine months ended September 30, 2012, the net cash used in investing activities primarily related to the purchase of short-term investments of approximately $4.9 million, partially offset by the maturity of approximately $3.6 million in short-term investments. For the nine months ended September 30, 2011, the net cash used in investing activities included the purchase of equipment of approximately $0.5 million, patents of approximately $0.3 million, and the issuance of a note to Panacela Labs, Inc. of approximately $0.3 million, which was partially offset by the sale of short-term investments of approximately $0.4 million.

Financing Activities

Net cash provided by financing activities decreased from approximately $25.8 million during the nine months ended September 30, 2011 to approximately $5.9 million for the nine months ended September 30, 2012, representing a

decrease of approximately $19.9 million, or 77%. For the nine months ended September 30, 2012, substantially all of the cash flows from financing activities were attributable to a capital contribution to our Incuron subsidiary by the noncontrolling interest holder. For the nine months ended September 30, 2011, cash provided by financing activities included a net cash receipt of approximately $21.9 million related to the issuance of our common stock, an investment in Incuron of approximately $2.3 million by the noncontrolling interest holder, and the exercise of options and warrants for approximately $1.5 million.

Other

We have incurred cumulative net losses and expect to incur additional losses to perform further 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, together with an assumed award of the BARDA proposal as submitted, will be sufficient to support our operations for at least 12 months. There can be no assurance that BARDA will fund the proposal or that our government grants and contracts, which may contain options exercisable at the discretion of the granting agency, will be funded as anticipated. Furthermore, our estimates are subject to other uncertainties and risks as described elsewhere in this Quarterly Report and in our Annual Report for the year ended December 31, 2011.

The success of our company is dependent upon commercializing our research and development programs and our ability to obtain adequate future financing. 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 September 30, 2012, we do not believe that exchange rate fluctuations for obligations we have in foreign currencies would significantly impact our results of operations or financial position.

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 nine months ended September 30, 2012. 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, 2011.

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 September 30, 2012. 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 September 30, 2012, 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.

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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 September 30, 2012, 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 September 30, 2012, we were not a party to any litigation or other legal proceeding.

Item 1A. Risk Factors

There have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the period ended December 31, 2011. For a further discussion of our Risk Factors, refer to the “Risk Factors” discussion contained in our Annual Report on Form 10-K for the period ended December 31, 2011.

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

On July 15, 2012, as consideration for consulting services to be provided, we issued 25,000 shares of our common stock to a consultant. These shares were issued without registration in reliance on the exemptions afforded by Section 4(2) of the Securities Act of 1933, as amended.

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
4.1	Form of Warrant Agreement by and between Cleveland BioLabs, Inc. and Continental Stock Transfer & Trust Company (Incorporated by reference to Form 8-K filed on October 22, 2012).
31.1	Certification of Yakov Kogan, Chief Executive Officer, pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
31.2	Certification of C. Neil Lyons, Chief Financial Officer, pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
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 September 30, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of September 30, 2012 and December 31, 2011; (ii) Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2012 and 2011; (iii) Consolidated Statements of Comprehensive Income/(Loss) for the Three and Nine Months Ended September 30, 2012 and 2011; (iv) Consolidated Statements of Cash Flows for the Nine Months ended September 30, 2012 and 2011; (v) Consolidated Statements of Stockholders' Equity for the Nine Months Ended September 30, 2012; 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: November 9, 2012	By:	/s/ YAKOV KOGAN Yakov Kogan Chief Executive Officer (Principal Executive Officer)
Dated: November 9, 2012	By:	/s/ C. NEIL LYONS C. Neil Lyons Chief Financial Officer (Principal Financial Officer)