CLEVELAND BIOLABS INC
Form 10-Q
August 15, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2016
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)

(716) 849-6810
(Registrant's telephone number, including area code)

N/A
(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 ¨
Non-accelerated filer ¨ Smaller reporting company x

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 29, 2016, there were 10,987,166 shares outstanding of the registrant's common stock, par value $0.005 per share.

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In this Quarterly Report on Form 10-Q, unless otherwise stated or the context otherwise requires, the terms "Cleveland BioLabs," the "Company," "CBLI," "we," "us" and "our" refer to Cleveland BioLabs, Inc. and its consolidated subsidiaries, BioLab 612, LLC and Panacela Labs, Inc. Our common stock, par value $0.005 per share, is referred to as “common stock.”

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
CONSOLIDATED CONDENDSED BALANCE SHEETS

	June 30, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$5,412,067	$5,918,424
Short-term investments	10,941,570	13,701,273
Accounts receivable	895,920	631,084
Other current assets	586,927	442,642
Total current assets	17,836,484	20,693,423
Equipment, net	54,394	122,958
Restricted cash	42,719	37,663
Other long-term assets	28,606	26,560
Total assets	$17,962,203	$20,880,604
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$144,166	$197,134
Accrued expenses	1,383,281	1,584,826
Deferred revenue	161,213	11,892
Accrued warrant liability	3,183,350	4,048,900
Total current liabilities	4,872,010	5,842,752
Commitments and contingencies	—	—
Total liabilities	4,872,010	5,842,752
Stockholders' equity:		
Preferred stock, $.005 par value; 10,000,000 shares authorized, 0 shares issued and outstanding as of June 30, 2016 and December 31, 2015	—	—
Common stock, $.005 par value; 160,000,000 shares authorized, 10,987,166 shares issued and outstanding as of June 30, 2016 and December 31, 2015	54,932	54,932
Additional paid-in capital	158,773,753	158,764,985
Other comprehensive loss	(409,926)	(408,051)
Accumulated deficit	(150,647,095)	(147,978,831)
Treasury stock, at cost; 0 and 158,900 shares as of June 30, 2016 and December 31, 2015, respectively	—	(544,853)
Total Cleveland BioLabs, Inc. stockholders' equity	7,771,664	9,888,182
Noncontrolling interest in stockholders' equity	5,318,529	5,149,670
Total stockholders' equity	13,090,193	15,037,852
Total liabilities and stockholders' equity	$17,962,203	$20,880,604

See Notes to Consolidated Financial Statements

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues:				
Grants and contracts	$575,025	$329,908	$1,387,525	$937,237
Operating expenses:				
Research and development	1,292,167	1,583,169	3,233,407	3,194,139
General and administrative	777,107	1,597,556	1,960,673	3,905,427
Total operating expenses	2,069,274	3,180,725	5,194,080	7,099,566
Loss from operations	(1,494,249)	(2,850,817)	(3,806,555)	(6,162,329)
Other income (expense):				
Interest and other income (expense)	121,969	(81,416)	303,734	(127,810)
Foreign exchange gain	33,102	65,058	80,188	21,323
Change in value of warrant liability	(547,163)	(1,480,048)	865,550	(1,529,406)
Equity in loss of Incuron, LLC	—	(114,571)	—	(362,137)
Total other income (expense)	(392,092)	(1,610,977)	1,249,472	(1,998,030)
Net loss	(1,886,341)	(4,461,794)	(2,557,083)	(8,160,359)
Net loss (gain) attributable to noncontrolling interests	(11,527)	17,141	(8,721)	65,384
Net loss attributable to Cleveland BioLabs, Inc.	$(1,897,868)	$(4,444,653)	(2,565,804)	(8,094,975)
Net loss attributable to common stockholders per share of common stock, basic and diluted	$(0.17)	$(1.12)	$(0.23)	$(2.25)
Weighted average number of shares used in calculating net loss per share, basic and diluted	10,987,166	3,979,783	10,987,166	3,595,153

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2016	2015	2016	2015
Net loss including noncontrolling interests	$(1,886,341)	$(4,461,794)	$(2,557,083)	$(8,160,359)
Other comprehensive loss:				
Unrealized gain on short-term investments	2,716	—	9,438	—
Foreign currency translation adjustment	23,044	41,748	46,365	2,009
Comprehensive loss including noncontrolling interests	(1,860,581)	(4,420,046)	(2,501,280)	(8,158,350)
Comprehensive loss (gain) attributable to noncontrolling interests	(32,084)	106	(59,166)	63,374
Comprehensive loss attributable to Cleveland BioLabs, Inc.	$(1,892,665)	$(4,419,940)	$(2,560,446)	$(8,094,976)

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

	Common Stock		Treasury Stock		Additional Paid-In Capital
	Shares	Amount	Shares	Amount	
Balance at December 31, 2015	10,987,166	$54,932	158,900	$(544,853)	$158,764,985
Stock based compensation	—	—	—	—	13,623
Sale of Treasury Stock	—	—	(158,900)	544,853	(4,855)
Increased ownership of Panacela Labs, Inc.	—	—	—	—	—
Net loss	—	—	—	—	—
Unrealized gain/loss on short-term investments	—	—	—	—	—
Foreign currency translation	—	—	—	—	—
Balance at June 30, 2016	10,987,166	$54,932	—	$—	$158,773,753

	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Noncontrolling Interests	Total
Balance at December 31, 2015	$ (408,051)	$(147,978,831)	$ 5,149,670	$15,037,852
Stock based compensation	—	—	—	13,623
Sale of Treasury Stock	—	—	—	539,998
Increased ownership of Panacela Labs, Inc.	(7,233)	(102,460)	109,693	—
Net loss	—	(2,565,804)	8,721	(2,557,083)
Unrealized gain on short-term investments	9,438	—	—	9,438
Foreign currency translation	(4,080)	—	50,445	46,365
Balance at June 30, 2016	$ (409,926)	$(150,647,095)	$ 5,318,529	$13,090,193

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

	For the Six Months Ended June 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(2,557,083)	$(8,160,359)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	41,565	126,498
Non-cash investment income	(20,189)	—
Non-cash compensation	13,624	40,506
Warrant issuance costs	—	617,776
Equity in loss of Incuron, LLC	—	362,137
Change in value of warrant liability	(865,550)	1,529,406
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	(342,684)	96,807
Other long-term assets	(1,838)	8,544
Accounts payable and accrued expenses	(342,675)	(104,909)
Deferred revenue	127,197	510,743
Net cash used in operating activities	(3,947,633)	(4,972,851)
Cash flows from investing activities:		
Purchase of short-term investments	(8,813,086)	(784,110)
Sale of short-term investments	11,658,162	348,452
Purchase of equipment	(4,235)	(13,288)
Proceeds from sale of equipment	16,665	—
Divestiture of Incuron	—	2,000,000
Decrease in restricted cash	—	834,989
Net cash provided by investing activities	2,857,506	2,386,043
Cash flows from financing activities:		
Issuance of common stock, net of offering costs	—	3,048,934
Repayment of long-term debt and capital leases	—	(375,972)
Net proceeds from sale of treasury stock	539,998	—
Net cash provided by financing activities	539,998	2,672,962
Effect of exchange rate change on cash and equivalents	43,772	(2)
Increase (decrease) in cash and cash equivalents	(506,357)	86,152
Cash and cash equivalents at beginning of period	5,918,424	3,103,969
Cash and cash equivalents at end of period	$5,412,067	$3,190,121
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$—	$91,614

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS
(UNAUDITED)

1. Description of Business

Cleveland BioLabs, Inc. ("CBLI" or the " Company") is an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. Our proprietary platform of Toll-like immune receptor activators has applications in radiation mitigation and immuno-oncology. We combine our proven scientific expertise and our depth of knowledge about our products' mechanisms of action into a passion for developing drugs to save lives. Our most advanced product candidate is entolimod, an immune-stimulatory agent, which we are developing as a radiation countermeasure and an immunotherapy for oncology and other indications.

CBLI was incorporated in Delaware in June 2003 and is headquartered in Buffalo, New York. CBLI conducts business in the United States (" U.S.") and in the Russian Federation ("Russia"), through several subsidiaries including: one wholly-owned subsidiary, BioLab 612, LLC ("BioLab 612"), which began operations in 2012; Panacela Labs, Inc. ("Panacela"), which was formed by us and Joint Stock Company "RUSNANO" ("RUSNANO") our financial partner in the venture, in 2011; and, Incuron LLC ("Incuron"), which was formed by us and Bioprocess Capital Ventures ("BCV") our financial partner in the venture, in 2010. During the eighteen months ended June 30, 2016 our ownership in Incuron has decreased from being a minority shareholder at January 1, 2015 to no longer being a shareholder as of April 29, 2015. Unless otherwise noted, references to the "Company," "we," "us" and "our" refer to Cleveland BioLabs, Inc. together with its subsidiaries.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying unaudited consolidated condensed financial statements include the accounts of CBLI, BioLab 612, and Panacela. The accounts of Incuron are presented using the equity method of accounting for the period from January 1, 2015 through April 29, 2015, the date that we completed a sale of our entire equity interests in Incuron. All significant intercompany balances and transactions have been eliminated in consolidation.

The consolidated condensed balance sheet as of December 31, 2015, which has been derived from audited financial statements, and the unaudited interim consolidated condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim consolidated financial information and in accordance with the instructions to Form 10-Q and Article 8 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 GAAP have been condensed or omitted pursuant to such rules and regulations. These consolidated condensed 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, 2015, 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 fairly present the financial position of the Company as of June 30, 2016, along with its results of operations for the three and six month periods ended June 30, 2016 and 2015 and cash flows for the six month periods ended June 30, 2016 and 2015. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

On January 28, 2015, the Company, after receiving approval from the Company's shareholders and board of directors, executed a reverse stock split of the Company's common stock at the ratio of 1:20. Unless otherwise indicated, all of the Company's historical share balances and share price-related data have been adjusted, on a retroactive basis, to reflect this ratio.

At June 30, 2016, we had cash, cash equivalents and short-term investments of $16.4 million in the aggregate. Management believes this capital will fund its operations and cash requirements beyond one year.

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (“FASB”) issued a new standard that changes the accounting for certain aspects of share-based payments to employees. The new guidance requires excess tax benefits and tax deficiencies to be recorded in the income statement when the awards vest or are settled. In addition, cash flows related to excess tax benefits will no longer be separately classified as a financing activity apart from other income tax cash flows. The standard also allows us to repurchase

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more of an employee's shares for tax withholding purposes without triggering liability accounting, clarifies that all cash payments made on an employee's behalf for withheld shares should be presented as a financing activity on our cash flows statement, and provides an accounting policy election to account for forfeitures as they occur. The new standard is effective for us beginning January 1, 2017, with early adoption permitted. This new standard is not expected to have a significant impact on the Company's financial statements.

In February 2016, the FASB issued a new standard related to leases to increase transparency and comparability among organizations by requiring the recognition of lease assets and lease liabilities on the balance sheet. Most prominent among the amendments is the recognition of assets and liabilities by lessees for those leases classified as operating leases under previous U.S. GAAP. Under the new standard, disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. The new standard will be effective for us beginning January 1, 2019, with early adoption permitted. We are currently evaluating the impact of this statement.

Use of Estimates

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

Short-Term Investments

The Company's short-term investments are classified as available for sale. Accordingly, these investments are carried at fair market value. Short-term investments consisted of United States Treasury securities in the amount of $10.3 million which were owned by CBLI and had maturities of less than 12 months. In addition, $0.6 million in certificates of deposit with maturity dates beyond three months and less than one year, and owned by Panacela, are also included. Unrealized gains and losses on available for-sale investments are reported as Other Comprehensive Loss, a separate component of stockholders' equity. Realized gains and losses, and interest and dividends on available-for-sale securities are recorded in our Consolidated Statement of Operations as Interest and Other Expense. The cost of securities sold is based on the specific identification method.

Significant Customers and Accounts Receivable

The following table presents our revenue by customer, on a proportional basis, for the three and six months ended June 30, 2016 and 2015.

	Three Months Ended June 30,			Six Months Ended June 30,		
Customer	2016	2015	Variance	2016	2015	Variance
Department of Defense	27.6 %	— %	27.6 %	29.2 %	— %	29.2 %
Russian Government Agencies	53.1 %	58.3 %	(5.2)%	46.0 %	58.2 %	(12.2)%
Incuron, LLC	19.3 %	41.7 %	(22.4)%	24.8 %	41.8 %	(17.0)%
Total	100.0%	100.0%	— %	100.0%	100.0%	— %

Although the Company anticipates recurring revenue from these customers, there is no guarantee that these revenue streams will continue in the future.

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

Restricted Cash

Restricted cash includes certificates of deposit, denominated in Russian rubles, which collateralize Panacela and BioLab 612 contracts with the Ministry of Industry and Trade of the Russian Federation. These deposits provide additional assurance that Panacela and BioLab 612 will satisfactorily perform their statements of work under the contracts. Both Panacela and BioLab 612 anticipate receiving these deposits at the completion of the contracts.

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We previously disclosed that the Bank of Russia appointed temporary management of NOTA-Bank and that we had written off the full value of our deposits with NOTA-Bank, as of the year ended December 31, 2015. The remaining amount of "Restricted Cash" at June 30, 2016, is on deposit with other banking institutions. In June 2016 the bankruptcy trustee appointed by the Moscow Arbitration Court awarded $73,443 in full settlement of our claims, which was recorded as Other Income in the Statement of Operations for the six months ended June 30, 2016.

Other Comprehensive Income (loss)

The Company applies the Codification on comprehensive income (loss) that requires disclosure of all components of comprehensive income (loss) on an annual and interim basis. Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The following table presents the changes in accumulated other comprehensive loss for the six months ended June 30, 2016.

	Unrealized gain (loss) on available-for-sale securities	Gains and losses on foreign exchange translations	Total
Beginning balance	$ (6,190)	$(401,861)	$(408,051)
Other comprehensive income/(loss) before reclassifications	9,438	46,365	55,803
Amounts reclassified from accumulated other comprehensive loss	—	(57,678)	(57,678)
Ending balance	$ 3,248	$(413,174)	$(409,926)

Accounting for Stock-Based Compensation

The 2006 Equity Incentive Plan, as amended, or the Plan, authorizes CBLI to grant (i) options to purchase common stock, (ii) restricted or unrestricted stock units, and (iii) stock appreciation rights, so long as the exercise or grant price of each are at least equal to the fair market value of the stock on the date of grant. As of June 30, 2016, an aggregate of 650,000 shares of common stock were authorized for issuance under the Plan, of which a total of 218,163 shares of common stock remained available for future awards and 303,293 shares of common stock have been reserved for issuance upon exercise of currently outstanding stock options. A single participant cannot be awarded more than 100,000 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 board of directors, compensation committee or its management delegates.

The 2013 Employee Stock Purchase Plan, or ESPP, which provides a means by which eligible employees of the Company and certain designated related corporations may be given an opportunity to purchase shares of common stock. As of June 30, 2016, there are 325,000 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) 100,000 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 during the six months ended June 30, 2015 and a discussion of the Company’s methodology for developing each of the assumptions used. No options were granted during the six

months ended June 30, 2016:

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	2015
Risk-free interest rate	1.35 - 1.59%
Expected dividend yield	0.0 %
Expected life	5 - 5.5 years
Expected volatility	76.66 - 116.10%

“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, 2016 and 2015, as the Company does not expect to have taxable income for 2016 and did not have taxable income in 2015. A full valuation allowance has been recorded against the Company’s deferred tax asset.

Additionally, as disclosed in Note 9, Income Taxes, to the Company’s consolidated financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2015 and filed with the SEC on February 23, 2016, the Company had U.S. federal net operating loss carryforwards of approximately $128,665,000, which begin to expire if not utilized by 2023, and approximately $3,750,000 of federal tax credit carryforwards which begin to expire if not utilized by 2024. The Company also has U.S. state net operating loss carryforwards of approximately $118,097,000, which begin to expire if not utilized by 2027 and state tax credit carryforwards of approximately $336,000, which begin to expire if not utilized by 2022. The purchase of 6,459,948 shares of common stock by Mr. Davidovich on July 9, 2015 resulted in Mr. Davidovich owning 60.2% of the Company. We therefore believe it highly likely that this transaction, more fully described in Note 6 Stockholders’ Equity, will be viewed by the U.S. Internal Revenue Service as a change of ownership as defined by Section 382 of the Internal Revenue Code, or Section 382. Consequently, the utilization of these net operating loss and tax credit carryforwards, as well as any additional net operating loss and tax credit carryforwards generated in 2015 through the issuance date, will be limited according to the provisions of Section 382, which will significantly limit the Company’s ability to use these carryforwards to offset taxable income on an annual basis in future periods. As such, a significant portion of these carryforwards will likely expire before they can be utilized, even if the Company is able to generate taxable income that, except for this transaction, would have been sufficient to fully utilize these carryforwards.

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 securities from the calculation of diluted net loss per share because all such securities were antidilutive for the periods presented:

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	As of June 30,	
Common Equivalent Securities	2016	2015
Warrants	2,148,741	2,272,523
Options	303,293	365,784
Total	2,452,034	2,638,307

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 was not a party to any pending material litigation that was estimable and had a probability of loss.

3. Fair Value of Financial Instruments

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

- Level 1 – Observable inputs for identical assets or liabilities such as quoted prices in active markets;
- Level 2 – Inputs other than quoted prices in active markets that are either directly or indirectly observable; and
- Level 3 – Unobservable inputs in which little or no market data exists, which are therefore developed by the Company using estimates and assumptions that reflect those that a market participant would use.

Cash equivalents include United States Treasury Notes with original maturities of three months or less, at time of purchase and money market funds. Short-term investments primarily include United States Treasury Notes, along with certificates of deposit at commercial banking institutions, both with maturities of three months or more at time of purchase.

The valuation methodologies used to measure the fair value of the company’s assets, and instruments classified in stockholders’ equity are described as follows: United States Treasury Notes and money market funds included in cash equivalents and short-term investments are valued at the closing price reported by an actively traded exchange and are included as Level 1 measurements in the table below. Certificates of deposit are carried at amortized cost, which approximates fair value and are included within short-term investments as a Level 2 measurement in the table below. 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 June 30, 2016			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$1,122,025	$—	$—	$1,122,025
Short-term investments	10,288,884	652,686	—	10,941,570
Total assets	$11,410,909	$652,686	$—	$12,063,595
Liabilities:				
Accrued warrant liability	$—	$—	$3,183,350	$3,183,350

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	As of December 31, 2015			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$1,885,826	$ —	$ —	$1,885,826
Short-term investments	13,701,273	—	—	13,701,273
Total assets	$15,587,099	$ —	$ —	$15,587,099
Liabilities:				
Accrued warrant liability	$—	$ —	$4,048,900	$4,048,900

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 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, 2016	December 31, 2015
Stock Price	$ 2.98	$ 3.49
Exercise Price	$3.00 - $60.00	$3.00 - $100.00
Term in years	0.67 – 5.10	0.48 - 5.60
Volatility	62.58% - 103.52%	64.00% - 114.74%
Annual rate of quarterly dividends	— %	— %
Discount rate- bond equivalent yield	.30% - 1.02%	.31% - 1.86%

The following table sets forth a summary of changes in the fair value of the Company's Level 3 fair value measurements for the periods indicated:

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	
	Accrued Warrant Liability	Accrued Warrant Liability	Compensatory Stock Options Issued After Year End
Beginning Balance	$2,636,187	$4,547,691	$ 132,295
Total (gains) or losses, realized and unrealized, included in earnings (1)	547,163	1,480,049	(26,381)
Issuances	—	—	—
Settlements	—	(671,349)	(105,914)
Ending Balance	$3,183,350	$5,356,391	$ —

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015

	Accrued Warrant Liability	Accrued Warrant Liability	Compensatory Stock Options Issued After Year End
Beginning Balance	$4,048,900	$862,074	$ 132,295
Total (gains) or losses, realized and unrealized, included in earnings (1)	(865,550)	1,529,406	(26,381)
Issuances	—	3,636,260	—
Settlements	—	(671,349)	(105,914)
Ending Balance	$3,183,350	$5,356,391	$ —

(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 months ended June 30, 2016 and 2015.

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As of June 30, 2016 and December 31, 2015, 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. 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. As of June 30, 2016, the Black-Scholes pricing model was used as the valuation technique for the accrued warrant liability and used the unobservable input for the expected term of 0.67 – 5.10 years.

Management believes the value of the accrued warrant liability 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 the unobservable input described above. The carrying amounts of the Company's short-term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable, approximate their fair values due to their short maturities.

4. Sale of Incuron

On April 29, 2015, CBLI entered into an agreement to sell its equity stake in Incuron to Dr. Mikhail Mogutov, Chairman of Incuron's Board of Directors and founder of BCV and/or his designee. The Company's equity stake in Incuron was sold for (i) $3 million in cash and, (ii) the transfer of 264,318 shares of the Company's common stock to escrow. The escrow agent was instructed to sale the shares and to remit the net proceeds from the sale of those share to CBLI after deducting sales commissions and escrow agent fees. At the time of sale, CBLI had a recorded asset value of $3,906,321. After recording the $3 million of cash proceeds from the sale, $906,321 remained as a cost basis associated with the transfer of the 264,318 shares of the Company's common stock to escrow and was recorded as treasury stock. As of December 31, 2015, 105,418 shares had been sold and $417,545 in cash had been received from the escrow agent. As of June 30, 2016, the remaining shares have been sold and $391,624 in cash has been received from the escrow agent. In addition, CBLI assigned its remaining intellectual property relating to Curaxin CBL0137 to Incuron in exchange for a 2% royalty on the future commercialization, licensing or sale of the Curaxin CBL0137 technology.

5. Debt

On September 30, 2013, CBLI and BioLab 612 entered into a Loan and Security Agreement (the "Loan Agreement"), with Hercules Technology II, L.P. ("Hercules") pursuant to which we issued a $6.0 million note. In June 2014, CBLI repaid $4.0 million of the loan. Between June 2014 and August 2015 CBLI repaid the remaining principal and interest in accordance with the provisions of the Loan Agreement. In August 2015, CBLI fully paid the remaining obligations of the Loan Agreement along with a prepayment penalty of approximately $28,000 and expensed approximately $76,000 in deferred charges.

On September 3, 2013, Panacela entered into a Master Agreement and a Convertible Loan Agreement, with RUSNANO, and CBLI pursuant to which Panacela issued a $1,530,000 note payable to RUSNANO (the "Panacela Loan"). The Panacela Loan bore interest at a rate of 16.3% per annum and matured on September 10, 2015. In December 2015, the Panacela Loan was fully retired.

6. Stockholders' Equity

The Company has granted options to purchase shares of common stock. The following is a summary of option award activity during the six months ended June 30, 2016:

	Total Stock Options Outstanding	Weighted Average Exercise Price per Share	Nonvested Stock Options	Weighted Average Grant Date Fair Value per Share
December 31, 2015	343,643	$ 46.60	42,000	$ 1.99
Granted	—	—	—	—

Vested	—	—	(42,000)	1.99
Forfeited, Canceled	(40,350)	81.09	—	—
June 30, 2016	303,293	$ 42.01	—	$ —

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The following is a summary of outstanding stock options as of June 30, 2016:

	As of June 30, 2016	
	Stock Options Outstanding	Vested Stock Options
Quantity	303,293	303,293
Weighted-average exercise price	$42.01	$ 42.01
Weighted Average Remaining Contractual Term (in Years)	6.53	6.53
Intrinsic value	$—	$ —

For the six months ended June 30, 2016 and 2015, the Company granted 0 and 131,500 stock options, respectively, with a weighted-average grant date fair value of $0.00 and $2.59, respectively. For the six months ended June 30, 2016 and 2015, the total fair value of options vested was $83,789 and $105,914, respectively.

As of June 30, 2016, there was no total compensation cost not yet recognized related to unvested stock options.

7. Warrants

In connection with sales of the Company's common stock and the issuance of debt instruments, warrants were issued which presently have exercise prices ranging from $3.00 to $60.00. The warrants expire between one and six years from the date of grant, and are subject to the terms applicable in each agreement. The following table summarizes the activity in our outstanding warrants since December 31, 2015:

	Number of Warrants	Weighted Average Exercise Price
December 31, 2015	2,222,155	$ 13.98
Granted	—	—
Exercised	—	—
Forfeited, Canceled	(73,414)	100.00
June 30, 2016	2,148,741	$ 11.04

8. Significant Alliances and Related Parties

Roswell Park Cancer Institute

The Company has entered into several agreements with Roswell Park Cancer Institute, or RPCI, including: various sponsored research agreements, an exclusive license agreement and clinical trial agreements for the conduct of the Phase 1 entolimod oncology study and the Phase 1 CBL137 intravenous administration study. Additionally, the Company's Chief Scientific Officer, or CSO, Dr. Andrei Gudkov, is the Senior Vice President of Basic Research at RPCI. The Company incurred $241,235 and $264,693 and $449,079 and $595,834 in expense to RPCI related to research grants and agreements for the three and six months ended June 30, 2016 and 2015, respectively. The Company had $2,770 and $381,837 included in accounts payable owed to RPCI at June 30, 2016 and 2015, respectively. In addition, the Company had $169,330 and $157,110 in accrued expenses payable to RPCI at June 30, 2016 and 2015, respectively.

The Cleveland Clinic

CBLI has entered into an exclusive license agreement, with The Cleveland Clinic pursuant to which CBLI was granted an exclusive license to The Cleveland Clinic's research base underlying our therapeutic platform and certain product candidates licensed to Panacela. CBLI has the primary responsibility to fund all newly developed patents; however, The Cleveland Clinic retains ownership of those patents covered by the agreement. CBLI also agreed to use commercially diligent efforts to bring

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one or more products to market as soon as practical, consistent with sound and reasonable business practices and judgments. There were no milestone or royalty payments paid to The Cleveland Clinic during the six months ended June 30, 2016 or 2015.

The Company incurred $0 and $0 and $0 and $9,700 in expense to The Cleveland Clinic related to research grants and agreements for the three and six months ended June 30, 2016 and 2015, respectively.

The Company did not have any liabilities to The Cleveland Clinic at June 30, 2016 or 2015.

Buffalo BioLabs, et. al.

Our CSO, Dr. Andrei Gudkov has business relationships with Buffalo BioLabs, LLC, or BBL, where Dr. Gudkov was a founder and currently serves as its Principal Scientific Advisor. The Company recognized $171,960 and $245,417 and $491,909 and $416,803 as research and development expense for the three and six months ended June 30, 2016 and 2015, respectively. In addition, the Company had $45,500 and $0 in accrued expenses payable to BBL and $0 and $0 in accounts payable to BBL at June 30, 2016 and 2015, respectively. We also recognized $7,819 and $55,962 from BBL for sublease and other income for the three months ended June 30, 2016 and 2015, respectively. Pursuant to our real estate sublease and equipment lease with BBL, we had gross accounts receivables of $206,651 and $227,086 and net accounts receivables of $0 and $0 at June 30, 2016 and 2015, respectively.

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 quarterly report on Form 10-Q contain forward-looking statements that involve risks and uncertainties. All statements other than statements of current or historical fact contained in this quarterly report, including statements regarding our future financial position, business strategy, new products, budgets, liquidity, cash flows, projected costs, regulatory approvals or the impact of any laws or regulations applicable to us, and plans and objectives of management for future operations, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “should,” “estimate,” “expect,” “int “may,” “plan,” “project,” “will,” and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements on our current expectations about future events. While we believe these expectations are reasonable, such forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. Our actual future results may differ materially from those discussed here for various reasons. 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, 2015. 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, 2015.

Given these uncertainties, you should not place undue reliance on these forward-looking statements. The forward-looking statements included in this quarterly report are made only as of the date hereof. We do not undertake any obligation to update any such statements or to publicly announce the results of any revisions to any of such statements to reflect future events or developments. 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 with our historical consolidated financial statements and the related notes thereto in our Annual Report on Form 10-K for the year ended December 31, 2015.

OVERVIEW

We are an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. Our proprietary platform of Toll-like immune receptor activators has applications in mitigation of radiation injury and immuno-oncology. We combine our proven scientific expertise and our depth of knowledge about our products’ mechanisms of action into a passion for developing drugs to save lives. Our most advanced product candidate is entolimod, an immune-stimulatory agent, which we are developing as a radiation countermeasure and an immunotherapy for oncology and other indications. We conduct business in the U.S. and Russia through several subsidiaries, one of which is wholly-owned, BioLab 612; one of which is owned in collaboration with a financial partner, Panacela; and, a former subsidiary, Incuron. We held a majority ownership interest in Incuron until November 25, 2014, at which time Incuron was deconsolidated, after which we recognized our equitable interest in Incuron’s results of operation as a single line item classified as "Equity in Loss of Incuron,

LLC" in our Statements of Operations through April 29, 2015, the date at which our equity interest in Incuron became less than 20%. Subsequent to April 29, 2015, Incuron was accounted for on the cost basis until we sold our remaining equity interest in Incuron on June 30, 2015.

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Financial Overview

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 ("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 base 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 revenue, operating results and profitability have varied, and we expect that they will continue to vary on a quarterly basis, primarily due to the timing of work completed under new and existing grants, development contracts and collaborative relationships.

Revenue

Our revenue originates from grants and contracts from both United States ("U.S.") federal government sources and Russian Federation ("Russia") government sources and service contracts with Incuron. U.S. federal grants and contracts are provided to advance research and development of entolimod, our lead product candidate, which we believe is of interest for potential sale to the U.S. Department of Defense ("DoD,") or the Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services ("BARDA.") Russian government contracts are provided to advance research and development of products that may eventually be licensed for sale in Russia. We provide various research, management, business development and clinical advisory and management services to Incuron.

Research and Development Expenses

Research and development ("R&D") costs are expensed as incurred. Advance payments are deferred and expensed as performance occurs. R&D costs include the cost of our personnel (which consists of salaries, incentive and stock-based compensation), out-of-pocket pre-clinical and clinical trial costs usually associated with contract research organizations, drug product manufacturing and formulation, and a pro-rata share of facilities expense and other overhead items.

General and Administrative Expenses

General and administrative ("G&A") functions include executive management, finance and administration, government affairs and regulations, corporate development, human resources, legal and compliance. The specific costs include the cost of our personnel consisting of salaries, incentive and stock-based compensation, out-of-pocket costs usually associated with attorneys (both corporate and intellectual property), bankers, accountants and other advisors and a pro-rata share of facilities expense and other overhead items.

Other Income and Expenses

Other recurring income and expenses primarily consists of interest income on our investments, changes in the market value of our derivative financial instruments and foreign currency transaction gains or losses.

Critical Accounting Policies and Significant Estimates

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2015. 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, 2015.

Fair Value of Financial Instruments

We use the Available-For-Sale accounting method to determine the fair value of certain cash equivalents and short-term investments invested in United States Treasury Notes or certificates of deposit. As of June 30, 2016, we held approximately $1.1 million in cash equivalents and $10.3 million in U.S. Treasury Notes which we classified as

Level 1.

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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, 2016, we held approximately $3.2 million in accrued expenses related to warrants to purchase common stock, which we classified as Level 3.

Three Months Ended June 30, 2016 Compared to Three Months Ended June 30, 2015

Revenue

Revenue increased from approximately $0.3 million for the three months ended June 30, 2015 to approximately $0.6 million three months ended June 30, 2016, representing an increase of approximately $0.2 million, or 74.3%, principally because of our JWMRP contract awarded to us in September 2015 for continued preclinical development of entolimod's biodefense indication and our grant from the Russian Federation Ministry of Industry and Trade ("MPT"), which continues to enroll patients in a clinical study of the safety and tolerability of entolimod as a neo-adjuvant therapy in treatment-naïve patients with primary colorectal cancer. Regarding our other Russian trials funded by MPT, reported contract revenue for the three months ended June 30, 2016 was approximately equal to the reported contract revenue for the three months ended June 30, 2015. Differences in our revenue sources, by program, between the years are set forth in the following table. Prospectively, the DoD contracts will gradually increase in significance and more significantly after the conclusion of a biocomparability study, required by the FDA as part of the pre-EUA review.

		Three Months Ended June 30,		
Funding Source	Program	2016	2015	Variance
DoD	JWMRP Contract (1)	$149,192	$—	$149,192
DoD	PRMRP Contract (2)	9,534	—	9,534
MPT	CBLB612 pre-clinical (3)	41,934	22,923	19,011
MPT	Entolimod colorectal cancer (3)	130,331	9,300	121,031
Incuron	Service contracts	111,113	137,705	(26,592)
		442,104	169,928	272,176
MPT	Mobilan pre-clinical (3)	132,921	159,980	(27,059)
		$575,025	$329,908	$245,117

(1) The Congressionally Directed Medical Research Programs (CDMRP) Joint Warfighter Medical Research Program (JWMRP) contract was awarded on September 1, 2015.

(2) The CDMRP Peer Reviewed Medical Research Program (PRMRP) grant was awarded effective as of September 30, 2015.

(3) 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 primarily from government grants and contracts. We plan to submit or have submitted proposals for government grants and contracts to various 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:

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Funding Source	Program	As of June 30, 2016 Total Award Value	Funded Award Value	Cumulative Revenue	Funded Backlog	Unfunded Backlog
DoD	JWMRP Contract	$9,226,455	$9,226,455	$561,509	$8,664,946	$ —
DoD	PRMRP Contract	6,573,992	6,573,992	57,489	6,516,503	—
MPT	CBLB612 Pre-clinical (1)	3,342,247	3,342,247	3,007,811	334,436	—
MPT	Entolimod Colorectal Cancer (1)	3,064,446	3,064,446	2,598,838	465,608	—
		22,207,140	22,207,140	6,225,647	15,981,493	—
MPT	Mobilan Pre-clinical (1)	3,203,117	3,203,117	2,769,549	433,568	—
		$25,410,257	$25,410,257	$8,995,196	$16,415,061	$ —

(1) The grants received from MPT are denominated in Russian Rubles (RUB). Cumulative Revenue includes contract receipts-to-date and outstanding receivables. Backlog amounts are valued at the period end exchange rate. Funded Award Value is the sum of Cumulative Revenue and Funded Backlog. Total Award Value is the sum of Funded Award Value and Unfunded Backlog.

Research and Development Expenses

R&D expenses decreased from $1.6 million for the three months ended June 30, 2015 to $1.3 million three months ended June 30, 2016, representing a decrease of $0.3 million, or 18.4%. Variances in individual development programs are noted in the table below. The net decrease is primarily attributable to (i) reduced expenses related to the development of entolimod for biodefense applications as a result of our streamlined focus on the submission of our Pre-EUA application and (ii) to the completion of preclinical studies of Curaxins in 2015, partially offset, in each case, by increased development activity related to CBLB612 and entolimod for oncology indications. The remaining variances are not significant and we anticipate an increase in spending for entolimod for biodefense applications as activities increase in the performance of the DoD contracts, which will primarily occur after the biocomparability study concludes.

	Three Months Ended June 30, 2016	2015	Variance
Entolimod for Biodefense Applications	$696,748	$908,138	$(211,390)
CBLB612	65,428	29,805	35,623
Entolimod for Oncology Indications	335,200	289,963	45,237
	1,097,376	1,227,906	(130,530)
Curaxins	101,729	254,072	(152,343)
Panacela product candidates	93,062	101,191	(8,129)
Total research & development expenses	$1,292,167	$1,583,169	$(291,002)

General and Administrative Expenses

G&A expenses decreased from $1.6 million for the three months ended June 30, 2015 to $0.8 million for the three months ended June 30, 2016, representing a decrease of $0.8 million, or 51.4%. These reductions consisted of $0.2 million in compensation expense due to reductions in personnel, $0.5 million in professional fees and $0.1 million in other operating expenses. The professional fee reduction primarily relates to non recurring activities in 2015 associated with strategic transactions.

Other Income and Expenses

Other expense decreased from $1.6 million for the three months ended June 30, 2015 to $0.4 million of other expense for the three months ended June 30, 2016, representing an expense decrease of $1.2 million, or 75.7%. This decrease was primarily related to a $0.9 million variance related to our warrant liability, $0.1 million related to our equity in the loss of Incuron accounted for as an equity investment during the three months ended June 30, 2015, and $0.2 million, in other income primarily due to a one-time gain in connection with the settlement of claims associated with our

Nota-Bank deposits.

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Six Months Ended June 30, 2016 Compared to Six Months Ended June 30, 2015

Revenue

Revenue increased from approximately $0.9 million for the six months ended June 30, 2015 to approximately $1.4 million for the six months ended June 30, 2016, representing an increase of approximately $0.5 million, or 48.0%, principally because of our JWMRP contract awarded to us in September 2015 for continued preclinical development of entolimod's biodefense indication. Regarding our other Russian trials funded by MPT, reported contract revenue increased by $0.1 million primarily due to variations in patient enrollment activity. Differences in our revenue sources, by program, between the years are set forth in the following table:

		Six months ended June 30,		
Funding Source	Program	2016	2015	Variance
DoD	JWMRP Contract (1)	368,293	—	$368,293
DoD	PRMRP Contract (2)	37,315	—	37,315
MPT	CBLB612 pre-clinical (3)	304,485	226,370	78,115
MPT	Entolimod colorectal cancer (3)	136,243	62,921	73,322
Incuron	Service contracts	343,592	391,439	(47,847)
		1,189,928	680,730	509,198
MPT	Mobilan pre-clinical (3)	197,597	256,507	(58,910)
		$1,387,525	$937,237	$450,288

(1) The Congressionally Directed Medical Research Programs (CDMRP) Joint Warfighter Medical Research Program (JWMRP) contract was awarded on September 1, 2015.

(2) The CDMRP Peer Reviewed Medical Research Program (PRMRP) grant was awarded effective as of September 30, 2015.

(3) 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 were relatively equal for the six months ended June 30, 2016 at approximately $3.2 million to the reported R&D expenses for the six months ended June 30, 2015. Variances in individual development programs are noted in the table below. Expenses for both CBLB612 and entolimod for oncology indications increased due to clinical studies in the Russian Federation that were not active in 2015. These expense increases were offset by reductions in expenses related to the submission of our Pre-EUA application and for the completion of preclinical studies of Curaxins in six months ended June 30, 2015. The remaining variances are not significant and we anticipate an increase in spending for entolimod for biodefense applications as activities increase in the performance of the DoD contracts.

	Six Months Ended June 30,		
	2016	2015	Variance
Entolimod for Biodefense Applications	$1,568,259	$1,813,621	$(245,362)
CBLB612	443,404	280,430	162,974
Entolimod for Oncology Indications	848,196	514,416	333,780
	2,859,859	2,608,467	251,392
Curaxins	219,308	412,349	(193,041)
Panacela product candidates	154,240	173,323	(19,083)
Total research & development expenses	$3,233,407	$3,194,139	$39,268

General and Administrative Expenses

G&A expenses decreased from $3.9 million for the six months ended June 30, 2015 to $2.0 million for the six months ended June 30, 2016, representing a net decrease of $1.9 million, or 49.8%. These net reductions consisted of a reduction of $0.5

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million in compensation expense, due to reductions in personnel, a reduction of $1.5 million in professional fees, and offset by an increase of $0.1 million in other operating expenses. The professional fee reduction primarily relates to non recurring activities in 2015 associated with strategic transactions, including a one-time expense of $0.6 million related to costs associated with our equity offering in February 2015. The majority of the costs of the February 2015 equity offering were expensed, and not otherwise charged to equity, as the majority of the net proceeds were considered derivative liabilities.

Other Income and Expenses

Other income increased from $2.0 million of Other expense for the six months ended June 30, 2015 to $1.2 million of other income for the six months ended June 30, 2016, representing an income increase of $3.2 million, or (162.5)%. This income increase was primarily related to a $2.4 million variance related to our warrant liability, $0.4 million related to our equity in the loss of Incuron accounted for as an equity investment during the six months ended June 30, 2016, and $0.4 million in other income primarily due to gains on the sale of equipment and a one-time gain in connection with the settlement of claims associated with our Nota-Bank deposits.

Liquidity and Capital Resources

We have incurred net losses of approximately $150.6 million from our inception through June 30, 2016. Historically, we have not generated, and do not expect to generate in the immediate future, revenue from sales of product candidates. Since our founding in 2003, we have funded our operations through a variety of means:

- From inception through June 30, 2016, we have raised $144.7 million of net equity capital, including amounts received from the exercise of options and warrants. We have also received $7.3 million in net proceeds from the issuance of long-term debt instruments;
- DoD and BARDA have funded grants and contracts totaling $60.4 million for the development of entolimod for its biodefense indication;
- The Russian Federation has funded a series of our contracts totaling $17.3 million, based on the exchange rates in effect on the date of funding. These contracts include a requirement for us to contribute matching funds, which we have satisfied or expect to satisfy with both the value of developed intellectual property at the time of award, incurred development expenses and future expenses;
- We have been awarded $4.0 million in grants and contracts not described above, all of which have been recognized at June 30, 2016;
- Incuron was formed to develop and commercialize the Curaxins product line, including its lead oncology drug candidate CBL0137. In 2015, we sold our ownership interest for approximately $4.0 million and retain a 2% royalty interest in the CBL0137 technology; and
- Panacela was formed to develop and commercialize preclinical compounds, which were transferred to Panacela through assignment and lease agreements. RUSNAO contributed $9.0 million to Panacela and CBLI contributed $3.0 million plus intellectual property to Panacela. As of the date of this filing, CBLI owns 67.57% of Panacela.

We have incurred cumulative net losses and expect to incur additional losses related to our R&D activities. We do not have commercial products and have limited capital resources. At June 30, 2016, we had cash, cash equivalents and short-term investments of $16.4 million which, along with the active government contracts described above, are expected to fund our projected operating requirements beyond one year. However, until we are able to commercialize our product candidates at a level that covers our cash expenses, we will need to raise substantial additional capital, which we may be unable to raise in sufficient amounts, when needed and at acceptable terms. Our plans with regard to these matters may include seeking additional capital through debt or equity financing, the sale or license of drug candidates, or obtaining additional research funding from the U.S. or Russian governments. There can be no assurance that we will be able to obtain future financing on acceptable terms, or that we can obtain additional government financing for our 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.

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Cash Flows:

The following table provides information regarding our cash flows for the six months ended June 30, 2016 and 2015:

	For the Six Months Ended June 30,		
	2016	2015	Variance
Cash flows used in operating activities	$(3,947,633)	$(4,972,851)	$1,025,218
Cash flows provided by investing activities	2,857,506	2,386,043	471,463
Cash flows provided by financing activities	539,998	2,672,962	(2,132,964)
Effect of exchange rate change on cash and equivalents	43,772	(2)	43,774
Increase in cash and cash equivalents	(506,357)	86,152	(592,509)
Cash and cash equivalents at beginning of period	5,918,424	3,103,969	2,814,455
Cash and cash equivalents at end of period	$5,412,067	$3,190,121	$2,221,946

Operating Activities

Net cash used in operating activities decreased by $1.0 million to $3.9 million for the six months ended June 30, 2016 from $5.0 million for the six months ended June 30, 2015. Net cash used in operating activities for the period ending June 30, 2016 consisted of a reported net loss of $2.6 million, which was adjusted down for $0.8 million of net noncash operating activities, and a $0.6 million net decrease due to changes in operating assets and liabilities. The $0.8 million of net non-cash operating activities substantially consisted of changes in the valuation of our warrant liability. Of the net $0.6 million of changes in operating assets and liabilities, $0.3 million was due to a net increase in accounts receivable and other currents assets, $0.3 million was due to a net decrease in accrued expenses and accounts payable and $0.1 million was due to a net increase in deferred revenue.

Net cash used in operating activities for the six months ended June 30, 2015 of $5.0 million consisted of a reported net loss of $8.2 million, which was reduced for $2.7 million of net noncash operating activities, and a $0.5 million net increase due to changes in operating assets and liabilities. Of the net noncash operating activities of $2.7 million, $0.6 million was due to warrant issuance costs, $0.4 million was due to our equity in Incuron, LLC losses, and $1.7 million was due to depreciation and other noncash expenses. The $1.7 million of depreciation and other noncash expenses substantially consisted of a $1.5 million change in the valuation of our warrant liability. Of the net $0.5 million of changes in operating assets and liabilities, $0.5 million was due to a net increase in deferred revenue, $(0.1) million was due to a net decrease in accrued expenses and accounts payable, and $0.1 million was due to a net decrease in accounts receivable and other currents assets.

Investing Activities

Net cash provided by investing activities increased by $0.5 million to $2.9 million for the six months ended June 30, 2016 from $2.4 million for the six months ended June 30, 2015. The net cash provided by investing activities for the six months ended June 30, 2016 consisted primarily of maturities of short-term investments of $11.7 million as offset by $8.8 million of purchases of short-term investments.

Net cash provided by investing activities for the six months ended June 30, 2015 consisted primarily of $2.0 million of proceeds received in connection with the sale of Incuron more fully described in Note 4 and $0.3 million of maturities of short-term investments. Additionally, $0.8 million of cash provided by the release of restricted cash was fully offset by purchases of short-term investments.

Financing Activities

Net cash provided by financing activities decreased by $2.1 million to $0.5 million for the six months ended June 30, 2016 from $2.7 million for the six months ended June 30, 2015. Net cash provided by financing activities for the six months ended June 30, 2016 consisted of the sale of $0.5 million in Treasury stock.

Net cash provided by financing activities for the six months ended June 30, 2015 of $2.7 million consisted of the sale of $3.1 million in equity securities offset primarily by $0.4 million in principal and interest payments associated with the repayment of the Hercules Loan more fully described in Note 5, "Debt" included our Annual Report on Form 10-K for the year ended December 31, 2015.

Impact of Exchange Rate Fluctuations

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Our reported financial results are affected by changes in foreign currency exchange rates between the U.S. dollar and the Russian ruble. Between January 1, 2016 and June 30, 2016, this rate fluctuated by 11.9%. For calendar 2015, this rate fluctuated by 29.6%. Translation gains or losses result primarily from the impact of exchange rate fluctuations on the reported U.S. dollar equivalent of ruble denominated cash and cash equivalents, restricted cash and short-term investments. Variances in the exchange rate for these items have not been realized; as such the resulting gains or losses are recorded as other comprehensive income in the equity section of the balance sheet.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required for smaller reporting company filers.

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, 2016. 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, 2016, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective to ensure that information required to be disclosed 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, 2016, 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

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially affect our results of operations, cash flows or financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management resources and other factors.

While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of June 30, 2016, that, in the opinion of management, might have a material adverse effect on our financial position, results of operations or cash flows.

Item 1A. Risk Factors

Not required for smaller reporting company filers.

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

None.

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Item 3. Defaults Upon Senior Securities
None.
Item 4. Mine Safety Disclosures
None.
Item 5. Other Information
None.

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Item 6. Exhibits

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

Exhibit Number	Description of Document
3.1	Restated Certificate of Incorporation filed with the Secretary of State of Delaware on March 18, 2010 (incorporated by reference to Exhibit 3.1 to Form 10-K for the year ended December 31, 2009, filed on March 22, 2010).
3.2	Certificate of Amendment to the Restated Certificate of Incorporation, filed with the Secretary of State of Delaware on June 20, 2013 (incorporated by reference to Exhibit 3.1 to Form 10-Q for the period ended June 30, 2013, filed on August 9, 2013).
3.3	Certificate of Amendment to Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Form 8-K filed on January 27, 2015)
3.4	Certificate of Amendment to Restated Certificate of Incorporation, filed with the Secretary of State of Delaware on April 20, 2016 (incorporated by reference to Exhibit 3.4 to Form 10-Q for the period ended March 31, 2016, filed on May 16, 2016)
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on February 9, 2015).
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on February 9, 2015).
3.7	Second Amended and Restated By-Laws (incorporated by reference to Exhibit 3.1 to Form 8-K filed on December 5, 2007).
10.1	Separation and Consulting Agreement between and C. Neil Lyons and Cleveland BioLabs, Inc., dated as of May 6, 2016 (incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 6, 2016)
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, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Condensed Balance Sheets as of June 30, 2016 and December 31, 2015; (ii) Consolidated Condensed Statements of Operations for the Three and Six Months Ended June 30, 2016 and 2015; (iii) Consolidated Condensed Statements of Comprehensive Loss for the Three and Six Months Ended June 30, 2016 and 2015; (iv) Consolidated Condensed Statements of Stockholders' Equity (Deficit) for the Six Months Ended June 30, 2016; (v) Consolidated Condensed Statements of Cash Flows for the Six Months ended June 30, 2016 and 2015; and (vi) Notes to Consolidated Condensed Financial Statements.

* Filed herewith.

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Signatures

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CLEVELAND BIOLABS, INC.

Dated: August 15, 2016 By: /s/ YAKOV KOGAN
Yakov Kogan
Chief Executive Officer
(Principal Executive Officer)

Dated: August 15, 2016 By: /s/ C. NEIL LYONS
C. Neil Lyons
Chief Financial Officer
(Principal Financial Officer)