CLEVELAND BIOLABS INC
Form 10-Q
August 14, 2017
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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, 2017
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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	¨	Smaller reporting company	x
Emerging Growth Company	¨		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the

Exchange Act. ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of July 31, 2017, there were 11,279,834 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, 2017 (Unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$3,932,001	$6,901,816
Short-term investments	7,524,765	8,343,657
Accounts receivable	427,184	352,700
Other current assets	292,783	289,768
Total current assets	12,176,733	15,887,941
Equipment, net	23,599	37,376
Other long-term assets	30,619	30,553
Total assets	$12,230,951	$15,955,870
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$298,280	$336,435
Accrued expenses	1,200,216	1,823,235
Accrued warrant liability	861,016	949,419
Total current liabilities	2,359,512	3,109,089
Commitments and contingencies	—	—
Total liabilities	2,359,512	3,109,089
Stockholders' equity:		
Preferred stock, $.005 par value; 1,000,000 and 10,000,000 shares authorized as of June 30, 2017 and December 31, 2016, respectively, 0 shares issued and outstanding as of June 30, 2017 and December 31, 2016	—	—
Common stock, $.005 par value; 25,000,000 and 160,000,000 shares authorized as of June 30, 2017 and December 31, 2016, respectively, 11,279,834 and 10,987,166 shares issued and outstanding as of June 30, 2017 and December 31, 2016, respectively	56,395	54,932
Additional paid-in capital	163,106,400	158,773,753
Other comprehensive loss	(539,000)	(564,559)
Accumulated deficit	(158,016,638)	(150,740,156)
Total Cleveland BioLabs, Inc. stockholders' equity	4,607,157	7,523,970
Noncontrolling interest in stockholders' equity	5,264,282	5,322,811
Total stockholders' equity	9,871,439	12,846,781
Total liabilities and stockholders' equity	$12,230,951	$15,955,870

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,	
	2017	2016	2017	2016
Revenues:				
Grants and contracts	$206,156	$575,025	$781,130	$1,387,525
Operating expenses:				
Research and development	1,188,380	1,292,167	2,605,378	3,233,407
General and administrative	588,288	777,107	1,365,712	1,960,673
Total operating expenses	1,776,668	2,069,274	3,971,090	5,194,080
Loss from operations	(1,570,512)	(1,494,249)	(3,189,960)	(3,806,555)
Other income (expense):				
Interest and other income	50,434	121,969	99,723	303,734
Foreign exchange gain (loss)	(4,055)	33,102	(12,285)	80,188
Change in value of warrant liability	(4,124,009)	(547,163)	(4,245,707)	865,550
Total other income (expense)	(4,077,630)	(392,092)	(4,158,269)	1,249,472
Net loss	(5,648,142)	(1,886,341)	(7,348,229)	(2,557,083)
Net loss (income) attributable to noncontrolling interests	35,354	(11,527)	71,747	(8,721)
Net loss attributable to Cleveland BioLabs, Inc.	$(5,612,788)	$(1,897,868)	$(7,276,482)	$(2,565,804)
Net loss attributable to common stockholders per share of common stock, basic and diluted	$(0.50)	$(0.17)	$(0.66)	$(0.23)
Weighted average number of shares used in calculating net loss per share, basic and diluted	11,218,727	10,987,166	11,103,586	10,987,166

See Notes to Consolidated Financial Statements

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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,	
	2017	2016	2017	2016
Net loss including noncontrolling interests	$(5,648,142)	$(1,886,341)	$(7,348,229)	$(2,557,083)
Other comprehensive income (loss):				
Unrealized gain (loss) on short-term investments	(292)	2,716	(3,410)	9,438
Foreign currency translation adjustment	(60,348)	23,044	42,187	46,365
Comprehensive loss including noncontrolling interests	(5,708,782)	(1,860,581)	(7,309,452)	(2,501,280)
Comprehensive loss (gain) attributable to noncontrolling interests	54,575	(32,084)	58,529	(59,166)
Comprehensive loss attributable to Cleveland BioLabs, Inc.	$(5,654,207)	$(1,892,665)	$(7,250,923)	$(2,560,446)

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

	Common Stock		Treasury Stock		Additional Paid-In			
	Shares	Amount	Shares	Amount	Capital			
Balance at December 31, 2016	10,987,166	$54,932	—	$ —	$158,773,753			
Exercise of warrants	292,668	1,463	—	—	4,332,647			
Net loss	—	—	—	—	—			
Unrealized loss on short-term investments	—	—	—	—	—			
Foreign currency translation	—	—	—	—	—			
Balance at June 30, 2017	11,279,834	$56,395	—	$ —	$163,106,400			

	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Noncontrolling Interests	Total
Balance at December 31, 2016	$ (564,559)	$(150,740,156)	$ 5,322,811	$12,846,781
Exercise of warrants	—	—	—	4,334,110
Net loss	—	(7,276,482)	(71,747)	(7,348,229)
Unrealized loss on short-term investments	(3,410)	—	—	(3,410)
Foreign currency translation	28,969	—	13,218	42,187
Balance at June 30, 2017	$ (539,000)	$(158,016,638)	$ 5,264,282	$9,871,439

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

	For the Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	$(7,348,229)	$(2,557,083)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	11,641	41,565
Non-cash investment income	(29,527)	(20,189)
Gain on equipment disposal	(6,727)	—
Non-cash compensation	—	13,624
Change in value of warrant liability	4,245,707	(865,550)
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	(77,375)	(342,684)
Other long-term assets	—	(1,838)
Accounts payable and accrued expenses	(694,170)	(342,675)
Deferred revenue	—	127,197
Net cash used in operating activities	(3,898,680)	(3,947,633)
Cash flows from investing activities:		
Purchase of short-term investments	(4,594,890)	(8,813,086)
Sale of short-term investments	5,460,087	11,658,162
Purchase of equipment	—	(4,235)
Proceeds from sale of equipment	8,970	16,665
Net cash provided by investing activities	874,167	2,857,506
Cash flows from financing activities:		
Net proceeds from sale of treasury stock	—	539,998
Net cash provided by financing activities	—	539,998
Effect of exchange rate change on cash and equivalents	54,698	43,772
Increase (decrease) in cash and cash equivalents	(2,969,815)	(506,357)
Cash and cash equivalents at beginning of period	6,901,816	5,918,424
Cash and cash equivalents at end of period	$3,932,001	$5,412,067
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$—	$—
Supplemental schedule of non-cash financing activities:		
Cashless exercise of warrants	$4,334,110	$—

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 medical 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 two subsidiaries: one wholly-owned subsidiary, BioLab 612, LLC ("BioLab 612"), which began operations in 2012; and Panacela Labs, Inc. ("Panacela"), which was formed by us and Joint Stock Company "RUSNANO" ("RUSNANO"), our financial partner in the venture, in 2011. 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. All significant intercompany balances and transactions have been eliminated in consolidation.

The consolidated condensed balance sheet as of December 31, 2016, 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, 2016, as filed with the SEC (the "2016 Form 10-K").

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, 2017, along with its results of operations for the three and six month periods ended June 30, 2017 and 2016 and cash flows for the six month periods ended June 30, 2017 and 2016. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

At June 30, 2017, we had cash, cash equivalents and short-term investments of $11.5 million in the aggregate. Management believes this capital will fund the Company's operations and cash requirements for at least 12 months beyond the filing date of this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard-setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

In November 2016, the FASB issued ASU 2016-18, "Statement of Cash Flows (Topic 230): Restricted Cash" ("ASU

2016-18”). ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2016-18 on its consolidated financial statements.

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In May 2016, the FASB issued ASU 2016-12, “Revenue from Contracts with Customers (Topic 606): Narrow Scope Improvements and Practical Expedients” (“ASU 2016-12”). The amendments in ASU 2016-12 affect the guidance in ASU 2014-09 by clarifying certain specific aspects of the guidance, including assessment of collectability, treatment of sales taxes and contract modifications, and providing certain technical corrections. The pronouncement has the same effective date as ASU 2014-09, which is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2017. The Company is currently evaluating the impact of ASU 2016-12 on its consolidated financial statements. In April 2016, the FASB issued ASU 2016-10, “Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing” (“ASU 2016-10”) related to identifying performance obligations and licensing. ASU 2016-10 is meant to clarify the guidance in FASB ASU 2014-09, “Revenue from Contracts with Customers.” Specifically, ASU 2016-10 addresses an entity’s identification of its performance obligations in a contract, as well as an entity’s evaluation of the nature of its promise to grant a license of intellectual property and whether or not that revenue is recognized over time or at a point in time. The pronouncement has the same effective date as ASU 2014-09, which is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2017. The Company is currently evaluating the impact of ASU 2016-10 on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, “Improvements to Employee Share-Based Payment Accounting” (“ASU 2016-09”). ASU 2016-09 affects entities that issue share-based payment awards to their employees. ASU 2016-09 is designed to simplify several aspects of accounting for share-based payment award transactions which include the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and forfeiture rate calculations. ASU 2016-09 is effective for annual periods beginning after December 15, 2016 and for interim periods thereafter. The Company adopted this pronouncement for the year ended December 31, 2016.

In February 2016, the FASB issued ASU 2016-02, “Leases (Topic 842)” (“ASU 2016-02”). ASU 2016-02 will require organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 will be effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018, with early adoption permitted. The Company expects to adopt this guidance when effective and is currently evaluating the effect that the updated standard will have on its consolidated balance sheets and related disclosures.

In January 2016, the FASB issued ASU 2016-01, “Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities.” The pronouncement requires equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income, requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes, requires separate presentation of financial assets and financial liabilities by measurement category and form of financial asset, and eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost. These changes become effective for the Company's fiscal year beginning January 1, 2018. The expected adoption method of ASU 2016-01 is being evaluated by the Company and the adoption is not expected to have a significant impact on the Company’s consolidated financial position or results of operations.

In May 2014, the FASB issued Accounting Standards Update (“ASU, 2014-9”), “Revenue from Contracts with Customers,” which updates the principles for recognizing revenue. ASU 2014-9 also amends the required disclosures

of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. ASU 2014-9 was scheduled to be effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. In August 2015, the FASB issued ASU 2015-14, “Revenue from Contracts with Customers (Topic 606): Deferral of Effective Date” (“ASU 2015-14”) which defers the effective date of ASU 2014-09 by one year. ASU 2014-9 is now effective for annual reporting periods after December 15, 2017 including interim periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. The Company is evaluating the potential impacts of the new standard on its existing revenue recognition policies and procedures.

In August 2014, the FASB issued ASU 2014-15, “Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern” (“ASU 2014-15”), which requires that an entity’s management evaluate whether there are conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued. ASU 2014-15 is effective for annual periods beginning after December 15, 2016 and for interim periods thereafter. The Company adopted this pronouncement during the year ended December 31, 2016.

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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 and held to maturity. Accordingly, these investments are carried at fair market value. Short-term investments consisted of U.S. Treasury securities in the amount of $6.5 million which were owned by CBLI and had maturities of less than 12 months. In addition, $1.0 million in certificates of deposit with maturity dates beyond three months and less than one year, and owned by Panacela, are also included. These investments are classified as held to maturity given the intent and ability to hold the investments to maturity. 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 Income. 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, 2017 and 2016.

	Three Months Ended June 30,			Six Months Ended June 30,		
Customer	2017	2016	Variance	2017	2016	Variance
Department of Defense	63.4 %	27.6 %	35.8 %	70.3 %	29.2 %	41.1 %
Russian Government Agencies	— %	53.1 %	(53.1)%	— %	46.0 %	(46.0)%
Incuron, LLC	36.6 %	19.3 %	17.3 %	29.7 %	24.8 %	4.9 %
Total	100.0%	100.0%	— %	100.0%	100.0%	— %

Our current Department of Defense ("DoD") revenues come from development contracts that expire in 2017 and 2018, although each contract may be extended. Our Russian Government Agencies revenues came from development contracts which expired in 2016. Our Incuron, LLC revenues come from a service agreement that is renegotiated annually.

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.

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, 2017.

	Unrealized loss on available-for-sale securities	Gains and losses on foreign exchange translations	Total
Beginning balance	$ (2,286)	$(562,273)	$(564,559)
Other comprehensive income (loss) before reclassifications	(3,410)	28,969	25,559

Amounts reclassified from accumulated other comprehensive loss	—	—	—
Ending balance	$ (5,696)	$(533,304)	$(539,000)

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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, 2017, an aggregate of 650,000 shares of common stock were authorized for issuance under the Plan, of which a total of 303,535 shares of common stock remained available for future awards and 217,921 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 or its management delegates.

The 2013 Employee Stock Purchase Plan, or ESPP, 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, 2017, there are 425,000 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. No options were granted during the six months ended June 30, 2017 and June 30, 2016.

"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 anticipated dividend return for an investor over the expected life. For the Company, this amount is zero as it is not anticipated that dividends will be paid for 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, 2017 and 2016, as the Company does not expect to have taxable income for 2017 and did not have taxable income in 2016. 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 the 2016 Form 10-K, the Company had U.S. federal net operating loss carryforwards of approximately $134,774,000, which begin to expire if not utilized by 2023, and approximately $3,905,000 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 $80,714,000, which begin to expire if not utilized by 2027 and state tax credit carryforwards of approximately $324,000, which begin to expire if not utilized by 2022. The purchase of 6,459,948 shares of common stock by Mr. David Davidovich, our majority stockholder, 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 7, Stockholders' Equity, to the Company's consolidated financial statements included in the 2016 Form 10-K 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

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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 loss per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net loss by the weighted average number of shares outstanding for the period. Diluted net 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. Additionally, there were no dilutive securities outstanding as of June 30, 2017.

	As of June 30,	
Common Equivalent Securities	2017	2016
Warrants	925,812	2,148,741
Options	217,921	303,293
Total	1,143,733	2,452,034

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 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.

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	As of June 30, 2017			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$23,087	$—	$—	$23,087
Short-term investments	6,509,287	1,015,478	—	7,524,765
Total assets	$6,532,374	$1,015,478	$—	$7,547,852
Liabilities:				
Accrued warrant liability	$—	$—	$861,016	$861,016

	As of December 31, 2016			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$2,436,589	$—	$—	$2,436,589
Short-term investments	7,487,365	856,292	—	8,343,657
Total assets	$9,923,954	$856,292	$—	$10,780,246
Liabilities:				
Accrued warrant liability	$—	$—	$949,419	$949,419

The Company uses the Black-Scholes model to measure the accrued warrant liability. The following are the assumptions used to measure the accrued warrant liability which were determined in a manner consistent with grants of options to purchase common stock:

	June 30, 2017	December 31, 2016
Stock Price	$ 2.95	$ 1.42
Exercise Price	$3.00 - $60.00	$3.00 - $60.00
Term in years	0.32 – 4.10	0.17 - 4.60
Volatility	104.39% - 232.14%	52.88% - 96.36%
Annual rate of quarterly dividends	— %	— %
Discount rate- bond equivalent yield	.39% - 1.74%	.15% - 1.84%

The following tables set 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, 2017	Three Months Ended June 30, 2016
	Accrued Warrant Liability	Accrued Warrant Liability
Beginning Balance	$1,071,117	$2,636,187
Total (gains) or losses, realized and unrealized, included in earnings (1)	4,124,009	547,163
Issuances	—	—
Settlements	(4,334,110)	—
Ending Balance	$861,016	$3,183,350

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	Six Months Ended June 30, 2017 Accrued Warrant Liability	Six Months Ended June 30, 2016 Accrued Warrant Liability
Beginning Balance	$949,419	$4,048,900
Total (gains) or losses, realized and unrealized, included in earnings (1)	4,245,707	(865,550)
Issuances	—	—
Settlements	(4,334,110)	—
Ending Balance	$861,016	$3,183,350

(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, 2017 and 2016.

As of June 30, 2017 and December 31, 2016, the Company had no assets or liabilities that were measured at fair value on a nonrecurring basis.

The Company considers the accrued warrant liability to be Level 3 because some of the inputs into the measurements are neither directly or indirectly observable. The accrued warrant liability uses management's estimate for the expected term. As of June 30, 2017, 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 0.32 – 4.10 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. 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, 2017:

	Total Stock Options Outstanding	Weighted Average Exercise Price per Share
December 31, 2016	233,367	$ 41.98
Granted	—	—
Vested	—	—
Forfeited, Canceled	(15,446)	80.88
June 30, 2017	217,921	$ 39.22

The following is a summary of outstanding stock options as of June 30, 2017:

	As of June 30, 2017	
	Stock Options Outstanding	Vested Stock Options
Quantity	217,921	217,921

Weighted-average exercise price	$39.22	$ 39.22
Weighted Average Remaining Contractual Term (in Years)	5.70	5.70
Intrinsic value	$—	$ —

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For the six months ended June 30, 2017 and 2016, the Company granted no stock options. For the six months ended June 30, 2017 and 2016, the total fair value of options vested was $0 and $83,789, respectively.
As of June 30, 2017, there was no total compensation cost not yet recognized related to unvested stock options.

5. 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 seven 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, 2016:

	Number of Warrants	Weighted Average Exercise Price
December 31, 2016	2,148,741	$ 11.04
Granted	—	—
Exercised	(1,181,235)	3.64
Forfeited, Canceled	(41,694)	3.00
June 30, 2017	925,812	$ 20.84

During April 2017, warrant holders exercised 1,181,235 warrants for 292,668 shares of the Company's common stock through cashless exercises. The fair value of the warrants exercised was valued using the Black-Scholes option pricing model based on the following assumptions:

	April 20, 2017
Stock Price	$4.84
Exercise Price	$3.64
Term in years	4.29
Volatility	101.93%
Annual rate of quarterly dividends	— %
Discount rate- bond equivalent yield	1.65 %

6. 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 $20,111 and $46,908 in research and development expense to RPCI for the three and six months ended June 30, 2017, respectively, and $241,235 and $449,079 in research and development expense to RPCI for the three and six months ended June 30, 2016, respectively. The Company had $87,964 and $2,770 included in accounts payable owed to RPCI at June 30, 2017 and 2016, respectively. In addition, the Company had $85,102 and $169,330 in accrued expenses payable to RPCI at June 30, 2017 and 2016, 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 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, 2017 or 2016.

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Buffalo BioLabs and Incuron

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 $84,519 and $154,065 in research and development expense to BBL for the three and six months ended June 30, 2017, respectively, and $171,960 and $491,909 in research and development expense to BBL for the three and six months ended June 30, 2016, respectively. In addition, the Company had $0 and $45,500 in accrued expenses payable to BBL, and $4,840 and $0 in accounts payable to BBL at June 30, 2017 and 2016, respectively. The Company also recognized $11,553 and $23,106 from BBL as sublease and other income for the three and six months ended June 30, 2017, respectively, and $7,819 and $63,001 from BBL as sublease and other income for the three and six months ended June 30, 2016, respectively. Pursuant to our real estate sublease and equipment lease with BBL, we had gross accounts receivables of $213,704 and $206,651 and net accounts receivables of $11,553 and $0 at June 30, 2017 and 2016, respectively.

Dr. Gudkov is also an uncompensated member of the board of directors for Incuron, LLC, or Incuron, a previously consolidated majority-owned subsidiary. Pursuant to master service and development agreements the Company has with Incuron, the Company performs various research, business development, clinical advisory, and management services. We recognized revenue from Incuron of $75,402 and $231,633 for the three and six months ended June 30, 2017, respectively, and revenue from Incuron of $111,113 and $343,592 for the three and six months ended June 30, 2016, respectively. In addition, we also recognized $1,776 and $3,552 from Incuron as sublease and other income for the three and six months ended June 30, 2017, respectively, and $1,776 and $3,552 from Incuron as sublease and other income for the three and six months ended June 30, 2016, respectively. Pursuant to these agreements, we had gross accounts receivable of $50,303 and $98,315 at June 30, 2017 and 2016, 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” “intend,” “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, 2016. 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, regulatory developments, our inability to obtain regulatory approval in a timely manner, or at all, 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, 2016.

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, 2016.

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 two subsidiaries, one of which is wholly-owned, BioLab 612, and one of which is owned in collaboration with a financial partner, Panacela. In addition, we conducted

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business with a former subsidiary, Incuron, which will pay us a 2% royalty on future commercialization, licensing, or sale of certain technology we sold to Incuron.

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, project management, business development, and clinical advisory 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 and regulatory affairs, corporate and business development, human resources, and 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 warrants, 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, 2016. 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, 2016.

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, 2017, we held approximately

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$0.02 million in cash equivalents, $6.5 million in U.S. Treasury Notes which we classified as Level 1, and $1.0 million in certificates of deposit which we classified as Level 2.

We use the Black-Scholes model to determine the fair value of certain common stock warrants 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 common stock and a group of comparable companies; and (iv) the risk-free market rate.

As of June 30, 2017, we held approximately $0.9 million in accrued expenses related to warrants to purchase common stock, which we classified as Level 3.

Three Months Ended June 30, 2017 Compared to Three Months Ended June 30, 2016

Revenue

Revenue decreased from approximately $0.6 million for the three months ended June 30, 2016 to approximately $0.2 million for the three months ended June 30, 2017, representing a decrease of approximately $0.4 million, or 64.1%, primarily due to the completion of our grants from the Russian Federation Ministry of Industry and Trade ("MPT") at December 31, 2016 and completion of manufacturing activities for entolimod under our Joint Warfighter Medical Research Program ("JWMRP") contract with the DoD. Prospectively, the DoD contracts will gradually increase as we (1) commence the in vivo biocomparability study in the scope of the JWMRP contract, as required by the U.S. Food and Drug Administration ("FDA") as part of the pre-Emergency Use Authorization ("pre-EUA") review, and (2) initiate studies for the continued preclinical and clinical development of entolimod for the preparation of a Biologics License Application ("BLA") of entolimod as a radiation countermeasure in the U.S. Our Incuron service contracts were recently renewed and are scheduled to complete in 2017. Differences in our revenue sources, by program, between the years are set forth in the following table.

		Three Months		
	Program	Ended June 30,		
Funding Source		2017	2016	Variance
DoD	JWMRP Contract (1)	$129,094	$149,192	$(20,098)
DoD	PRMRP Contract (2)	1,660	9,534	(7,874)
DoD	DTRA Contract (3)	—	—	—
MPT	CBLB612 pre-clinical (4)	—	41,934	(41,934)
MPT	Entolimod colorectal cancer (4)	—	130,331	(130,331)
Incuron	Service contract	75,402	111,113	(35,711)
		206,156	442,104	(235,948)
MPT	Mobilan pre-clinical (4)	—	132,921	(132,921)
		$206,156	$575,025	$(368,869)

(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 Defense Threat Reduction Agency (DTRA) contract had additional revenue recognized upon acknowledgment of final annual indirect rates for the fiscal year ended December 31, 2013.

(4) 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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				As of June 30, 2017		
Funding Source	Program	Total Award Value	Funded Award Value	Cumulative Revenue	Funded Backlog	Unfunded Backlog
DoD	JWMRP Contract	$9,226,455	$ 9,226,455	$1,935,651	$7,290,804	$ —
DoD	PRMRP Contract	6,573,992	6,573,992	72,674	6,501,318	—
		$15,800,447	$ 15,800,447	$2,008,325	$13,792,122	$ —

Research and Development Expenses

R&D expenses decreased from $1.3 million for the three months ended June 30, 2016 to $1.2 million for the three months ended June 30, 2017, representing a decrease of $0.1 million, or 7.7%. Variances in individual development programs are noted in the table below. The net decrease is primarily attributable to a $0.3 million reduction in spending on entolimod for oncology indications due to completion of a clinical study of the safety and tolerability of entolimod as a neo-adjuvant therapy in treatment-naïve patients with primary colorectal cancer and completion of associated preparatory research studies, offset by a $0.3 million increase in spending on entolimod for biodefense applications for continued preclinical development along with drug manufacturing activities associated with our JWMRP contract and expenses associated with our regulatory activities in support of filing a Marketing Authorization Application (“MAA”) with European Medicines Agency (“EMA”). The remaining variances are not significant. We anticipate an increase in spending for entolimod for biodefense applications as activities increase in connection with the performance of the DoD contracts and our pursuit of approval by the EMA and the FDA.

	Three Months Ended June 30,		
	2017	2016	Variance
Entolimod for Biodefense Applications	$950,305	$696,748	$253,557
CBLB612	3,412	65,428	(62,016)
Entolimod for Oncology Indications	79,685	335,200	(255,515)
	1,033,402	1,097,376	(63,974)
Incuron service contract	88,939	101,729	(12,790)
Panacela product candidates	66,039	93,062	(27,023)
Total research and development expenses	$1,188,380	$1,292,167	$(103,787)

General and Administrative Expenses

G&A expenses decreased from $0.8 million for the three months ended June 30, 2016 to $0.6 million for the three months ended June 30, 2017, representing a decrease of $0.2 million, or 24.3%. These reductions consisted of a $0.2 million reduction in compensation expense due to reductions in personnel and a $0.1 million reduction in professional fees due to streamlining efforts, offset by a $0.1 million increase in subcontractor expenses.

Other Income and Expenses

Other expense increased from $0.4 million of other expense for the three months ended June 30, 2016 to $4.1 million of other expense for the three months ended June 30, 2017, representing an expense increase of $3.7 million, or 940.0%. This increase was primarily related to a $3.6 million non-cash loss related to the change in value of our warrant liability.

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Six Months Ended June 30, 2017 Compared to Six Months Ended June 30, 2016

Revenue

Revenue decreased from approximately $1.4 million for the six months ended June 30, 2016 to approximately $0.8 million for the six months ended June 30, 2017, representing a decrease of approximately $0.6 million, or 43.7%. This decrease is principally due to completion of our grants from the MPT at December 31, 2016 and a decrease in Incuron service contract revenue due to reduced research and development services provided to Incuron during the first six months of 2017, partially offset by increased revenues from our JWMRP contract due to increased activity related to entolimod manufacturing and performance of certain preclinical work required during the first six months of 2017. Differences in our revenue sources, by program, between the years are set forth in the following table:

Funding Source	Program	Six Months Ended June 30, 2017	2016	Variance
DoD	JWMRP Contract (1)	$544,188	$368,293	$175,895
DoD	PRMRP Contract (2)	3,423	37,315	(33,892)
DoD	DTRA Contract (3)	1,886	—	1,886
MPT	CBLB612 pre-clinical (4)	—	304,485	(304,485)
MPT	Entolimod colorectal cancer (4)	—	136,243	(136,243)
Incuron	Service contract	231,633	343,592	(111,959)
		781,130	1,189,928	(408,798)
MPT	Mobilan pre-clinical (4)	—	197,597	(197,597)
		$781,130	$1,387,525	$(606,395)

(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 Defense Threat Reduction Agency (DTRA) contract had additional revenue recognized upon acknowledgment of final annual indirect rates for the fiscal year ended December 31, 2013.

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

Research and Development Expenses

R&D expenses decreased from approximately $3.2 million for the six months ended June 30, 2016 to approximately $2.6 million for the six months ended June 30, 2017, representing a decrease of approximately $0.6 million, or 19.4% . Variances in individual development programs are noted in the table below. Expenses for the CBLB612 project decreased due to completion of the clinical studies in the Russian Federation. In addition, we experienced reductions in expenses related to submission of our pre-EUA application and for preclinical studies of entolimod for oncology indications and the Incuron service contract. These decreases were offset by an increase in expenses for our entolimod for biodefense applications for continued development along with drug manufacturing activities associated with our JWMRP contract and expenses associated with our regulatory efforts in support of filing a MAA with EMA. The remaining variances are not significant. 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, 2017	2016	Variance
Entolimod for Biodefense Applications	$2,153,142	$1,568,259	$584,883
CBLB612	25,144	443,404	(418,260)
Entolimod for Oncology Indications	150,365	848,196	(697,831)

	2,328,651	2,859,859	(531,208)
Incuron service contract	142,571	219,308	(76,737)
Panacela product candidates	134,156	154,240	(20,084)
Total research and development expenses	$2,605,378	$3,233,407	$(628,029)

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General and Administrative Expenses

G&A expenses decreased from $2.0 million for the six months ended June 30, 2016 to $1.4 million for the six months ended June 30, 2017, representing a net decrease of $0.6 million, or 30.3%. These net reductions consisted of a reduction of $0.4 million in compensation expense due to reductions in personnel, a reduction of $0.1 million in professional fees, and a reduction of $0.2 million in other expenses, partially offset by a $0.2 million increase in subcontractor expenses.

Other Income and Expenses

Other expense increased from $1.2 million of other income for the six months ended June 30, 2016 to $4.2 million of other expense for the six months ended June 30, 2017, representing an expense increase of $5.4 million, or 432.8%. This expense increase was primarily related to a $5.1 million non-cash loss related to our warrant liability, a $0.2 million decrease in interest and other income due to a decrease in invested assets, and a $0.1 million increase in foreign exchange losses.

Liquidity and Capital Resources

We have incurred net losses of approximately $158.0 million from our inception through June 30, 2017. 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, 2017, 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 included a requirement for us to contribute matching funds, which we have satisfied with both the value of developed intellectual property at the time of award and incurred development expenses;
- We have been awarded $4.0 million in grants and contracts not described above, all of which have been recognized at June 30, 2017;
- 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. RUSNANO 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, 2017, we had cash, cash equivalents and short-term investments of $11.5 million which, along with the active government contracts described above, are expected to fund our projected operating requirements for at least 12 months beyond the filing date of this Quarterly Report on Form 10-Q. 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.

Cash Flows:

The following table provides information regarding our cash flows for the six months ended June 30, 2017 and 2016:

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	For the Six Months Ended June 30,		
	2017	2016	Variance
Cash flows used in operating activities	$(3,898,680)	$(3,947,633)	$48,953
Cash flows provided by investing activities	874,167	2,857,506	(1,983,339)
Cash flows provided by financing activities	—	539,998	(539,998)
Effect of exchange rate change on cash and equivalents	54,698	43,772	10,926
Decrease in cash and cash equivalents	(2,969,815)	(506,357)	(2,463,458)
Cash and cash equivalents at beginning of period	6,901,816	5,918,424	983,392
Cash and cash equivalents at end of period	$3,932,001	$5,412,067	$(1,480,066)

Operating Activities

Net cash used in operating activities decreased by $0.05 million to $3.9 million for the six months ended June 30, 2017 from $3.9 million for the six months ended June 30, 2016. Net cash used in operating activities for the period ending June 30, 2017 consisted of a reported net loss of $7.3 million, which was adjusted up for $4.2 million of net non-cash operating activities, and a $0.8 million net decrease due to changes in operating assets and liabilities. The $4.2 million of net non-cash operating activities substantially consisted of changes in the valuation of our warrant liability. Of the net $0.8 million of changes in operating assets and liabilities, $0.1 million was due to a net increase in accounts receivable and other current assets, and $0.7 million was due to a net decrease in accrued expenses and accounts payable.

Net cash used in operating activities for the six months ended June 30, 2016 of $3.9 million consisted of a reported net loss of $2.6 million, which was reduced for $0.8 million of net non-cash operating activities, and a $0.6 million net decrease due to changes in operating assets and liabilities. Of the net non-cash operating activities of $0.8 million, $0.9 million was due to changes in the valuation of our warrant liability, offset by $0.1 million due primarily to depreciation expense. Of the net decrease $0.6 million in operating assets and liabilities, $0.3 million was due to a net increase in accounts receivable and other current assets, and $0.3 million was due to a net decrease in accrued expenses and accounts payable.

Investing Activities

Net cash provided by investing activities decreased by $2.0 million to $0.9 million for the six months ended June 30, 2017 from net cash provided by investing activities of $2.9 million for the six months ended June 30, 2016. The net cash provided by investing activities for the six months ended June 30, 2017 consisted primarily of $0.9 million of net maturities of short-term investments.

Net cash provided by investing activities for the six months ended June 30, 2016 consisted primarily of $2.8 million of net maturities of short-term investments.

Financing Activities

Net cash provided by financing activities decreased by $0.5 million to $0.0 million for the six months ended June 30, 2017 from $0.5 million for the six months ended June 30, 2016. There was no net cash provided by or used in financing activities for the six months ended June 30, 2017.

Net cash provided by financing activities for the six months ended June 30, 2016 of $0.5 million consisted of the sale of Treasury stock.

Impact of Exchange Rate Fluctuations

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, 2017 and June 30, 2017, this rate fluctuated by 2.6%. For calendar 2016, this rate fluctuated by 16.8%. 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.

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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 (performing the functions of the Company's principal executive officer and principal 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, 2017. 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, 2017, our Chief Executive Officer (performing the functions of the Company's principal executive officer and principal 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 time periods specified in the SEC’s rules and forms, and (2) accumulated and communicated to our management, including our Chief Executive Officer (performing the functions of the Company's principal executive officer and principal 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, 2017 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, 2017, 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

In a series of transactions occurring in April 2017, we issued an aggregate of 292,668 shares of our common stock upon the cashless exercise of previously outstanding warrants to purchase an aggregate of 1,181,235 shares of our common stock. The exercise of the warrants did not involve any underwriters, underwriting discounts or commissions, or any public offering, and the Company believes that such transactions were exempt from the registration requirements of the Securities Act in reliance on Section 4(a)(2) of the Securities Act as transactions by an issuer not involving a public offering.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

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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 Amendment to Restated Certificate of Incorporation, filed with the Secretary of State of Delaware on April 24, 2017 (incorporated by reference to Exhibit 3.5 to Form 10-Q for the period ending March 31, 2017, filed on May 15, 2017).
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	Amendment to Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 to Form 8-K filed on February 9, 2015).
3.8	Second Amended and Restated By-Laws (incorporated by reference to Exhibit 3.1 to Form 8-K filed on December 5, 2007).
31.1*	Rule 13a-14(a)/15d-14(a) Certification of Yakov Kogan.
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, 2017, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Condensed Balance Sheets as of June 30, 2017 and December 31, 2016; (ii) Consolidated Condensed Statements of Operations for the Three and Six Months Ended June 30, 2017 and 2016; (iii) Consolidated Condensed Statements of Comprehensive Loss for the Three and Six Months Ended June 30, 2017 and 2016; (iv) Consolidated Condensed Statements of Stockholders' Equity for the Six Months Ended June 30, 2017; (v) Consolidated Condensed Statements of Cash Flows for the Six Months ended June 30, 2017 and 2016; 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 14, 2017 By: /s/ YAKOV KOGAN
Yakov N. Kogan
Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)