CLEVELAND BIOLABS INC
Form 10-Q
November 14, 2018
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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 September 30, 2018
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 every Interactive Data File required to be submitted 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 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. (Check one):

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	x	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 October 31, 2018, there were 11,298,239 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 CONDENSED BALANCE SHEETS
(UNAUDITED)

	September 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$4,378,739	$4,230,548
Short-term investments	956,608	4,561,357
Accounts receivable	199,212	554,468
Other current assets	104,700	233,617
Total current assets	5,639,259	9,579,990
Equipment, net	25,349	18,588
Other long-term assets	33,540	30,684
Total assets	$5,698,148	$9,629,262
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$120,456	$201,396
Accrued expenses	1,231,110	970,547
Accrued warrant liability	241,400	1,041,455
Total current liabilities	1,592,966	2,213,398
Non-current liabilities	8,794	7,494
Total liabilities	1,601,760	2,220,892
Stockholders' equity:		
Preferred stock, $.005 par value; 1,000,000 shares authorized as of September 30, 2018 and December 31, 2017; 0 shares issued and outstanding as of September 30, 2018 and December 31, 2017	—	—
Common stock, $.005 par value; 25,000,000 shares authorized as of September 30, 2018 and December 31, 2017; 11,298,239 and 11,279,834 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	56,487	56,395
Additional paid-in capital	163,161,523	163,106,400
Accumulated other comprehensive loss	(588,899)	(516,457)
Accumulated deficit	(163,626,703)	(160,446,612)
Total Cleveland BioLabs, Inc. stockholders' equity	(997,592)	2,199,726
Noncontrolling interest in stockholders' equity	5,093,980	5,208,644
Total stockholders' equity	4,096,388	7,408,370
Total liabilities and stockholders' equity	$5,698,148	$9,629,262

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 September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Grants and contracts	$283,307	$296,881	$902,474	$1,078,011
Operating expenses:				
Research and development	839,413	919,067	3,084,790	3,524,445
General and administrative	711,660	575,136	1,989,596	1,940,848
Total operating expenses	1,551,073	1,494,203	5,074,386	5,465,293
Loss from operations	(1,267,766)	(1,197,322)	(4,171,912)	(4,387,282)
Other income (expense):				
Interest and other income	16,191	67,738	109,591	167,461
Foreign exchange gain (loss)	1,772	(447)	2,868	(12,732)
Change in value of warrant liability	121,442	(166,287)	800,055	(4,411,994)
Total other income (expense)	139,405	(98,996)	912,514	(4,257,265)
Net loss	(1,128,361)	(1,296,318)	(3,259,398)	(8,644,547)
Net loss attributable to noncontrolling interests	23,917	35,454	79,307	107,201
Net loss attributable to Cleveland BioLabs, Inc.	$(1,104,444)	$(1,260,864)	$(3,180,091)	$(8,537,346)
Net loss attributable to common stockholders per share of common stock, basic and diluted	$(0.10)	$(0.11)	$(0.28)	$(0.76)
Weighted average number of shares used in calculating net loss per share, basic and diluted	11,298,239	11,279,834	11,292,365	11,162,981

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss including noncontrolling interests	$(1,128,361)	$(1,296,318)	$(3,259,398)	$(8,644,547)
Other comprehensive loss:				
Unrealized gain (loss) on short-term investments	(137)	3,226	1,841	(184)
Foreign currency translation adjustment	(34,788)	20,732	(109,640)	62,919
Comprehensive loss including noncontrolling interests	(1,163,286)	(1,272,360)	(3,367,197)	(8,581,812)
Comprehensive loss attributable to noncontrolling interests	35,039	28,846	114,664	87,375
Comprehensive loss attributable to Cleveland BioLabs, Inc.	$(1,128,247)	$(1,243,514)	$(3,252,533)	$(8,494,437)

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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, 2017	11,279,834	$56,395	—	$ —	$163,106,400
Exercise of warrants	18,405	92	—	—	55,123
Net loss	—	—	—	—	—
Unrealized loss on short-term investments	—	—	—	—	—
Foreign currency translation	—	—	—	—	—
Balance at September 30, 2018	11,298,239	$56,487	—	$ —	$163,161,523

	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Noncontrolling Interests	Total
Balance at December 31, 2017	$ (516,457)	$(160,446,612)	$ 5,208,644	$7,408,370
Exercise of warrants	—	—	—	55,215
Net loss	—	(3,180,091)	(79,307)	(3,259,398)
Unrealized loss on short-term investments	1,841	—	—	1,841
Foreign currency translation	(74,283)	—	(35,357)	(109,640)
Balance at September 30, 2018	$ (588,899)	$(163,626,703)	$ 5,093,980	$4,096,388

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

	For the Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(3,259,398)	$(8,644,547)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	14,084	16,802
Non-cash investment income	(30,312)	(42,687)
Gain on equipment disposal	(35,274)	(6,727)
Change in value of warrant liability	(800,055)	4,411,994
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	482,860	(121,633)
Other long-term assets	(3,386)	—
Accounts payable and accrued expenses	190,405	(944,765)
Net cash used in operating activities	(3,441,076)	(5,331,563)
Cash flows from investing activities:		
Purchase of short-term investments	(6,795,170)	(6,133,755)
Sale of short-term investments	10,341,526	9,092,512
Purchase of equipment	(21,376)	—
Proceeds from sale of equipment	35,770	8,956
Net cash provided by investing activities	3,560,750	2,967,713
Cash flows from financing activities:		
Exercise of warrants	55,215	—
Net cash provided by financing activities	55,215	—
Effect of exchange rate change on cash and equivalents	(26,698)	52,890
Increase (decrease) in cash and cash equivalents	148,191	(2,310,960)
Cash and cash equivalents at beginning of period	4,230,548	6,901,816
Cash and cash equivalents at end of period	$4,378,739	$4,590,856
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

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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 ("TLR") activators has applications in radiation protection and 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 other indications in radiation oncology.

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.

On August 6, 2018, the Company entered into a series of transactions with Genome Protection, Inc. ("GPI"), a corporation formed by the Company for the purpose of creating a joint venture between the Company and Everon Biosciences, Inc. ("Everon") that would be focused on developing anti-aging medications and would seek investment capital from third parties. On August 6, 2018, the Company entered into a License Agreement with GPI (the "License Agreement") pursuant to which the Company licensed to GPI, on an exclusive basis, the right to develop, manufacture, commercialize and sell products utilizing the Company's intellectual property underlying the Company's entolimod drug candidate, solely in the field of use related to the prevention or treatment of any disease, disorder or frailty in humans caused by aging. Simultaneous with its entry into the License Agreement, the Company also entered into an Assignment Agreement with GPI (the "Assignment Agreement"), under which the Company assigned certain intellectual property underlying its superentolimod product candidate and its entolimod vaccine product candidate and GPI licensed back to the Company, on an exclusive, irrevocable basis, the right to develop manufacture, commercialize and sell products relating to the assigned intellectual property for use as a medical countermeasure to treat acute radiation exposure or as a cancer treatment.

As consideration for the licenses granted to GPI under the License Agreement and the assignment of the intellectual property to GPI under the Assignment Agreement, GPI issued to the Company 1,000 shares of GPI's common stock. Contemporaneously with the Company's entry into the License Agreement and Assignment Agreement, Everon contributed certain of its intellectual property related to the potential development of treatments that address serious medical needs associated with human aging to GPI, also in exchange for 1,000 shares of GPI's common stock. As a result of each of the Company's and Everon's receipt of 1,000 shares of GPI's common stock, each of the Company and Everon became the owner of 50% of all of the outstanding capital stock of GPI.

Subsequent to the intellectual property transfers described above, the Company, GPI and Everon entered into agreements with a third-party investor for the purpose of providing GPI with capital. On August 10, 2018, GPI, Norma Investments Limited, a British Virgin Islands company ("Norma"), the Company and Everon entered into a certain Simple Agreement for Future Equity (the "SAFE"). Under the SAFE, GPI granted Norma the right to purchase shares of GPI's capital stock in exchange for the payment of up to $30,000,000, of which $10,500,000 was paid shortly after the execution of the SAFE and the remainder may be paid, if at all, in tranches over time. Norma may exercise its right to purchase shares of GPI's capital stock upon the occurrence of certain events, or otherwise may alternatively be paid an amount equal to its investment amount (plus accrued interest, in certain cases). Under the SAFE, the parties agreed that GPI's board of directors (the "GPI Board") will consist of four members, two of whom will be selected by Norma, one of whom will be selected by the Company and one of whom will be selected by Everon. The SAFE also provides that the parties will agree that a quorum of the GPI Board will require that at least one of the directors

selected by Norma be present. Additionally, the SAFE sets forth a number of actions that GPI will be prohibited from taking without the unanimous consent of all of the members of the GPI Board and sets forth other matters that must be approved by a majority of the members of the GPI Board. The Company and Everon have each guaranteed, to the extent of their powers as stockholders of GPI, the due and punctual performance by GPI of all of its obligations under the SAFE. In connection with the execution of the SAFE, the Company, Everon, GPI and Norma entered into a Director Designation Agreement, dated as of August 10, 2018, pursuant to which the parties made certain commitments as to voting and transfer of their shares of GPI and GPI's governance.

The Company has accounted for its investment in GPI under the equity method of accounting in the accompanying financial statements. In addition, the Company has not recorded its 50% share of the losses of GPI through September 30, 2018 as the

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impact would have reduced the Company's equity method investment in GPI below zero, and there are no requirements to fund the Company's share of these losses or contribute additional capital as of the date of these statements.

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, 2017, 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, 2017, as filed with the SEC (the "2017 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 September 30, 2018, along with its results of operations for the three and nine month periods ended September 30, 2018 and 2017 and cash flows for the nine month periods ended September 30, 2018 and 2017. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year. At September 30, 2018, we had cash, cash equivalents and short-term investments of $5.3 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 May 2017, the FASB issued Accounting Standards Update ("ASU") No. 2017-09, "Scope of Modification Accounting" ("ASU 2017-09"), which amends the scope of modification accounting for share-based payment arrangements. The ASU provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting. ASU 2017-09 is applied prospectively to awards modified on or after the effective date. The Company adopted this ASU in 2018 with no significant impact on its consolidated financial statements.

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. The Company adopted this ASU in 2018 with no significant impact on its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-9, "Revenue from Contracts with Customers" ("ASU 2014-09"), 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. The Company

adopted this ASU in 2018 with no significant impact on its consolidated financial statements.

In May 2016, the FASB issued ASU 2016-12, "Revenue from Contracts with Customers (Topic 606): Narr

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ow 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 adopted this ASU in 2018 with no significant impact 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 adopted this ASU in 2018 with no significant impact on its consolidated financial statements.

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" ("ASU 2016-01"). 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. The Company adopted this ASU in 2018 with no significant impact on its consolidated financial statements.

Use of Estimates

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

Short-Term Investments

The Company’s short-term investments are classified as available for sale recorded at fair value, and held to maturity recorded at amortized cost. Short-term investments consisted of U.S. Treasury securities in the amount of $0.5 million which were owned by CBLI and had maturities of less than 12 months. In addition, $0.5 million in certificates of deposit with maturity dates beyond three months and less than one year, and owned by Panacela, are also included in short-term investments. 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 nine months ended September 30, 2018 and 2017.

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	Three Months Ended September 30,			Nine Months Ended September 30,		
Customer	2018	2017	Variance	2018	2017	Variance
Department of Defense	43.7 %	44.3 %	(0.6)%	50.0 %	63.2 %	(13.2)%
Incuron	56.3 %	55.7 %	0.6 %	50.0 %	36.8 %	13.2 %
Total	100.0%	100.0%	— %	100.0%	100.0%	— %

Our current Department of Defense ("DOD") revenues come from development contracts that expire in 2019 and 2018, although each contract may be extended. Our Incuron 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 Accounting Standards Codification ("Codification") on comprehensive income (loss) that requires disclosure of all components of comprehensive income (loss) on an annual and interim basis. Other 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 nine months ended September 30, 2018.

	Unrealized income (loss) on available-for-sale securities	Gains and losses on foreign exchange translations	Total
Beginning balance	$ (1,924)	$(514,533)	$(516,457)
Other comprehensive income (loss) before reclassifications	1,841	(74,283)	(72,442)
Amounts reclassified from accumulated other comprehensive loss	—	—	—
Ending balance	$ (83)	$(588,816)	$(588,899)

Accounting for Stock-Based Compensation

The Cleveland Biolabs, Inc. Equity Incentive Plan, adopted in 2018 (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 September 30, 2018, an aggregate of 597,557 shares of common stock were authorized for issuance under the Plan, of which a total of 425,029 shares of common stock remained available for future awards. In addition, a total of 172,528 shares of common stock reserved for issuance were subject to currently outstanding stock options granted under The Cleveland BioLabs, Inc. Equity Incentive Plan, as in effect prior to the 2018 amendment and restatement. 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 (the "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 September 30, 2018, there are 525,000 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 nine months ended September 30, 2018 and September 30, 2017.

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Income Taxes

No income tax expense was recorded for the three and nine months ended September 30, 2018 and 2017 as the Company does not expect to have taxable income for 2018 and did not have taxable income in 2017. A full valuation allowance has been recorded against the Company's deferred tax asset.

Additionally, as disclosed in Note 7, Income Taxes, to the Company's consolidated financial statements included in the 2017 Form 10-K, the Company had U.S. federal net operating loss carryforwards of approximately $139,700,000, which begin to expire if not utilized by 2023, and approximately $4,046,000 of 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 $84,200,000, which begin to expire if not utilized by 2027 and state tax credit carryforwards of approximately $311,000, which begin to expire if not utilized by 2022. The purchase of 6,459,948 shares of common stock by David Davidovich, our majority stockholder, on July 9, 2015 resulted in Mr. Davidovich owning 60.2% of the Company at that time. We therefore believe it highly likely that this transaction, more fully described in Note 7, Income Taxes, to the Company's consolidated financial statements included in the 2017 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 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 September 30, 2018.

	As of September 30,	
Common Equivalent Securities	2018	2017
Warrants	528,054	925,812
Options	172,528	214,987
Total	700,582	1,140,799

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

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- 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: U.S. 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 September 30, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$587,328	$—	$—	$587,328
Short-term investments	499,225	457,383	—	956,608
Total assets	$1,086,553	$457,383	$—	$1,543,936
Liabilities:				
Accrued warrant liability	$—	$—	$241,400	$241,400

	As of December 31, 2017			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$551,088	$—	$—	$551,088
Short-term investments	3,606,499	954,858	—	4,561,357
Total assets	$4,157,587	$954,858	$—	$5,112,445
Liabilities:				
Accrued warrant liability	$—	$—	$1,041,455	$1,041,455

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:

	September 30, 2018	December 31, 2017
Stock Price	$ 2.01	$ 4.01
Exercise Price	$3.64 - $24.40	$ 3.00 - 24.40
Term in years	0.29 – 2.85	0.25 - 3.60
Volatility	59.50% - 103.09%	71.48 - 139.58%
Annual rate of quarterly dividends	— %	— %
Discount rate- bond equivalent yield	0.76% - 2.87%	0.44 - 2.05%

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:

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	Three Months Ended September 30, 2018 Accrued Warrant Liability	Three Months Ended September 30, 2017 Accrued Warrant Liability
Beginning Balance	$362,842	$861,016
Total (gains) or losses, realized and unrealized, included in earnings (1)	(121,442)	166,287
Issuances	—	—
Settlements	—	—
Ending Balance	$241,400	$1,027,303

	Nine Months Ended September 30, 2018 Accrued Warrant Liability	Nine Months Ended September 30, 2017 Accrued Warrant Liability
Beginning Balance	$1,041,455	$949,419
Total (gains) or losses, realized and unrealized, included in earnings (1)	(800,055)	4,411,994
Issuances	—	—
Settlements	—	(4,334,110)
Ending Balance	$241,400	$1,027,303

(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 nine months ended September 30, 2018 and 2017.

As of September 30, 2018 and December 31, 2017, 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 nor indirectly observable. The accrued warrant liability uses management’s estimate for the expected term. As of September 30, 2018, 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 0.29 – 2.85 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 nine months ended September 30, 2018:

	Total Stock Options Outstanding	Weighted Average Exercise Price per Share

December 31, 2017	211,487	$ 36.94
Granted	—	—
Vested	—	—
Forfeited, Canceled	(38,959)	44.70
September 30, 2018	172,528	$ 35.19

The following is a summary of outstanding stock options as of September 30, 2018:

	As of September 30, 2018	
	Stock Options Outstanding	Vested Stock Options
Quantity	172,528	172,528
Weighted Average Exercise Price	$35.19	$ 35.19
Weighted Average Remaining Contractual Term (in Years)	4.89	4.89
Intrinsic Value	$—	$ —

For the nine months ended September 30, 2018 and 2017, the Company granted no stock options. For September 30, 2018 and 2017, the total fair value of options vested was $0.

As of September 30, 2018, there was no total compensation cost not yet recognized related to unvested stock options.

5. Warrants

In connection with previous sales of the Company's common stock and the issuance of debt instruments, warrants were issued which presently have exercise prices ranging from $3.64 to $24.40. 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, 2017:

	Number of Warrants	Weighted Average Exercise Price
December 31, 2017	710,174	$ 8.95
Granted	—	—
Exercised	(18,405)	3.00
Forfeited, Canceled	(163,715)	3.00
September 30, 2018	528,054	$ 10.90

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 Curaxin CBL0137 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 $138,817 and $187,262 in research and development expense to RPCI for the three and nine months ended September 30,

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2018, respectively, and $0 and $46,908 in research and development expense to RPCI for the three and nine months ended September 30, 2017, respectively. The Company had $0 and $78,337 included in accounts payable owed to RPCI at September 30, 2018 and 2017, respectively. In addition, the Company had $214,429 and $85,102 in accrued expenses payable to RPCI at September 30, 2018 and 2017, 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. On August 6, 2018, CBLI sublicensed the intellectual property underlying entolimod's composition that CBLI licenses from The Cleveland Clinic to GPI. There were no milestone or royalty payments paid to The Cleveland Clinic during the nine months ended September 30, 2018 or 2017.
The Company had no accrued expenses payable to The Cleveland Clinic at September 30, 2018 and 2017.

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 uncompensated Principal Scientific Advisor. The Company recognized $122,929 and $454,937 in research and development expense to BBL for the three and nine months ended September 30, 2018, respectively, and $20,348 and $174,412 in research and development expense to BBL for the three and nine months ended September 30, 2017, respectively. In addition, the Company had $53,000 and $0 in accrued expenses payable to BBL, and $0 and $0 in accounts payable to BBL at September 30, 2018 and 2017, respectively. The Company also recognized $11,553 and $34,659 from BBL as sublease and other income for the three and nine months ended September 30, 2018, respectively, and $7,702 and $30,808 from BBL as sublease and other income for the three and nine months ended September 30, 2017, respectively. Pursuant to our real estate sublease and equipment lease with BBL, the Company had gross accounts receivables of $206,747 and $206,002, and net accounts receivables of $4,956 and $3,851 from BBL at September 30, 2018 and 2017, respectively.
Dr. Gudkov is also an uncompensated member of the board of directors for Incuron. Pursuant to master service and development agreements we have with Incuron, the Company performs various research, business development, clinical advisory, and management services. The Company recognized revenue of $199,324 and $291,445 for the three and nine months ended September 30, 2018, respectively, and recognized revenue of $165,502 and $397,134 for the three and nine months ended September 30, 2017, respectively. In addition, we also recognized $1,134 and $4,044 from Incuron for sublease and other income for the three and nine months ended September 30, 2018, respectively, and $1,776 and $5,328 from Incuron for sublease and other income for the three and nine months ended September 30, 2017, respectively. Pursuant to these agreements, the Company had gross accounts receivable of $13,457 and $61,297 from BBL at September 30, 2018 and 2017, respectively.

Genome Protection

Our CSO, Dr. Andrei Gudkov, is also the CSO for Everon, which is the Company's joint venture partner in GPI. GPI recognized $1,201,200 in research and development expense to Everon during the three months ended September 30, 2018. In addition, GPI incurred $9,000 in research and development expense, and $25,471 in consultant expenses to Tartis-Aging, LLC, a subsidiary of Everon, during the three months ended September 30, 2018, of which $25,471 remained in GPI accounts payable and accrued expenses as of September 30, 2018. GPI also incurred $39,083 in consultant expenses with members of the Company's Board of Directors and management team during the three months ended September 30, 2018, of which $39,083 remained in GPI accounts payable and accrued expenses as of September 30, 2018 . The Company also recognized $675 in sublease and other income from GPI during the three months ended September 30, 2018.

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

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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, 2017. Factors that may cause such differences include, but are not limited to, our need for additional financing to meet our business objectives, 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, government contracting processes and requirements, the exercise of control over our company by our majority stockholder, 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, 2017.

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, 2017.

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 radiation 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 other indications in radiation oncology. 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 conduct 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 our oncology product candidates that may eventually be licensed for sale in Russia. We provide various research, 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 and 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, 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 foreign currency transaction gains or losses.

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Recent Developments

As previously reported, on August 6, 2018, the Company entered into a series of transactions with Genome Protection, Inc. ("GPI"), a corporation formed by the Company for the purpose of creating a joint venture between the Company and Everon Biosciences, Inc. that would be focused on developing anti-aging medications and would seek investment capital from third parties. On August 6, 2018, the Company entered into a License Agreement with GPI (the "License Agreement") pursuant to which the Company licensed to GPI, on an exclusive basis, the right to develop, manufacture, commercialize and sell products utilizing the Company's intellectual property underlying the Company's entolimod drug candidate, solely in the field of use related to the prevention or treatment of any disease, disorder or frailty in humans caused by aging. Simultaneous with its entry into the License Agreement, the Company also entered into an Assignment Agreement (the "Assignment Agreement") with GPI, under which the Company assigned certain intellectual property underlying its superentolimod product candidate and its entolimod vaccine product candidate and GPI licensed back to the Company, on an exclusive, irrevocable basis, the right to develop manufacture, commercialize and sell products relating to the assigned intellectual property for use as a medical countermeasure to treat acute radiation exposure or as a cancer treatment.

As consideration for the licenses granted to GPI under the License Agreement and the assignment of the intellectual property to GPI under the Assignment Agreement, GPI issued to the Company 1,000 shares of GPI's common stock. Contemporaneously with the Company's entry into the License Agreement and Assignment Agreement, Everon contributed certain of its intellectual property related to the potential development of treatments that address serious medical needs associated with human aging to GPI, also in exchange for 1,000 shares of GPI's common stock. As a result of each of the Company's and Everon's receipt of 1,000 shares of GPI's common stock, each of the Company and Everon became the owner of 50% of all of the outstanding capital stock of GPI.

Subsequent to the intellectual property transfers described above, the Company, GPI and Everon entered into agreements with a third-party investor for the purpose of providing GPI with capital. On August 10, 2018, GPI, Norma Investments Limited, a British Virgin Islands company ("Norma"), the Company and Everon entered into a certain Simple Agreement for Future Equity (the "SAFE"). Under the SAFE, GPI granted Norma the right to purchase shares of GPI's capital stock in exchange for the payment of up to $30,000,000, of which $10,500,000 was paid shortly after the execution of the SAFE and the remainder may be paid, if at all, in tranches over time. Norma may exercise its right to purchase shares of GPI's capital stock upon the occurrence of certain events, or otherwise may alternatively be paid an amount equal to its investment amount (plus accrued interest, in certain cases). Under the SAFE, the parties agreed that GPI's board of directors (the "GPI Board") will consist of four members, two of whom will be selected by Norma, one of whom will be selected by the Company and one of whom will be selected by Everon. The SAFE also provides that the parties will agree that a quorum of the GPI Board will require that at least one of the directors selected by Norma be present. Additionally, the SAFE sets forth a number of actions that GPI will be prohibited from taking without the unanimous consent of all of the members of the GPI Board and sets forth other matters that must be approved by a majority of the members of the GPI Board. The Company and Everon have each guaranteed, to the extent of their powers as stockholders of GPI, the due and punctual performance by GPI of all of its obligations under the SAFE. In connection with the execution of the SAFE, the Company, Everon, GPI and Norma entered into a Director Designation Agreement, dated as of August 10, 2018, pursuant to which the parties made certain commitments as to voting and transfer of their shares of GPI and GPI's governance.

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, 2017. 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, 2017.

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 in United States Treasury Notes or certificates of deposit. As of September 30, 2018, we held approximately $0.6 million in cash equivalents, $0.5 million in U.S. Treasury Notes which we classified as Level 1, and $0.5 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 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.

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As of September 30, 2018, we held approximately $0.2 million in accrued expenses related to warrants to purchase common stock, which we classified as Level 3.

Three Months Ended September 30, 2018 Compared to Three Months Ended September 30, 2017

Revenue

Revenue decreased from approximately $0.297 million for the three months ended September 30, 2017 to approximately $0.283 million for the three months ended September 30, 2018, representing a decrease of approximately $0.014 million, or 4.6%. This decrease is primarily due to a reduction in revenues from our Joint Warfighter Medical Research Program ("JWMRP") contract with the DoD for continued preclinical development along with other drug manufacturing activities for entolimod due to previously disclosed vendor delays in the analytical analyses required to complete the biocomparability study, and decreases in revenues from our Incuron service contract. Differences in our revenue sources, by program, between the years are set forth in the following table.

Funding Source	Program	Three Months Ended September 30, 2018	2017	Variance
DoD	JWMRP Contract (1)	$122,759	$130,618	$(7,859)
DoD	PRMRP Contract (2)	1,017	762	255
Incuron	Service contract	159,531	165,501	(5,970)
		$283,307	$296,881	$(13,574)

(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.

We anticipate our revenue over the next year will continue to be derived primarily from government grants and contracts. We anticipate that DoD revenue will be similar in the next quarter, as we expect to finalize the biocomparability study, and grow in the first quarter of next year as additional DoD-supported studies are expected to be initiated. We also plan to submit proposals for government grants and contracts to various funding sources, but there can be no assurance that we will receive future funding awards. The following table sets forth information regarding our currently active grants and contracts:

				As of September 30, 2018		
Funding Source	Program	Total Award Value	Funded Award Value	Cumulative Revenue	Funded Backlog	Unfunded Backlog
DoD	JWMRP Contract	$9,226,455	$9,226,455	$3,178,258	$6,048,197	$ —
DoD	PRMRP Contract	6,573,992	6,573,992	76,420	6,497,572	—
		$15,800,447	$15,800,447	$3,254,678	$12,545,769	$ —

Research and Development Expenses

R&D expenses decreased from $0.92 million for the three months ended September 30, 2017 to $0.84 million for the three months ended September 30, 2018, representing a decrease of $0.08 million, or 8.7%. Variances in individual development programs are noted in the table below. The net decrease is primarily attributable to a $0.2 million reduction in R&D spending for biodefense applications of entolimod and a $0.1 million reduction in R&D spending on Panacela's product candidates, partially offset by a $0.2 million increase in R&D expenses related to the oncology applications of the entolimod family of compounds. The remaining variances are not significant.

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	Three Months Ended September 30,		
	2018	2017	Variance
Entolimod for Biodefense Applications	$408,358	$623,331	$(214,973)
CBLB612	12	420	(408)
Entolimod for Oncology Indications	259,465	71,718	187,747
	667,835	695,469	(27,634)
Curaxins	158,237	148,898	9,339
Panacela product candidates	13,341	74,700	(61,359)
Total research & development expenses	$839,413	$919,067	$(79,654)

General and Administrative Expenses

G&A expenses increased from $0.58 million for the three months ended September 30, 2017 to $0.71 million for the three months ended September 30, 2018, representing a increase of $0.14 million, or 23.7%. This increase consisted primarily of a $0.12 million increase in CBLI's legal and professional fees relating to one time legal costs associated with the corporate formation of GPI and Norma's investment in GPI, and a $0.2 million increase in expense relating to a potential one-time settlement for the previously completed research contracts with the Russian Ministry of Trade (MPT) partially offset by $0.11 decrease in property tax expense and a $0.07 decrease in personnel and subcontractor expenses relating to outsourced finance department assistance.

Other Income and Expenses

Other expense increased from $0.1 million of other expense for the three months ended September 30, 2017 to $0.1 million of other income for the three months ended September 30, 2018, representing an income increase of $0.2 million, or 240.8%. This increase was primarily related to a $0.3 million non-cash gain related to the change in valuation of our warrant liability as a result of stock price changes as well as warrant expirations.

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Nine Months Ended September 30, 2018 Compared to Nine Months Ended September 30, 2017

Revenue

Revenue decreased from approximately $1.08 million for the nine months ended September 30, 2017 to approximately $0.90 million for the nine months ended September 30, 2018, representing a decrease of approximately $0.18 million, or 16.3%, principally due to the decrease in activity under our JWMRP contract for continued preclinical development of entolimod's biodefense indication while we await the results of the biocomparability study which as previously disclosed, has been delayed as a result of vendor delays in completing the analytical analyses, partially offset by an increase in our Incuron service contract revenues. Differences in our revenue sources, by program, between the years are set forth in the following table:

		Nine Months Ended September 30,		
Funding Source	Program	2018	2017	Variance
DoD	JWMRP Contract (1)	$449,403	$674,806	$(225,403)
DoD	PRMRP Contract (2)	2,095	4,185	(2,090)
DoD	DTRA Contract	—	1,886	(1,886)
Incuron	Service contract	450,976	397,134	53,842
		$902,474	$1,078,011	$(175,537)

(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.

Research and Development Expenses

R&D expenses decreased from approximately $3.5 million for the nine months ended September 30, 2017 to approximately $3.1 million for the nine months ended September 30, 2018, representing a decrease of approximately $0.4 million, or 12.5%. Variances in individual development programs are noted in the table below. The net decrease is primarily attributable to a $1.0 million reduction in R&D spending for biodefense applications of entolimod under our DoD contracts, partially offset by a $0.6 million increase in R&D expenses related to the oncology applications of the entolimod family of compounds. 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 following the expected completion of our biocomparability study.

	Nine Months Ended September 30,		
	2018	2017	Variance
Entolimod for Biodefense Applications	1,731,932	2,776,473	$(1,044,541)
CBLB612	593	25,564	(24,971)
Entolimod for Oncology Indications	894,019	222,083	671,936
	2,626,544	3,024,120	(397,576)
Curaxins	373,698	291,469	82,229
Panacela product candidates	84,548	208,856	(124,308)
Total research & development expenses	3,084,790	3,524,445	$(439,655)

General and Administrative Expenses

G&A expenses increased from $1.9 million for the nine months ended September 30, 2017 to $2.0 million for the nine months ended September 30, 2018, representing a increase of $0.1 million, or 2.5%. The increase consisted primarily of a $0.1 million decrease in subcontractor expense relating to outsourced finance department assistance, offset by a $0.2 million increase in professional fees relating to the formation of GPI and Norma's investment in GPI and potential one-time legal settlement for the previously completed research contracts with the Russian Ministry of Trade (MPT).

Other Income and Expenses

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Other income increased from $4.3 million of other expense for the nine months ended September 30, 2017 to $0.9 million of other income for the nine months ended September 30, 2018, representing an income increase of $5.2 million, or 121.4%. This income increase was primarily related to a $5.2 million variance related to the valuation of our warrant liability.

Liquidity and Capital Resources

We have incurred net losses of approximately $163.6 million from our inception through September 30, 2018. 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 September 30, 2018, 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 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 September 30, 2018;
- 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 September 30, 2018, we had cash, cash equivalents and short-term investments of $5.3 million which represents a decrease of $3.5 million or 39.8% since the end of our last fiscal year. This decrease was caused primarily by our net loss of $3.3 million over the last nine months ended September 30, 2018. We expect our cash, cash equivalents, and short-term investments, along with the active government contracts described above, 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 government research funding. 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 nine months ended September 30, 2018 and 2017:

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	For the Nine Months Ended September 30,		
	2018	2017	Variance
Cash flows used in operating activities	$(3,441,076)	$(5,331,563)	$1,890,487
Cash flows provided by investing activities	3,560,750	2,967,713	593,037
Cash flows provided by financing activities	55,215	—	55,215
Effect of exchange rate change on cash and equivalents	(26,698)	52,890	(79,588)
Increase (decrease) in cash and cash equivalents	148,191	(2,310,960)	2,459,151
Cash and cash equivalents at beginning of period	4,230,548	6,901,816	(2,671,268)
Cash and cash equivalents at end of period	$4,378,739	$4,590,856	$(212,117)

Operating Activities

Net cash used in operating activities decreased by $1.9 million to $3.4 million for the nine months ended September 30, 2018 from $5.3 million for the nine months ended September 30, 2017. Net cash used in operating activities for the period ending September 30, 2018 consisted of a reported net loss of $3.3 million, which was adjusted down for $0.9 million of net non-cash operating activities, and a $0.7 million net increase due to changes in operating assets and liabilities. The $0.9 million of net non-cash operating activities substantially consisted of changes in the valuation of our warrant liability. Of the $0.7 million of changes in operating assets and liabilities, $0.5 million was due to a net decrease in accounts receivable and other current assets, and $0.2 million was due to a net increase in accrued expenses and accounts payable.

Net cash used in operating activities for the nine months ended September 30, 2017 of $5.3 million consisted of a reported net loss of $8.6 million, which was reduced for $4.4 million of net non-cash operating activities, and a $1.1 million net decrease due to changes in operating assets and liabilities. Of the net non-cash operating activities of $4.4 million, $4.4 million was due to changes in the valuation of our warrant liability. Of the $1.1 million of changes in operating assets and liabilities, $0.1 million was due to a net increase in accounts receivable and other currents assets, and $0.9 million was due to a net decrease in accrued expenses and accounts payable.

Investing Activities

Net cash provided by investing activities increased by $0.6 million to $3.6 million for the nine months ended September 30, 2018 from net cash provided by investing activities of $3.0 million for the nine months ended September 30, 2017. The net cash provided by investing activities for the nine months ended September 30, 2018 consisted of net sales of short-term investments. Net cash provided by investing activities for the nine months ended September 30, 2017 consisted of net sales of short-term investments.

Financing Activities

Net cash provided by financing activities increased by $0.1 million to $0.1 million for the nine months ended September 30, 2018 from $0.0 million for the nine months ended September 30, 2017. Net cash provided by financing activities during the nine months ended September 30, 2018 consisted of proceeds from the exercise of warrants.

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, 2018 and September 30, 2018, this rate fluctuated by 13.9%. For calendar 2017, this rate fluctuated by 5.0%. 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, 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

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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 September 30, 2018. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, 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 September 30, 2018 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 September 30, 2018, that, in the opinion of management, might have a material adverse effect on our financial position, results of operations or cash flows, or that are required to be disclosed under the rules of the SEC, other than as set forth below.

On October 22, 2018, the Russian Federation Ministry of Industry and Trade (the "MPT") filed a complaint against BioLab 612 one of our subsidiaries operating in the Russian Federation, in the Arbitration court of Moscow city. The complaint alleges that BioLab 612 breached its 2012 and 2013 contracts with the MPT by completing its 3rd stage of the 502 clinical study and 7th stage of the 612 clinical study in an untimely manner. The MPT is seeking 19,819,281 rubles (or approximately $0.3 million) in damages and penalties for breach of the 502 contract and 49,519,600 rubles (or approximately $0.75 million) in damages and penalties for breach of the 612 contract. While the outcome of this lawsuit is uncertain, we intend to vigorously defend against the claims.

Item 1A. Risk Factors

Not required for smaller reporting company filers.

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

None.

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 of 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 May 16, 2016.
3.5	Certificate of Amendment to Restated Certificate of Incorporation, filed with the Secretary of State of Delaware on April 21, 2017 (incorporated by reference to Exhibit 3.5 to Form 10-Q for the period ended March 31, 2017, filed 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	Certificate of Amendment of 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).
3.9	Amendment to Second Amended and Restated By-Laws of Cleveland BioLabs, Inc. (Incorporated by reference to Exhibit 3.1 to Form 8-K filed on May 18, 2015).
10.1	License Agreement, dated as of August 6, 2018, between Cleveland BioLabs, Inc. and Genome Protection, Inc. (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on August 10, 2018).
10.2	Assignment Agreement, dated as of August 6, 2018, between Cleveland BioLabs, Inc. and Genome Protection, Inc. (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on August 10, 2018).
10.3	Simple Agreement for Future Equity, dated as of August 10, 2018, among Genome Protection, Inc., Norma Investments Limited, Cleveland BioLabs, Inc. and Everon Biosciences, Inc. (Incorporated by reference to Exhibit 10.1 to Form 8-K filed on August 14, 2018).
10.4	

	Director Designation Agreement, dated as of August 10, 2018, among Genome Protection, Inc., Everon Biosciences, Inc., Cleveland BioLabs, Inc. and Norma Investments Limited (Incorporated by reference to Exhibit 10.2 to Form 8-K filed on August 14, 2018).
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 September 30, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Condensed Balance Sheets as of September 30, 2018 and December 31, 2017; (ii) Consolidated Condensed Statements of Operations for the Three and Nine Months Ended September 30, 2018 and 2017; (iii) Consolidated Condensed Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2018 and 2017; (iv) Consolidated Condensed Statements of Stockholders' Equity for the Nine Months Ended September 30, 2018; (v) Consolidated Condensed Statements of Cash Flows for the Nine Months Ended September 30, 2018 and 2017; 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: November 14, 2018 By: /s/ YAKOV KOGAN
Yakov N. Kogan
Chief Executive Officer
(Principal Executive and Principal Financial Officer)