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	— %	