CLEVELAND BIOLABS INC
Form 10-Q
August 12, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2015

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	**(I.R.S. Employer**
incorporation or organization)	**Identification No.)**
73 High Street, Buffalo, New York	**14203**
(Address of principal executive offices)	**(Zip Code)**

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

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company x

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

As of July 31, 2015, there were 10,729,123 shares outstanding of the registrant s common stock, par value $0.005 per share.

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CLEVELAND BIOLABS, INC.

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In this report, except as otherwise stated or the context otherwise requires, the terms Cleveland BioLabs and CBLI refer to Cleveland BioLabs, Inc. but not its consolidated subsidiaries, and the Company, we, us and our refer to Cleveland BioLabs, Inc. together with its consolidated subsidiaries. Our common stock, par value $0.005 per share, is referred to as common stock.

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	June 30, 2015 (Unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,190,121	$ 3,103,969
Short-term investments	450,256	
Accounts receivable	133,476	267,199
Receivable for divestiture of Incuron, LLC	1,000,000	
Other current assets	215,699	174,179
Total current assets	4,989,552	3,545,347
Equipment, net	182,957	244,537
Restricted cash	859,088	1,699,759
Other long-term assets	41,650	56,131
Deferred Transaction Costs	775,037	
Investment in Incuron, LLC		4,268,458
Total assets	$ 6,848,284	$ 9,814,232
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 950,431	$ 1,057,743
Accrued expenses	2,025,702	1,804,456
Deferred revenue	466,590	156,317
Accrued warrant liability	5,356,391	862,074
Current portion of notes payable	2,836,723	2,640,968
Current portion of capital lease obligation		7,522
Total current liabilities	11,635,837	6,529,080
Long-term debt	1,135,769	1,499,050
Commitments and contingencies		
Total liabilities	12,771,606	8,028,130
Stockholders equity:		
Preferred stock, $.005 par value; 10,000,000 shares authorized, 0 shares issued and outstanding as of June 30, 2015 and 2014, respectively		
Common stock, $.005 par value; 160,000,000 shares authorized, 4,269,175 and 2,858,126 shares issued and outstanding as of June 30, 2015 and 2014, respectively	21,342	14,287
Additional paid-in capital	134,042,180	132,693,988
Other comprehensive loss	(425,459)	(380,110)

Accumulated deficit	(142,706,512)	(133,935,562)
Treasury Stock, at cost; 264,318 and 0 shares, respectively	(906,321)	
Total Cleveland BioLabs, Inc. stockholders deficit	(9,974,770)	(1,607,397)
Noncontrolling interest in stockholders equity	4,051,448	3,393,499
Total stockholders equity	(5,923,322)	1,786,102
Total liabilities and stockholders equity	$ 6,848,284	$ 9,814,232

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2015	2014	2015	2014
Revenues:				
Grants and contracts	$ 329,908	$ 562,087	$ 937,237	$ 1,896,341
Operating expenses:				
Research and development	1,583,169	2,324,223	3,194,139	4,763,996
General and administrative	1,597,556	2,250,368	3,905,427	4,663,911
Total operating expenses	3,180,725	4,574,591	7,099,566	9,427,907
Loss from operations	(2,850,817)	(4,012,504)	(6,162,329)	(7,531,566)
Other income (expense):				
Interest and other expense	(81,416)	(623,786)	(127,810)	(941,708)
Foreign exchange gain (loss)	65,058	92,594	21,323	(59,177)
Change in value of warrant liability	(1,480,048)	412,125	(1,529,406)	2,499,683
Equity in loss of Incuron, LLC	(114,571)		(362,137)	
Total other income (expense)	(1,610,977)	(119,067)	(1,998,030)	1,498,798
Net loss	(4,461,794)	(4,131,571)	(8,160,359)	(6,032,768)
Net loss attributable to noncontrolling interests	17,141	170,410	65,384	486,235
Net loss attributable to Cleveland BioLabs, Inc.	$ (4,444,653)	$ (3,961,161)	$ (8,094,975)	$ (5,546,533)
Net loss per share, basic and diluted	$ (1.12)	$ (1.53)	$ (2.25)	$ (2.18)
Weighted average number of shares, basic and diluted	3,979,783	2,594,582	3,595,153	2,546,760

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2015	**2014**	**2015**	**2014**
Net loss including noncontrolling interests	$ (4,461,794)	$ (4,131,571)	$ (8,160,359)	$ (6,032,768)
Other comprehensive loss - Foreign currency translation adjustment	41,748	199,052	2,009	(92,414)
Comprehensive loss including noncontrolling interests	(4,420,046)	(3,932,519)	(8,158,350)	(6,125,182)
Comprehensive loss attributable to noncontrolling interests	106	90,531	63,374	507,807
Comprehensive loss attributable to Cleveland BioLabs, Inc.	$ (4,419,940)	$ (3,841,988)	$ (8,094,976)	$ (5,617,375)

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY (DEFICIT)

(UNAUDITED)

	Common Stock		Teasury Stock		Additional Paid-in
	Shares	Amount	Shares	Amount	Capital
Balance at December 31, 2014	2,858,126	$ 14,287		$	$ 132,693,988
Stock based compensation	5,023	25			200,900
Issuance of common stock, net of offering costs of $98,846	1,406,026	7,030			1,147,292
Repurchase of Treasury Stock			264,318	(906,321)	
Increased Ownership of Panacela Labs, Inc.					
Net loss					
Foreign currency translation					
Balance at June 30, 2015	4,269,175	$ 21,342	264,318	$ (906,321)	$ 134,042,180

	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Noncontrolling Interests	Total
Balance at December 31, 2014	$ (380,110)	$ (133,935,562)	$ 3,393,499	$ 1,786,102
Stock based compensation				200,925
Issuance of common stock, net of offering costs of $98,846				1,154,322
Repurchase of Treasury Stock				(906,321)
Increased Ownership of Panacela Labs, Inc.	(45,348)	(675,975)	721,323	
Net loss		(8,094,975)	(65,384)	(8,160,359)
Foreign currency translation	(1)		2,010	2,009
Balance at June 30, 2015	$ (425,459)	$ (142,706,512)	$ 4,051,448	$ (5,923,322)

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For the Six Months Ended June 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	$ (8,160,359)	$ (6,032,768)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	126,498	686,471
Loss on equipment disposal		24,685
Noncash compensation	40,506	182,617
Warrant issuance costs	617,776	171,116
Equity in loss of Incuron, LLC	362,137	
Change in value of warrant liability	1,529,406	(2,499,683)
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	96,807	(56,302)
Other long-term assets	8,544	15,879
Accounts payable and accrued expenses	(104,909)	(47,251)
Deferred revenue	510,743	(170,766)
Net cash used in operating activities	(4,972,851)	(7,726,002)
Cash flows from investing activities:		
Purchase of short-term investments	(784,110)	
Sale of short-term investments	348,452	285,881
Purchase of equipment	(13,288)	(10,803)
Divestiture of Incuron	2,000,000	
Decrease in restricted cash	834,989	
Net cash provided by investing activities	2,386,043	275,078
Cash flows from financing activities:		
Issuance of common stock, net of offering costs	3,048,934	9,697,501
Repayment of long-term debt and capital leases	(375,972)	(4,040,329)
Noncontrolling interest capital contribution to Incuron, LLC		2,915,239
Net cash provided by financing activities	2,672,962	8,572,411
Effect of exchange rate change on cash and equivalents	(2)	(66,357)
Increase in cash and cash equivalents	86,152	1,055,130
Cash and cash equivalents at beginning of period	3,103,969	10,048,466
Cash and cash equivalents at end of period	$ 3,190,121	$ 11,103,596

Supplemental disclosure of cash flow information:

Cash paid during the period for interest	$ 91,614	$ 360,642
Supplemental schedule of noncash financing activities:		
Noncash financing costs on common stock offering		50,505
Noncash warrant issuance costs		15,993

See Notes to Consolidated Financial Statements

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CLEVELAND BIOLABS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Description of Business

Cleveland BioLabs, Inc. is an innovative biopharmaceutical company developing novel approaches to activate the immune system and address serious medical needs. Our proprietary platform of Toll-like immune receptor activators has applications in radiation mitigation, oncology immunotherapy, and vaccines. Our most advanced product candidate is entolimod, which we are developing as a radiation countermeasure and an immunotherapy for oncology and other indications. We conduct business in the United States and in the Russian Federation, or Russia, through a wholly-owned subsidiary and a consolidated joint venture owned in collaboration with a financial partner. As used throughout these unaudited consolidated financial statements, the terms Cleveland BioLabs and CBLI refer to Cleveland BioLabs, Inc. and its wholly-owned subsidiary, BioLab 612, LLC, but not its consolidated joint venture, Panacela Labs, Inc. The Company, we, us and our refer to Cleveland BioLabs, Inc. together with its consolidated subsidiaries.

CBLI was incorporated in Delaware in June 2003 and is headquartered in Buffalo, New York. As of June 30, 2015, the Company had one wholly-owned subsidiary, Biolab 612, LLC, or Biolab 612, which began operations in 2012, and one consolidated joint venture, Panacela Labs, Inc., or Panacela, which was formed by us and a financial partner in 2011. Panacela has a wholly-owned subsidiary, Panacela Labs, LLC, which was formed in 2011. Additionally, the Company formed a consolidated joint venture, Incuron LLC, or Incuron, with a financial partner in 2010. As of November 25, 2014, the Company no longer maintained a controlling interest in Incuron. On April 29, 2015, the Company sold 75% of its interest in Incuron, and on June 30, 2015 the Company sold its remaining interest in Incuron.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements include the accounts of CBLI, BioLab 612, and Panacela. The accounts of Incuron are also included through November 25, 2014, the date at which CBLI no longer maintained a controlling interest in Incuron. For the period from November 25, 2014 through April 29, 2015, the Company s interest in Incuron is presented using the equity method of accounting, with the completed sale of our entire equity interests in Incuron recorded in the quarter ended June 30, 2015. All significant intercompany balances and transactions have been eliminated in consolidation.

The unaudited consolidated financial statements included herein have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP, for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission, or the 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 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, 2014, as filed with the Securities and Exchange Commission, or the SEC.

In the opinion of the Company s management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of June 30, 2015, along with its results of operations for the three and six month periods ended June 30, 2015 and 2014 and cash flows for the six month periods ended June 30, 2015 and 2014. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

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

At June 30, 2015, we had cash, cash equivalents and short-term investments of $3.6 million in the aggregate. Of that amount, $1.3 million ($0.9 million of cash and cash equivalents and $0.4 million of short-term investments) was restricted for the use of our consolidated joint venture, Panacela, leaving $2.3 million available for general use. As more fully described in Note 9, Subsequent Events, the Company raised $25 million through the sale of common stock in a private placement which closed on July 9, 2015. Management believes this additional capital will fund its operations and cash requirements for at least the next 12 months.

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Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers*, which updates the principles for recognizing revenue. ASU 2014-09 also amends the required disclosures of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. The Company is evaluating the potential impacts of the new standard on its existing revenue recognition policies and procedures.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern.* ASU 2014-15 requires that an entity s management evaluate whether there are conditions or events that raise substantial doubt about the entity s ability to continue as a going concern within one year after the date that the financial statements are issued. ASU 2014-15 is effective for annual periods beginning after December 15, 2016 and for interim periods thereafter. The Company is evaluating the potential impacts of this new standard on its quarterly reporting process.

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.

Cash and Cash Equivalents

As of June 30, 2015, $0.9 million of the Company s cash and cash equivalents was restricted for the use of Panacela, leaving $2.3 million available for general use.

Short-Term Investments

The Company s short-term investments are classified as held to maturity given the intent and ability to hold the investments to maturity. Accordingly, these investments are carried at amortized cost. Short-term investments classified as held-to-maturity consisted of certificates of deposit with maturity dates beyond three months and less than one year. As of June 30, 2015, all of the Company s short-term investments were restricted for the use of Panacela.

Significant Customers and Accounts Receivable

Grant and contract revenue from the U.S. government accounted for 0% and 1.2% of total revenue for the three and six months ended June 30, 2014, respectively. No such revenue was reported for the three and six months ended June 30, 2015. Grant and contract revenue received by the Company s subsidiaries from Russian government agencies accounted for 58.3% and 58.2% of total revenues for the three and six months ended June 30, 2015, respectively and 100% and 98.8% of total revenue for the three and six months ended June 30, 2014, respectively. Although the Company anticipates ongoing U.S. and Russian government contract and grant revenue, there is no guarantee that these revenue streams will continue in the future.

Service contract revenue received by us from Incuron accounted for 41.7% and 41.8% of total revenues for the three and six months ended June 30, 2015, respectively. No such revenue was reported for the three and six months ended

June 30, 2014.

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

Intellectual Property

Costs related to filing and pursuing patent applications are recognized as general and administrative expenses, or G&A expenses, as incurred, since the recoverability of such expenditures is uncertain. Upon marketing approval by the U.S. Food and Drug Administration, or FDA, or a respective foreign governing body, such costs will be capitalized and depreciated over the expected life of the related patent.

Accounting for Stock-Based Compensation

The 2006 Equity Incentive Plan, as amended, or the Plan, authorizes CBLI to grant (i) options to purchase common stock, (ii)

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restricted or unrestricted stock units, and (iii) stock appreciation rights, so long as the exercise or grant price of each are at least equal to the fair market value of the stock on the date of grant. As of June 30, 2015 and taking into consideration the increase in authorized shares under the Plan as approved by our shareholders in April 2015, an aggregate of 650,000 shares of common stock were authorized for issuance under the Plan, of which a total of 158,585 shares of common stock remained available for future awards. A single participant cannot be awarded more than 100,000 shares annually. Awards granted under the Plan have a contractual life of no more than 10 years. The terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Plan are specified in an award document, and approved by the Company s board of directors, compensation committee or its management delegates.

In June 2013, the Company s stockholders approved the 2013 Employee Stock Purchase Plan, or ESPP, which provides a means by which eligible employees of the Company and certain designated related corporations may be given an opportunity to purchase shares of common stock. As of June 30, 2015, and taking into consideration the increase in authorized shares under the ESPP as approved by our shareholders in April 2015, there are 225,000 shares of common stock reserved for purchase under the ESPP. The number of shares reserved for purchase under the ESPP increases on January 1 of each calendar year by the lesser of: (i) 10% of the total number of shares of common stock outstanding on December 31st of the preceding year, or (ii) 100,000 shares of common stock. The ESPP allows employees to use up to 15% of their compensation to purchase shares of common stock at an amount equal to 85% of the fair market value of the Company s common stock on the offering date or the purchase date, whichever is less.

The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted where the vesting period is based on length of service or performance, while a Monte Carlo simulation model is used for estimating the fair value of stock options with market-based vesting conditions. Set forth below are the assumptions used in valuing the stock options granted and a discussion of the Company s methodology for developing each of the assumptions used:

	For the six months ended June 30,	
	2015	2014
Risk-free interest rate	1.35 - 1.59%	1.59 - 1.98%
Expected dividend yield	0.00%	0%
Expected life	5 - 5.5 Years	5 - 6 Years
Expected volatility	76.66 - 116.10%	71.24 - 77.99%

Risk-free interest rate means the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date the option is granted.

Expected dividend yield means the Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.

Expected life means the period of time that options granted are expected to remain outstanding, based wholly on the use of the simplified (safe harbor) method. The simplified method is used because the Company does not yet have adequate historical exercise information to estimate the expected life the options granted.

Expected volatility means a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (implied volatility) during a period. Expected volatility is based on the Company s historical volatility and incorporates the volatility of the common stock of comparable companies when the

expected life of the option exceeds the Company s trading history.

Income Taxes

No income tax expense was recorded for the three and six months ended June 30, 2015 and 2014, as the Company does not expect to have taxable income for 2015 and did not have taxable income in 2014. A full valuation allowance has been recorded against the Company s deferred tax asset.

Earnings (Loss) per Share

Basic net income (loss) per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net income (loss) by the weighted average number of shares outstanding for the period. Diluted net income (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Diluted net loss per share is identical to basic net loss per share as potentially dilutive securities have been excluded from the calculation of diluted net loss per common share because the inclusion of such securities would be antidilutive.

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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:

	As of June 30,	
Common Equivalent Securities	**2015**	**2014**
Warrants	2,272,523	1,030,711
Options	365,784	311,206
Total	2,638,307	1,341,917

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues for liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. For all periods presented, the Company was not a party to any pending material litigation that was estimable and had a probability of loss.

3. Fair Value of Financial Instruments

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

Level 1 Observable inputs for identical assets or liabilities such as quoted prices in active markets;

Level 2 Inputs other than quoted prices in active markets that are either directly or indirectly observable; and

Level 3 Unobservable inputs in which little or no market data exists, which are therefore developed by the Company using estimates and assumptions that reflect those that a market participant would use.

The following tables represent the Company s fair value hierarchy for its financial liabilities measured at fair value on a recurring basis:

	As of June 30, 2015			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities:				
Accrued warrant liability	$	$	$ 5,356,391	$ 5,356,391
Total liabilities	$	$	$ 5,356,391	$ 5,356,391

	As of December 31, 2014			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Accrued warrant liability	$	$	$ 862,074	$ 862,074
Compensatory stock options not yet issued (1)			132,295	132,295
Total liabilities	$	$	$ 994,369	$ 994,369

(1) Included in accrued expenses in the accompanying Consolidated Balance Sheets

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The Company uses the Black-Scholes model to measure the accrued warrant liability and its accrual for compensatory stock options not yet issued. The following are the assumptions used to measure the accrued warrant liability which were determined in a manner consistent with that described for grants of options to purchase common stock as set forth in Note 2:

	June 30, 2015	December 31, 2014
Stock Price	$ 4.34	$ 5.60
Exercise Price	$ 3.00 - 100.00	$ 10.10 - 100.00
Term in years	0.04 - 6.10	0.46 - 6.04
Volatility	83.99 - 327.4%	70.69 - 100.08%
Annual rate of quarterly dividends	0%	0%
Discount rate- bond equivalent yield	.01 - 1.87%	.12 - 1.65%

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

	Three Months Ended June 30, 2015		Six Months Ended June 31, 2015	
	Accrued Warrant Liability	Compensatory Stock Options Issued After Year End	Accrued Warrant Liability	Compensatory Stock Options Issued After Year End
Beginning Balance	$ 4,547,691	$ 132,295	$ 862,074	$ 132,295
Total (gains) or losses, realized and unrealized, included in earnings (1)(2)	1,480,049	(26,381)	1,529,406	(26,381)
Issuances			3,636,260	
Settlements	(671,349)	(105,914)	(671,349)	(105,914)
Balance, June 30, 2015	$ 5,356,391	$	$ 5,356,391	$

	Three Months Ended June 30, 2014		Six Months Ended June 30, 2014	
	Accrued Warrant Liability	Compensatory Stock Options Issued After Year End	Accrued Warrant Liability	Compensatory Stock Options Issued After Year End
Beginning Balance	$ 1,436,845	$	$ 1,241,311	$ 309,450
Total (gains) or losses, realized and unrealized, included in earnings (1)(2)	(412,125)		(2,499,683)	(21,055)
Issuances			2,283,092	
Settlements				(288,395)
Balance, June 30, 2014	$ 1,024,720	$	$ 1,024,720	$

(1) Unrealized gains or losses related to the accrued warrant liability were included as change in value of accrued warrant liability. There were no realized gains or losses for the three and six months ended June 30, 2015 and 2014.
(2) Expenses recorded for compensatory stock options not yet issued are included in research & development expense and general and administrative expense.

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As of June 30, 2015 and December 31, 2014, the Company had no assets or liabilities that were measured at fair value on a nonrecurring basis.

The Company considers the accrued warrant liability and compensatory stock options not yet issued to be Level 3 because some of the inputs into the measurements are neither directly or indirectly observable. Both the accrued warrant liability and compensatory stock options not yet issued use management s estimate for the expected term. Additionally, the number of compensatory options awarded involves an estimate of management s performance in relation to the targets set forth in the Company s Executive Compensation Plan. The following table summarizes the unobservable inputs into the fair value measurement for the accrued warrant liability as of June 30, 2015:

		June 30, 2015		
Description	**Fair Value**	**Valuation Technique**	**Unobservable Input**	**Range in years**
Accrued warrant liability	5,356,391	Black-scholes pricing model	Expected term	0.04 - 6.10
	$ 5,356,391			

Management believes the value of both the accrued warrant liability and compensatory stock options is more sensitive to a change in the Company s stock price at the end of the respective reporting period as opposed to a change in one of the unobservable inputs described above.

The carrying amounts of the Company s short-term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable, approximate their fair values due to their short maturities.

4. Sale of Incuron

On April 29, 2015, CBLI entered into an agreement to sell its equity stake in Incuron to Dr. Mikhail Mogutov, Chairman of Incuron s Board of Directors and founder of Bioprocess Capital Ventures and/or his designee. The transaction was split into two tranches, with 75% of the Company s equity stake in Incuron being sold for approximately $3 million on April 29, 2015, and an option being given to Dr. Mogutov to purchase CBLI s remaining ownership interest in Incuron for approximately $1 million, which was exercised by his affiliate, BioProcess Capital Ventures, on June 30, 2015. The purchase price was paid in the form of (i) $2 million in cash received in April 2015, (ii) the transfer of 264,318 shares of the Company s common stock to escrow with instructions to either return the shares to CBLI or pay the proceeds from the sale of such shares to CBLI, and (iii) $1 million in cash paid in July 2015. Consequently, the June 30, 2015 consolidated balance sheet presents a $1 million receivable, and has classified the cost basis of $906,321, that resulted from an independent valuation reported in the Company s Annual Report on Form 10-K for the year ended December 31, 2014, as a reduction in equity in the form of treasury stock. At June 30, 2015, the governing agreement related to the 264,318 shares of the Company s common stock provides the Company with an option to either have the shares returned to the treasury or sold. In addition, CBLI assigned its remaining intellectual property relating to Curaxin CBL0137 to Incuron in exchange for a 2% royalty on the future commercialization, licensing or sale of the Curaxin CBL0137 technology.

5. Debt

On September 30, 2013, CBLI and BioLab 612 entered into a Loan and Security Agreement, or the Loan Agreement, with Hercules Technology II, L.P., or Hercules, pursuant to which we issued a $6.0 million note and received net

proceeds of $5.9 million. The loan bears interest at the greater of (i) 10.45% per annum or (ii) 10.45% plus the prevailing prime rate minus 4.25%. The loan matures on January 1, 2017, and requires interest-only payments for the initial 12 months and principal and interest payments in 27 monthly installments thereafter. In June 2014, CBLI repaid $4.0 million of the loan using net proceeds from a sale of equity and other cash.

In connection with the Loan Agreement, CBLI granted a first priority lien in substantially all of CBLI s assets (exclusive of intellectual property) to Hercules. The Loan Agreement also contains representations and warranties by CBLI and Hercules, indemnification provisions in favor of Hercules, customary covenants (including limitations on other indebtedness, liens, acquisitions, investments and dividends, but excluding any financial covenants), and events of default (including payment defaults, breaches of covenants, material adverse events and events leading to bankruptcy or insolvency). Prepayment of the loan is subject to a penalty rate applied to the balance of the secured obligation and ranges from 1% to 3% based on the date the loan is prepaid. The prepayment penalty was waived in connection with the above referenced prepayment in June 2014.

Additional loan features, all of which are recorded debt issuance costs and loan discounts in non-current assets, include: $102,000 related to legal fees and a $100,000 facility fee both of which were paid in cash, a $550,000 end-of-term charge which is due upon full repayment of the loan or on the maturity date, whichever occurs sooner and is included in long-term liabilities, and a five-year

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warrant to purchase 7,813 shares of CBLI common stock. The warrant had an initial exercise price of $32.00 per share, which was subsequently lowered to $10.10 per share in accordance with its terms. The Black-Scholes pricing model yielded $117,999 as the fair value of the warrant upon issuance which was recorded as equity.

CBLI will amortize the loan discounts and debt issuance costs to interest expense over the term of the loan using the effective interest rate method, which approximates 16.6%.

The following schedule shows the remaining payments for principal and the end of term charge on the Hercules loan by calendar year:

	June 30,
2016	$ 788,877
2017	1,279,220
Total	$ 2,068,097

On September 3, 2013, Panacela entered into a Master Agreement and a Convertible Loan Agreement, with Open Joint Stock Company RUSNANO, or Rusnano, and CBLI pursuant to which Panacela issued a $1,530,000 note to Rusnano, or the Panacela Loan. The Panacela Loan bears interest at a rate of 16.3% per annum and matures on September 10, 2015, at which time Panacela must repay all unpaid principal and accrued interest. As of June 30, 2015, Panacela had $510,977 of interest accrued associated with the Panacela Loan. Rusnano has the option to convert the unpaid principal plus interest into shares of Panacela preferred stock at a conversion price of $1,057 per share, or if Panacela has a qualified financing event, at a discounted price of 0.75 times the purchase price per share.

6. Stockholders Equity

On February 4, 2015, CBLI entered into a Securities Purchase Agreement with certain institutional investors providing for the issuance and sale of 572,205 registered shares, or the Shares, of the Company s common stock, at an offering price of $3.00 per share, or the Share Offering, and Series B pre-funded warrants, or the Pre-Funded Warrants, to purchase an aggregate of 594,688 registered shares of its common stock, or the Pre-Funded Warrants Offering. The Share Offering and the Pre-Funded Warrants Offering are referred to collectively as the Offerings.

In a concurrent private placement, or the Private Placement Transaction, and, together with the Offerings, CBLI sold to the purchasers of our Shares and Pre-Funded Warrants, 717.4 shares of our Series A Convertible Preferred Stock, stated value of $1,000 per share, or the Preferred Stock, which are convertible into 239,134 shares of our common stock. Gross proceeds from the Offerings amounted to approximately $4.2 million before deducting placement agent fees and expenses. In addition, Series A warrants, or the Series A Warrants, were issued to purchase one share of our common stock for each share of common stock purchased or prefunded in the Offerings and each share of Series A Convertible Preferred Stock purchased in the Private Placement Transaction. The Series A Warrants cover, in the aggregate, 1,406,028 shares of common stock and become exercisable six months following the date of issuance at an exercise price of $3.64 and expire six years from the date they become exercisable.

The Series A Warrants and Series B Warrants contain provisions that could require CBLI to settle the warrants in cash, and also provide for price or share issuance adjustments in the event of a subsequent qualified issuance of common stock at a price below $3.64 for the Series A Warrants or $3.00 for the Pre-Funded Warrants, and accordingly have been classified as a liability. As of February 6, 2015, the closing date, the fair value of the Preferred

Stock and the Pre-Funded Warrants amounted to $3,636,260 and was determined based on the following assumptions using the Black-Scholes valuation model:

	Series A	Series B
Stock Price	$ 3.16	$ 3.16
Exercise Price	$ 3.64	$ 3.00
Term in years	6.50	1.00
Volatility	0.83%	0.88%
Annual rate of quarterly dividends	0%	0%
Discount rate- bond equivalent yield	1.48%	0.26%

As of June 30, 2014, the Pre-Funded Warrants and the Preferred Stock had fully converted into common stock and as such, no balances other than stockholders equity remain for these securities.

The Company has granted options to purchase shares of common stock. The following is a summary of option award activity during the six months ended June 30, 2015:

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	Six Months Ended June 30, 2015			
	Total Stock Options Outstanding	Weighted Average Exercise Price per Share	Nonvested Stock Options	Weighted Average Grant Date Fair Value per Share
December 31, 2014	261,389	$ 67.89	21,287	$ 22.34
Granted	131,500	3.19	90,750	2.58
Vested			(842)	19.88
Exercised				
Forfeited, Canceled	(27,105)	10.47	(18,750)	3.63
June 30, 2015	365,784	$ 48.89	92,445	$ 6.76

The following is a summary of outstanding stock options as of June 30, 2015:

	As of June 30, 2015	
	Stock Options Outstanding	Vested Stock Options
Quantity	365,784	273,339
Weighted-average exercise price	$ 48.89	$ 62.51
Weighted Average Remaining Contractual Term (in Years)	7.11	6.33
Intrinsic value	$	$

For the six months ended June 30, 2015 and 2014, the Company granted 131,500 and 49,550 stock options, respectively, with a weighted-average grant date fair value of $2.59 and $7.60, respectively. For the six months ended June 30, 2015 and 2014, the total fair value of options vested was $105,914 and $200,658, respectively.

As of June 30, 2015, total compensation cost not yet recognized related to unvested stock options was $164,425. The Company expects to recognize this cost over a weighted average period of approximately 0.45 years.

7. Warrants

In connection with sales of the Company s common stock and the issuance of debt instruments, warrants were issued which presently have exercise prices ranging from $3.00 to $100.00. The warrants expire between one and seven years from the date of grant, and are subject to the terms applicable in each agreement. The following table summarizes the activity in our outstanding warrants since December 31, 2014:

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	Number of Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2014	875,304	$ 33.72
Granted	1,406,028	3.64
Forfeited, Canceled	(8,809)	100.00
Outstanding at June 30, 2015	2,272,523	14.16

In addition, the Company has issued a warrant to Rusnano, our financial partner in Panacela, or the Rusnano Warrant, that can only be exercised in the event Panacela defaults on a loan from Rusnano, or the Rusnano Loan. The maximum number of shares issuable under the Rusnano Warrant as of June 30, 2015 is 41,706. At June 30, 2015, Panacela was not in default of the Rusnano Loan.

8. Significant Alliances and Related Parties

Roswell Park Cancer Institute

The Company has entered into several agreements with Roswell Park Cancer Institute, or RPCI, including: various sponsored research agreements, an exclusive license agreement and clinical trial agreements for the conduct of the Phase 1 entolimod oncology study and the Phase 1 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 $264,693 and $469,371 in expense to RPCI related to research grants and agreements for the quarters ended June 30, 2015 and 2014, respectively. The Company had $381,837 and $210,882 included in accounts payable owed to RPCI at June 30, 2015 and 2014, respectively. In addition, the Company had $157,110 and $210,882 in accrued expenses payable to RPCI at June 30, 2015 and 2014, respectively.

The Cleveland Clinic

CBLI entered into an exclusive license agreement, or the License, with The Cleveland Clinic pursuant to which CBLI was granted an exclusive license to The Cleveland Clinic s research base underlying our therapeutic platform and certain product candidates licensed to Panacela. CBLI has the primary responsibility to fund all newly developed patents; however, The Cleveland Clinic retains ownership of those patents covered by the agreement. CBLI also agreed to use commercially diligent efforts to bring one or more products to market as soon as practical, consistent with sound and reasonable business practices and judgments. There were no milestone or royalty payments paid to CCF during the six months ended June 30, 2015 or 2014.

The Company did not have any liabilities to The Cleveland Clinic at June 30, 2015 or 2014.

Buffalo BioLabs, et. al.

Our CSO, Dr. Andrei Gudkov has business relationships with several entities with which we transact business, the most significant of which is Buffalo BioLabs, LLC, or BBL, where Dr. Gudkov was a founder and currently serves as their Principal Scientific Advisor. Such description of services is more thoroughly discussed in Note 8, Restructuring, of our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC on February 27, 2015. The Company recognized $245,417 and $359,823 as research and development expense for the quarters ended June 30, 2015 and 2014, respectively, and included $0 and $9,836 in accounts payable to BBL at June 30, 2015 and 2014. In addition, the Company had $0 and $66,077 in

accrued expenses payable to BBL at June 30, 2015 and 2014, respectively. We also recognized $55,962 and $87,490 from BBL for sublease and other income for the quarters ended June 30, 2015 and 2014, respectively. Pursuant to our real estate sublease and equipment lease with BBL, we had gross and net accounts receivable of $227,086, and 0 at June 30, 2015, respectively and a gross receivable of $67,915 at June 30, 2014.

9. Subsequent Events

On July 9, 2015, the Company sold 6,459,948 shares of the Company s common stock to David Davidovich, a venture capital, accredited investor, for $25 million, or $3.87 per share, the July Equity Investment. Additionally, the Company has elected to prepay the remaining obligations due under its loan with Hercules, the Hercules Prepayment. Considering therefore the subsequent receipt of approximately $23.5 million in net proceeds from the July Equity Investment, the subsequent receipt of $1.0 million from the sale of the Company s remaining equity interest in Incuron as further described in Note 4, Sale of Incuron, and approximately $2.0 million subsequently disbursed for the Hercules Prepayment, the Company had approximately $26.1 million in cash, cash equivalents and short-term investments on a pro-forma basis as of June 30, 2015. As a result of the foregoing and other changes occurring in the normal course of the Company s business since June 30, 2015, 10,729,123 shares of the Company s common stock are currently issued and outstanding, along with 2,227,232 warrants that have a weighted average exercise price of $13.95 per share, exclusive of the Rusnano Warrant described in Note 7, Warrants, and 365,784 options with a weighted average exercise price of $48.89.

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Additionally, as disclosed in Note 10, Income Taxes, of the Company s consolidated financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2014 and filed with the SEC on February 27, 2015, the Company had U.S. federal net operating loss carryforwards of approximately $120,934,000, which begin to expire if not utilized by 2023, and approximately $3,565,000 of federal tax credit carryforwards which begin to expire if not utilized by 2024. The Company also has U.S. state net operating loss carryforwards of approximately $110,957,000, which begin to expire if not utilized by 2027 and state tax credit carryforwards of approximately $337,000, which begin to expire if not utilized by 2022. The purchase of 6,459,948 shares of common stock by Mr. Davidovich yields a post-transaction ownership percentage of 60.2% for him. We believe it highly likely that this transaction 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 (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.

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

This management s discussion and analysis of financial condition and results of operations and other portions of this filing contain forward-looking information that involves risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as anticipates, believes, could, estimates, expects, intends, may, plans, potential, predicts, projects, should, will, would and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, and because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not transpire. 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, 2014 and in subsequent filings, including in Item 1A under the heading Risk Factors in this Quarterly Report on Form 10-Q. Factors that may cause such differences include, but are not limited to, availability and cost of financial resources, results of our research and development efforts and clinical trials, product demand, market acceptance and other factors discussed below and in our other SEC filings, including our Annual Report on Form 10-K for the year ended December 31, 2014.

Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this report. You should read this report with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we do not undertake any obligation to publicly update or revise any forward-looking statements contained in this report, whether as a result of new information, future events or otherwise. 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, 2014.

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 radiation mitigation, oncology immunotherapy, and vaccines. Our most advanced product candidate is entolimod, which we are developing as a radiation countermeasure and an immunotherapy for oncology and other indications. We also have an additional clinical stage program and multiple innovative projects in different stages of preclinical drug development.

See Part I, Item 1. Business in our Annual Report on Form 10-K for the year ended December 31, 2014 for more information on our product candidates. As more fully described in Note 4, Sale of Incuron to our unaudited consolidated financial statements, we no longer have an equity interest in Incuron and in its product candidate CBL0137, but retain a 2% royalty interest.

Critical Accounting Policies and Significant Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or 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 critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2014. 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, 2014.

Fair Value of Financial Instruments

We use the Black-Scholes model to determine the fair value of certain common stock warrants and stock options not yet issued on a recurring basis, and classify such warrants and options as Level 3 in the fair value hierarchy. The Black-Scholes model utilizes inputs consisting of: (i) the closing price of our common stock; (ii) the expected remaining life; (iii) the expected volatility using a weighted average of historical volatilities of CBLI and a group of comparable companies; and (iv) the risk-free market rate.

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As of June 30, 2015, we held approximately $5.4 million in accrued expenses related to warrants to purchase common stock, which we classified as Level 3.

Three Months Ended June 30, 2015 Compared to Three Months Ended June 30, 2014

Revenue

Revenue decreased from approximately $0.6 million for the three months ended June 30, 2014 to approximately $0.3 million for the three months ended June 30, 2015, representing a decrease of approximately $0.3 million, or 41%. During these periods, we received revenues associated with our contracts and/or grants from the Ministry of Industry and Trade of the Russian Federation, or MPT, and the Skolkovo Foundation, or Skolkovo. The revenues related to our contracts and grants are cost-based and vary as a direct function of the underlying contracted work, which varies between periods. Additionally, beginning in December 2014, we recognized service contract revenue from Incuron, LLC, which was deconsolidated in the fourth quarter of 2014. The revenue differences related to our contracts, grants, and service contracts between the periods are set forth in the following table:

		Three Months Ended June 30,		
Funding Source	**Program**	**2015**	**2014**	**Variance**
MPT	CBLB612 Pre-clinical (1)	$ 22,923	$ (82,572)	$ 105,495
MPT	Entolimod Colorectal Cancer (1)	9,300	87,143	(77,843)
Incuron	Service Contracts	137,705		137,705
		169,928	4,571	165,357
Skolkovo	Curaxin research (1)		388,111	(388,111)
MPT	Mobilan Pre-clinical (1)	159,980	169,405	(9,425)
		$ 329,908	$ 562,087	$ (232,179)

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

We anticipate our revenue over the next year will continue to be derived mainly from government grants and contracts. We plan to submit or have submitted proposals for government grants and contracts to various funding sources that have awarded us grants and contracts in the past, but there can be no assurance that we will receive future funding awards. The following table sets forth information regarding our currently active grants and contracts:

				As of June 30, 2015		
Funding Source	**Program**	**Total Award Value**	**Funded Award Value**	**Cumulative Revenue**	**Funded Backlog**	**Unfunded Backlog**
MPT	CBLB612 Pre-clinical (1)	$ 3,481,828	$ 3,481,828	$ 3,094,788	$ 387,040	$
MPT	Entolimod Colorectal Cancer (1)	3,266,035	2,549,228	2,041,286	507,942	716,807

		6,747,863	6,031,056	5,136,074	894,982	716,807
MPT	Mobilan Pre-clinical (1)	3,382,509	2,665,702	2,157,759	507,943	716,807
		$ 10,130,372	$ 8,696,758	$ 7,293,833	$ 1,402,925	$ 1,433,614

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

Research and Development Expenses

Research and development, or R&D, expenses decreased from $2.3 million for the three months ended June 30, 2014 to $1.6 million for the three months ended June 30, 2015, representing a decrease of $0.7 million, or 30%. $0.3 million of this decrease was due to the deconsolidation of Incuron, which occurred in the fourth quarter of 2014. $0.4 million was due to variances in the levels of outsourced research as set forth, by drug candidate. These variances are noted in the table below.

	Three Months Ended June 30,		
	2015	2014	Variance
Entolimod for Biodefense Applications	$ 908,138	$ 1,067,053	$ (158,915)
CBLB612	29,805	60,117	(30,312)
Entolimod for Oncology Indications	289,963	402,410	(112,447)
	1,227,906	1,529,580	(301,674)
Curaxins	254,072	515,637	(261,565)
Panacela product candidates	101,191	279,006	(177,815)
Total research & development expenses	$ 1,583,169	$ 2,324,223	$ (741,054)

General and Administrative Expenses

G&A expenses decreased from $2.3 million for the three months ended June 30, 2014 to $1.6 million for the three months ended June 30, 2015, representing a decrease of $0.7 million, or 30%. $0.3 million of this decrease was due to the deconsolidation of Incuron, which occurred in the fourth quarter of 2014, and the remainder was due to $0.2 million in reductions in each of personnel and recurring professional fees.

Other Income and Expenses

Other expense increased from $0.1 million for the three months ended June 30, 2014 to $1.6 million for the three months ended June 30, 2015, representing an expense increase of $1.5 million, or 1,500%. This expense increase was primarily related to the change in the periodic warrant liability valuation.

Six Months Ended June 30, 2015 Compared to Six Months Ended June 30, 2014

Revenue

Revenue decreased from $1.9 million for the six months ended June 30, 2014 to $0.9 million for the six months ended June 30, 2015, representing a decrease of $1.0 million, or 53%. During these periods, we received revenues associated with our contracts and/or grants from the Department of Defense, or DoD, MPT and Skolkovo. The revenues related to our contracts and grants are cost-based and vary as a direct function of the underlying contracted work, which

varies between periods. DoD and Skolkovo contracts completed in the first half of 2014 and there were differences in the underlying research activities associated with the MPT contracts, which collectively resulted in decreased revenues. Additionally, beginning in December 2014, we recognized service contract revenue from Incuron, LLC, which was deconsolidated in the fourth quarter of 2014. The revenue differences related to our contracts, grants, and service contracts between the periods are set forth in the following table:

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Funding Source	Program	Six Months Ended June 30, 2015	2014	Variance
DoD	MCS Contract (1)	$	$ 23,390	$ (23,390)
MPT	CBLB612 Pre-clinical (2)	62,921	97,639	(34,718)
MPT	Entolimod Colorectal Cancer (2)	226,370	124,329	102,041
Incuron	Service Contracts	391,439		391,439
		680,730	245,358	435,372
Skolkovo	Curaxin research (2)		1,000,770	(1,000,770)
MPT	Xenomycins Pre-clinical (2)		28,605	(28,605)
MPT	Mobilan Pre-clinical (2)	256,507	621,608	(365,100)
		$ 937,237	$ 1,896,341	$ (959,103)

(1) The Medical Countermeasure Systems, or MCS, Contract was formerly known as the Chemical Biological Medical Systems- Medical Identification and Treatment Systems, or CBMS-MITS Contract.

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

Research and Development Expenses

R&D expenses decreased from $4.8 million for the six months ended June 30, 2014 to $3.2 million for the six months ended June 30, 2015, representing a decrease of $1.6 million, or 33%. $0.7 million of the decrease for the period was due to the deconsolidation of Incuron, which occurred in the fourth quarter of 2014. $0.9 million of the decrease for the period was due to variances in the levels of outsourced research as set forth, by drug candidate, as noted in the table below, with the most significant variances being an increase in the cost of CBLB612 development due to increased clinical activity during the six months ended June 30, 2015 and a reduction in Panacela s product candidate development. During the six months ended June 30, 2014, Panacela was in the planning stages for its Phase 1 trial. Such trial commenced and enrolled its first patient in June 2015.

	Six Months Ended June 30, 2015	2014	Variance
Entolimod for Biodefense Applications	$ 1,813,621	$ 1,949,160	$ (135,539)
CBLB612	280,430	195,836	84,594
Entolimod for Oncology Indications	514,416	600,085	(85,669)
	2,608,467	2,745,081	(136,614)
Curaxins	412,349	1,156,846	(744,497)
Panacela product candidates	173,323	862,069	(688,746)
Total research & development expenses	$ 3,194,139	$ 4,763,996	$ (1,569,857)

General and Administrative Expenses

G&A expenses decreased from $4.7 million for the six months ended June 30, 2014 to $3.9 million for the six months ended June 30, 2015, representing a decrease of $0.8 million, or 17%. $0.5 million of this decrease was due to the deconsolidation of Incuron, which occurred in the fourth quarter of 2014. In addition, compensation expense decreased by $0.2 million and recurring professional fees and other costs decreased by $0.7 million. These reductions were partially offset by a one-time increase of $0.6 million related to costs associated with our equity offering in February 2015, as more fully described in Note 6, Stockholders Equity, to our unaudited consolidated financial statements. The majority of the costs of the February equity offering were expensed, and not otherwise charged to equity, as the majority of the net proceeds were considered derivative liabilities.

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Other Income and Expenses

Other income decreased from $1.5 million for the six months ended June 30, 2014 to $2.0 million of other expense for the six months ended June 30, 2015, representing an expense increase of $3.5 million, or -233%. The decrease is attributable to the change in periodic warrant valuation of $4.0 million and $0.4 million related to the loss of Incuron accounted for as an equity investment during the six months ended June 30, 2015. These additional expenses were offset by expense reductions of $0.7 million, which were primarily attributable to a one-time, non-cash debt extinguishment charge incurred in 2014 and less interest expense incurred on a lower outstanding loan balance.

Liquidity and Capital Resources

We have incurred net losses in excess of $140 million from our inception through June 30, 2015. 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 July 31, 2015, and including the most recent equity raise more fully described in Note 9, Subsequent Events, to our unaudited consolidated financial statements, we have raised $144.6 million of net equity capital, including amounts received from the exercise of options and warrants. We have also received $5.8 million in net proceeds from the issuance of long-term debt instruments;

DoD and the Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services have funded grants and contracts totaling $44.6 million for the development of entolimod for biodefense indication;

Entities affiliated with the Russian Federation have awarded us contracts totaling $12.3 million through a series of awards. All awards are valued based on revenue recognized to date, with the remaining backlog valued at the June 30, 2015 exchange rate. These contracts include a requirement for us to contribute matching funds, which we have satisfied or expect to satisfy with both the value of developed intellectual property at the time of award, incurred development expenses and future expenses;

We have been awarded $4.0 million in grants and contracts not described above, all of which has been recognized at June 30, 2015;

Incuron was formed to develop and commercialize the Curaxins product line, including their lead oncology drug candidate CBL0137. In April 2015, we sold 75% of our ownership interest for approximately $3 million and also gave the purchaser an option to buy our remaining ownership interest for approximately $1 million. As more fully descried on Note 4, Sale of Incuron, to our unaudited consolidated financial statements, such option was exercised on June 30, 2015. We also assigned the remainder of our Curaxin intellectual property to Incuron for a 2% royalty; 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 at formation and has options to contribute up to $15.5 million of additional funding. CBLI contributed $3.0 million plus intellectual property at formation and has an option to contribute additional capital based on agreed-upon terms. As of the date of this filing, CBLI owns 60.47% of Panacela.

At June 30, 2015, after giving pro forma effect to the subsequent receipt of net proceeds of approximately $23.5 million from our recent private placement, subsequent receipt of $1.0 million in connection with the sale of Incuron, LLC and the subsequent prepayment of approximately $2.0 million of Hercules loan obligations, as more fully described in Note 9, Subsequent Events, to our unaudited consolidated financial statements, we had cash, cash equivalents and short-term investments of $26.1 million. Of that total, $1.3 million was restricted for the use of our consolidated joint venture, Panacela, leaving $24.8 million available for general use. Furthermore, Panacela and Biolab 612 had an additional $0.9 million of restricted cash held for performance bonds in connection with their respective MPT grants, which are classified as a long-term asset.

Operating Activities

Net cash used in operations decreased by $2.7 million to $5.0 million for the six months ended June 30, 2015 from $7.7 million for the six months ended June 30, 2014. After adjusting for certain non-cash items, the net loss decreased by $2.0 million, while changes in working capital provided cash and cash equivalents of $0.7 million between the periods.

Investing Activities

Net cash provided by investing activities increased by $2.1 million for the six months ended June 30, 2015, primarily due to $2.0 million in cash received upon the divestiture of Incuron LLC and $0.1 million due to the release of restricted cash.

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Financing Activities

Cash flows provided by financing activities decreased by $5.9 million to $2.7 million for the six months ended June 30, 2015, as compared to $8.5 million for the six months ended June 30, 2014. The net decrease is due to a reduction in net equity proceeds of $6.7 million. We also incurred a $2.9 million capital contribution to Incuron in 2014, which was not reflected in 2015. These reduced equity investments were offset by less loan repayments in the amount of $3.7 million due primarily to the $4.0 million loan prepayment in June 2014.

Other

We have incurred cumulative net losses and expect to incur additional losses related to our research and development activities. We do not have commercial products and have limited capital resources. In July 2015, we closed a private placement transaction and raised $25 million in gross proceeds. As a result of this recent financing, we believe that our current funds and cash flows from existing government grants and contracts will be sufficient to fund our projected operating requirements for at least the next 12 months. 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 in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms. Our plans with regard to these matters may include seeking additional capital through debt or equity financing, the sale or license of our drug candidates, or the issuance of equity and additional revenues from the U.S. or Russian governments. There is no assurance that we will be successful in obtaining additional financing on commercially reasonable terms or that we will be able to secure funding from anticipated government contracts and grants.

Our auditors, Meaden & Moore, LLP, have indicated in their report on our financial statements for the year ended December 31, 2014, that conditions exist that raise substantial doubt about our ability to continue as a going concern due to our recurring losses and substantial decline in our working capital. We believe we have generated sufficient cash flow to sustain our operations for at least the next 12 months. However, we do not have any firm commitments for funding beyond our recent financing. If we are unable to raise adequate capital and/or achieve profitable operations, our future operations might need to be scaled back or discontinued. The financial statements do not include any adjustments relating to the recoverability of the carrying amount of recorded assets and liabilities that might result from the outcome of these uncertainties.

Impact of Inflation

We believe that our results of operations are not dependent upon moderate changes in inflation rates.

Impact of Exchange Rate Fluctuations

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, 2015 and June 30, 2015, this rate fluctuated by 1.3%. For calendar 2014, this rate fluctuated over 70%. Translation gains or losses result primarily from the impact of exchange rate fluctuations on the reported U.S. dollar equivalent of ruble denominated cash and cash equivalents, restricted cash and short-term investments. Variances in the exchange rate for these items have not been realized; as such the resulting gains or losses are recorded as other comprehensive income in the equity section of the balance sheet. We expect transaction gains or losses result from cross-currency transactions will be less significant in 2015 due to the deconsolidation of Incuron in the fourth quarter of 2014. At June 30, 2015, we held approximately 90 million rubles in cash and cash equivalents, 25 million rubles in short-term investments and 48 million rubles in restricted cash. For these items, a 10% change in the U.S. dollar to Russian ruble foreign exchange rate would yield a $0.3 million variance. Other foreign exchange transactions among CBLI and its subsidiaries are typically not material.

Off-Balance Sheet Arrangements

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

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

There has been no significant change in our exposure to market risk during the first six months of 2015. For a discussion of our exposure to market risk, refer to Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk, contained in our Annual Report on Form 10-K for the year ended December 31, 2014.

Item 4. Controls and Procedures

Effectiveness of Disclosure

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of June 30, 2015. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2015, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective to assure that information required to be declared by us in reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the periods specified in the SEC s rules and forms, and (2) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) during the fiscal quarter ended June 30, 2015, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II Other Information

Item 1. Legal Proceedings

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

While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of June 30, 2015, that, in the opinion of management, might have a material adverse effect on our financial position, results of operations or cash flows.

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Item 1A. Risk Factors

The risk factors in this report have been revised to incorporate changes to our risk factors from those included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014. The risk factors set forth below with an asterisk (*) next to the title are new risk factors or risk factors containing changes, which may be material, from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, as filed with the Securities and Exchange Commission on February 27, 2015.

***We will require substantial additional financing in order to meet our business objectives.**

Since our inception, most of our resources have been dedicated to the pre-clinical and clinical development of our product candidates. In particular, we are currently conducting multiple clinical trials of our product candidates, each of which will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future developing our pre-clinical and clinical product candidates. These expenditures will include costs associated with research and development, conducting pre-clinical and clinical trials, obtaining regulatory approvals and products from third-party manufacturers, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts of capital necessary to successfully complete the development and commercialization of our product candidates.

As of June 30, 2015, our cash, cash equivalents and short-term investments amounted to $3.6 million. After giving pro forma effect to the subsequent receipt of net proceeds of approximately $23.5 million from our recent private placement, subsequent receipt of $1.0 million in connection with the sale of Incuron, LLC and the subsequent prepayment of approximately $2.0 million of Hercules loan obligations, as more fully described in Note 9, Subsequent Events, to our unaudited consolidated financial statements,, we believe that our existing cash, cash equivalents, and marketable securities will allow us to fund our operating plan for at least the next 12 months.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amounts of our total capital requirements. Our future capital requirements depend on many factors, including:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting pre-clinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities for any of our product candidates that are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates and any products we successfully commercialize;

our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;

whether we realize the full amount of any projected cost savings associated with our strategic restructuring;

the occurrence of a breach or event of default under our loan agreement with Hercules or under any other agreements with third parties;

the success of the pre-EUA submission we made with the FDA and any future submissions that we may make; and

the timing, receipt and amount of sales of, or royalties on, our future products, if any.

When our available cash and cash equivalents become insufficient to satisfy our liquidity requirements, or if and when we identify additional opportunities to do so, we will likely seek to sell additional equity or debt securities or obtain additional credit facilities. The sale of additional equity or convertible debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock or through additional credit facilities, these securities and/or the loans under credit facilities could provide for rights senior to those of our common stock and could contain covenants that would restrict our operations. Furthermore, any funds raised through collaboration and licensing arrangements with third parties may require us to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. In any such event, our business prospects, financial condition and results of operations could be materially adversely affected.

We may require additional capital beyond our currently forecasted amounts and additional funds may not be available when we need them, on terms that are acceptable to us, or at all. In particular, the decline in the market price of our common stock could make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. In addition, as we are a controlled company following our July 2015 transaction, our principal stockholder has the ability to control all matters requiring approval by our stockholders, including the election and removal of directors, amendments to our certificate of incorporation and bylaws, any proposed merger, consolidation or sale of all or substantially all of our assets and other corporate transactions. Additionally, our corporate structure, including the ownership of several of our product candidates in our joint ventures, may deter

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third parties from entering into collaboration and licensing arrangements with us. If we fail to raise sufficient additional financing, on terms and dates acceptable to us, we may not be able to continue our operations and the development of our product candidates, our patent licenses may be terminated, and we may be required to reduce staff, reduce or eliminate research and development, slow the development of our product candidates, outsource or eliminate several business functions or shut down operations.

***We have a history of operating losses. We expect to continue to incur losses and may not continue as a going concern.**

We have incurred significant losses to date. We have incurred net losses of approximately $8.2 million and over $140 million for the six months ended June 30, 2015 and since inception, respectively. We expect significant losses to continue for the next few years as we spend substantial sums on the continued research and development of our proprietary product candidates, and there is no certainty that we will ever become profitable as a result of these expenditures. As a result of losses that will continue throughout our development stage, we may exhaust our financial resources and be unable to complete the development of our product candidates.

Our ability to become profitable depends primarily on the following factors:

- our ability to obtain adequate sources of continued financing;
- our ability to obtain approval for, and if approved, to successfully commercialize our product candidates;
- our ability to successfully enter into license, development or other partnership agreements with third-parties for the development and/or commercialization of one or more of our product candidates;
- our R&D efforts, including the timing and cost of clinical trials; and
- our ability to enter into favorable alliances with third-parties who can provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales, marketing and distribution.

Even if we successfully develop and market our product candidates, we may not generate sufficient or sustainable revenue to achieve or sustain profitability.

Additionally, in September 2013, our majority-owned joint venture Panacela entered into a $1.5 million Convertible Loan Agreement with Rusnano, or the Rusnano Loan, and is required to pay all unpaid principal and interest under the loan in September 2015. The loan may be converted into shares of Panacela stock at any time at Rusnano s option. In the event Panacela defaults on the loan and such default is not cured, Rusnano shall have the right to exercise a warrant to purchase shares of our common stock equal to 69.2% of the outstanding amount remaining unpaid under the Rusnano Loan at the time of exercise, divided by the exercise price of $33.88 per share. As of June 30, 2015, this would amount to 41,706 shares.

***Our ability to use our net operating loss carryforwards may be limited.**

As of December 31, 2014, we had U.S. federal net operating loss carryforwards of approximately $120,934,000, which begin to expire if not utilized by 2023, and approximately $3,565,000 of federal tax credit carryforwards which begin to expire if not utilized by 2024. The Company also has U.S. state net operating loss carryforwards of approximately $110,957,000, which begin to expire if not utilized by 2027 and state tax credit carryforwards of approximately $337,000, which begin to expire if not utilized by 2022. The purchase of 6,459,948 shares of common stock by Mr. Davidovich yields a post-transaction ownership percentage of 60.2% for him. We believe it highly likely that this transaction 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 (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 carry forwards.

RISKS RELATED TO PRODUCT DEVELOPMENT

We may not be able to successfully and timely develop our products.

Our product candidates range from ones currently in the research stage to ones currently in the clinical stage of development and all require further testing to determine their technical and commercial viability. Our success will depend on our ability to achieve scientific, clinical and technological advances and to translate such advances into reliable, commercially competitive products in a timely manner. In addition, the success of our subsidiaries and joint ventures will depend on their ability to meet developmental milestones in a timely manner or to fulfill certain other development requirements under contractual agreements, which are pre-requisites to their receipt of additional funding from their non-controlling interest holders or the government agency funding their government contracts. Products that we may develop are not likely to be commercially available for several years. The proposed development schedules for our products may be affected by a variety of factors, including, among

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others, technological difficulties, proprietary technology of others, the government approval process, the availability of funds, disagreements with the financial partners in our joint ventures, and changes in government regulation, many of which will not be within our control. Any delay in the development, introduction or marketing of our products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects and the unproven technology involved, we may not be able to complete successfully the development or marketing of any products.

We may fail to develop and commercialize some or all of our products successfully or in a timely manner because:

- pre-clinical or clinical study results may show the product to be less effective than desired (e.g., a study may fail to meet its primary objectives) or to have harmful or problematic side effects;
- we fail to receive the necessary regulatory approvals or there may be a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or pre-EUA, NDA or BLA preparation, discussions with the FDA, an FDA request for additional pre-clinical or clinical data or unexpected safety or manufacturing issues;
- we fail to receive funding necessary for the development of one or more of our products;
- they fail to conform to a changing standard of care for the diseases they seek to treat;
- they are less effective or more expensive than current or alternative treatment methods;
- of manufacturing costs, pricing or reimbursement issues, or other factors that make the product not economically feasible;
- one or more of our financial partners in our joint ventures and us do not agree on the development strategy of our products;
- proprietary rights of others and their competing products and technologies may prevent our product from being commercialized; or
- our collaborative relationships with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return.

We anticipate substantial reliance upon strategic collaborations for marketing and commercialization of our product candidates and we may rely even more on strategic collaborations for R&D of our product candidates. Our business

depends on our ability to sell drugs to both government agencies and to the general pharmaceutical market. Offering entolimod for its biodefense indication use to government agencies may require us to develop new sales, marketing or distribution capabilities beyond those already existing in the Company and we may not be successful in selling entolimod for its biodefense indication use in the United States or in foreign countries despite our efforts. Selling oncology drugs will require a more significant infrastructure. We plan to sell oncology drugs through strategic partnerships with pharmaceutical companies. If we are unable to establish or manage such strategic collaborations on terms favorable to us in the future, our revenue and drug development may be limited. To date, we have not entered into any strategic collaboration with a third party capable of providing these services and we can make no guarantee that we will be able to enter into a strategic collaboration in the future. In addition, we have not yet marketed or sold any of our product candidates or entered into successful collaborations for these services in order to ultimately commercialize our product candidates. We also rely on third-party collaborations with our manufacturers. Manufacturers producing our product candidates must follow cGMP regulations enforced by the FDA and foreign equivalents.

Establishing strategic collaborations is difficult and time-consuming. Our discussion with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of our product candidates or the generation of sales revenue. In addition, to the extent that we enter into collaborative arrangements, our drug revenues are likely to be lower than if we directly marketed and sold any drugs that we may develop.

***We will not be able to commercialize our product candidates if our pre-clinical development efforts are not successful, our clinical trials do not demonstrate safety or our clinical trials or pivotal animal studies do not demonstrate efficacy.**

Before obtaining required regulatory approvals for the commercial sale of any of our product candidates, we must conduct extensive pre-clinical and clinical studies to demonstrate that our product candidates are safe and clinical or pivotal animal trials to demonstrate that our product candidates are efficacious. Pre-clinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful and interim results of a clinical trial or animal efficacy study do not necessarily predict final results. In addition, we must outsource our clinical trials and our animal studies required to obtain regulatory approval of our products. We are not certain that we will successfully or promptly finalize agreements for the conduct of these studies. Delay in finalizing such agreements would delay the commencement of our pre-clinical and clinical studies, such as animal efficacy studies for entolimod s biodefense indication and clinical trials of entolimod, CBLB612 and, Mobilan for oncology indications. In addition, we are seeking final FDA agreement on the scope and design of our pivotal animal efficacy and human safety program for an entolimod biodefense BLA. Delay in agreement with the FDA on this program will delay conduct of the pivotal animal efficacy and human safety studies.

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Agreements with contract research organizations, or CROs, and study investigators, for clinical or animal testing and with other third parties for data management services place substantial responsibilities on these parties, which could result in delays in, or termination of, our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with Good Clinical Practices or our pivotal animal studies fail to comply with Good Laboratory Practices we may be unable to use the data generated at those sites. In these studies, if contracted CROs or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or for other reasons, our clinical or animal studies may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for or successfully commercialize our product candidates.

Our clinical trial operations will be subject to regulatory inspections at any time. If regulatory inspectors conclude that we or our clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, we or they may receive warning letters or other correspondence detailing deficiencies and we will be required to implement corrective actions. If regulatory agencies deem our responses to be inadequate, or are dissatisfied with the corrective actions that we or our clinical trial sites have implemented, our clinical trials may be temporarily or permanently discontinued, we may be fined, we or our investigators may be the subject of an enforcement action, the government may refuse to approve our marketing applications or allow us to manufacture or market our products or we may be criminally prosecuted.

In addition, a failure of one or more of our clinical trials or animal studies can occur at any stage of testing and such failure could have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations. We may experience numerous unforeseen events during, or as a result of, pre-clinical testing and the clinical trial or animal study process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators or IRBs may not authorize us to commence a clinical trial, conduct a clinical trial at a prospective trial site or continue a clinical trial following amendment of a clinical trial protocol or an IACUC may not authorize us to commence an animal study at a prospective study site;

- we may decide, or regulators may require us, to conduct additional pre-clinical or clinical studies, or we may abandon projects that we expect to be promising, if our pre-clinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;

- we may have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable safety risks;

- regulators or IRBs may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or if it is believed that the clinical trials present an unacceptable safety risk to the patients enrolled in our clinical trials;

- the cost of our clinical trials or animal studies could escalate and become cost prohibitive;

any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;

we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials or certain animals used in our animal studies or facilities conducting our studies may not be available at the time that we plan to initiate a study;

the effects of our product candidates may not be the desired effects, may include undesirable side effects, or the product candidates may have other unexpected characteristics; and

our collaborators that conduct our clinical or pivotal animal studies could go out of business and not be available for FDA inspection when we submit our product for approval.

Even if we or our collaborators complete our animal studies and clinical trials and receive regulatory approval, it is possible that a product may be found to be ineffective or unsafe due to conditions or facts that arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such product from the market. To the extent that our success will depend on any regulatory approvals from government authorities outside of the United States that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist.

***Our joint ventures have significant non-controlling interest holders and, as such, are not operated solely for our benefit.**

As of the date of this filing, we owned 60.47% of the equity interests in Panacela. Panacela has significant non-controlling interest holders, including funds regulated by the Russian Federation government. As such, we share ownership and management of these entities with one or more parties who may not have the same goals, strategies, priorities or resources as we do.

Both we and our co-owner of Panacela have certain rights. We each have the right to designate certain of the board members and certain decisions in respect of these entities may not be made without a supermajority vote of the equity holders or the consent of all of the equity holders. The right to transfer ownership interests in Panacela is restricted by provisions such as rights of first refusal and tag along and drag along rights. In addition, the use of funds and other matters are subject to monitoring and oversight by both groups of equity holders. Furthermore, we are required to pay more attention to our relationship with our co-owner as well as with Panacela, and

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if our co-owner changes, our relationship may be materially adversely affected. These various restrictions may lead to additional organizational formalities as well as time-consuming procedures for sharing information and making decisions. In addition, the benefits from a successful joint venture are shared among the co-owners, so that we would not receive all the benefits from our successful joint ventures.

Panacela is in need of additional financial resources. In addition, as Panacela has not received additional funding since their loan from Rusnano in late 2013 and grant funding under their MPT contract, Panacela has not been able to pay certain of their obligations as they become due and may be unable to continue operations. Management is pursuing sources of additional financing. If Panacela does not receive additional financing and is unable to continue operations, it may cause us to experience a material adverse effect on our business, financial condition and results of operations.

If parties on whom we rely to manufacture our product candidates do not manufacture them in satisfactory quality, in a timely manner, in sufficient quantities or at an acceptable cost, clinical development and commercialization of our product candidates could be delayed.

We do not own or operate manufacturing facilities. Consequently, we rely on third parties as sole suppliers of our product candidates. We do not expect to establish our own manufacturing facilities and we will continue to rely on third-party manufacturers to produce supplies for pre-clinical, clinical and pivotal animal studies and for commercial quantities of any products or product candidates that we market or may supply to our collaborators. We also rely on third parties as sole providers of certain testing of our products. Our dependence on third parties for the manufacture and testing of our product candidates may adversely affect our ability to develop and commercialize any product candidates on a timely and competitive basis.

To date, our product candidates have only been manufactured in quantities sufficient for pre-clinical studies and initial clinical trials. We rely on a single collaborator for production of each of our product candidates. For a variety of reasons, dependence on any single manufacturer may adversely affect our ability to develop and commercialize our product candidates in a timely and competitive basis. In addition, our current contractual arrangements alone may not be sufficient to guarantee that we will be able to procure the needed supplies as we complete clinical development and/or enter commercialization.

Additionally, in connection with our application for commercial approvals and if any product candidate is approved by the FDA or other regulatory agencies for commercial sale, we will need to procure commercial quantities of the product candidate from qualified third-party manufacturers. We may not be able to contract for increased manufacturing capacity for any of our product candidates in a timely or economic manner or at all. A significant scale-up in manufacturing may require additional validation studies and commensurate financial investments by the contract manufacturers. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage of supply, which could limit our sales and could initiate regulatory intervention to minimize the public health risk.

Other risks associated with our reliance on contract manufacturers include the following:

- contract manufacturers may encounter difficulties in achieving volume production, quality control and quality assurance and also may experience shortages in qualified personnel and obtaining active ingredients for our product candidates;

if, for any circumstance, we are required to change manufacturers, we could be faced with significant monetary and lost opportunity costs with switching manufacturers. Furthermore, such change may take a significant amount of time. The FDA and foreign regulatory agencies must approve these manufacturers in advance. This requires prior approval of regulatory submissions as well as successful completion of pre-approval inspections to ensure compliance with FDA and foreign regulations and standards;

contract manufacturers are subject to ongoing periodic, unannounced inspection by the FDA and state and foreign agencies or their designees to ensure strict compliance with cGMP and other governmental regulations and corresponding foreign standards. We do not have control over compliance by our contract manufacturers with these regulations and standards. Our contract manufacturers may not be able to comply with cGMP and other FDA requirements or other regulatory requirements outside the United States. Failure of contract manufacturers to comply with applicable regulations could result in delays, suspensions or withdrawal of approvals, seizures or recalls of product candidates and operating restrictions, any of which could significantly and adversely affect our business; and

contract manufacturers may breach the manufacturing agreements that we have with them because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient to us.

Changes to the manufacturing process during the conduct of clinical trials or after marketing approval also require regulatory submissions and the demonstration to the FDA or other regulatory authorities that the product manufactured under the new conditions complies with cGMP requirements. These requirements especially apply to moving manufacturing functions to another facility. In each phase of investigation, sufficient information about changes in the manufacturing process must be submitted to the regulatory authorities and may require prior approval before implementation with the potential of substantial delay or the inability to implement the requested changes.

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RISKS RELATING TO REGULATORY APPROVAL

***We may not be able to obtain regulatory approval in a timely manner or at all and the results of future clinical trials and pivotal efficacy studies may not be favorable.**

The testing, marketing and manufacturing of any product for use in the United States will require approval from the FDA. We cannot predict with any certainty the amount of time necessary to obtain FDA approval and whether any such approval will ultimately be granted. Obtaining approval for products requires testing in animals and human subjects of substances whose effects on humans are not fully understood or documented. Pre-clinical studies, animal efficacy studies or clinical trials may reveal that one or more products are ineffective or unsafe, in which event, further development of such products could be seriously delayed, terminated or rendered more expensive.

In addition, we expect to rely on an FDA regulation known as the Animal Rule to obtain approval for entolimod s biodefense indication. The Animal Rule permits the use of animal efficacy studies together with human clinical safety trials to support an application for marketing approval of products when human efficacy studies are neither ethical nor feasible. These regulations have limited prior use and we have limited experience in the application of these rules to the product candidates that we are developing. Additionally, we submitted an application with the FDA for pre-EUA in June 2015, so that entolimod may be used in an emergency situation. We cannot guarantee that the FDA will review the data submitted in a timely manner, or that the FDA will accept the data when reviewed. The FDA may decide that our data are insufficient for pre-EUA or BLA approval and require additional pre-clinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. If we are not successful in completing the development, licensure and commercialization of entolimod for its biodefense indication, or if we are significantly delayed in doing so, our business will be materially harmed.

The receipt of FDA approval may be delayed for reasons other than the results of pre-clinical studies and clinical trials. For example, in 2011, the IND application for entolimod s biodefense indication was transferred within the FDA from the Division of Biologic Oncology Products, or DBOP, to the Division of Medical Imaging Products, or DMIP. As a result of this transfer, we requested and participated in nine meetings with DMIP during 2011-2014 to review the product mechanisms of action, safety profile and preliminary estimation of an effective human dose. In 2013, DMIP has agreed on the scope and design of the proposed pivotal animal efficacy program and has acknowledged that specific cytokines do play an important role in entolimod s mechanism of action and, as such, can be used as biomarkers for animal-to-human dose-conversion. In order to maintain a competitive edge following the March 2015 approval of Neupogen for a related radiation countermeasure indication, we plan to modify the remaining entolimod BLA efficacy program. Therefore, we will return to FDA to reach an agreement on the elements of the design of our remaining clinical studies for entolimod. There can be no guarantee that we will reach a satisfactory agreement in a timely manner, or at all, or that DMIP will not request any additional information related to our pre-clinical or clinical programs.

Delays in obtaining FDA or any other necessary regulatory approvals of any proposed product or the failure to receive such approvals would have an adverse effect on our ability to develop such product, the product s potential commercial success and/or on our business, prospects, financial condition and results of operations.

Failure to obtain regulatory approval in international jurisdictions could prevent us from marketing our products abroad.

We intend to market our product candidates, including specifically the product candidates being developed by our subsidiaries and joint ventures, in the United States, Russia and other countries and regulatory jurisdictions. In order to market our product candidates in the United States, Russia and other jurisdictions, we must obtain separate

regulatory approvals in each of these countries and territories. The procedures and requirements for obtaining marketing approval vary among countries and regulatory jurisdictions and may involve additional clinical trials or other tests. In addition, we do not have in-house experience and expertise regarding the procedures and requirements for filing for and obtaining marketing approval for drugs in countries outside of the United States, Europe and Japan and may need to engage and rely upon expertise of third parties when we file for marketing approval in countries outside of the United States, Europe and Japan. Also, the time required to obtain approval in markets outside of the United States may differ from that required to obtain FDA approval, while still including all of the risks associated with obtaining FDA approval. We may not be able to obtain all of the desirable or necessary regulatory approvals on a timely basis, if at all. Approval by a regulatory authority in a particular country or regulatory jurisdiction, such as the FDA in the United States or the Roszdravnadzor in Russia, does not ensure approval by a regulatory authority in another country.

We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any or all of the countries or regulatory jurisdictions in which we desire to market our product candidates. At this time, other countries do not have an equivalent to the Animal Rule and, as a result, such countries do not have established criteria for review and approval for this type of product outside their normal review process. Specifically, because such other countries do not have an equivalent to the Animal Rule, we may not be able to file for or receive regulatory approvals for entolimod s biodefense indication outside the United States based on our animal efficacy and human safety data.

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The Fast Track designation for entolimod may not actually lead to a faster development or regulatory review or approval process.

We have obtained a Fast Track designation from the FDA for entolimod s biodefense indication. However, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw our Fast Track designation if the FDA believes that the designation is no longer supported by data from our clinical or pivotal development program. Our Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the FDA s expedited review procedures or that any application that we may submit to the FDA for regulatory approval will be accepted for filing or ultimately approved.

***The pre-EUA submission we made to the FDA in June 2015 may not be successful and, even if such submission is successful, it may not accelerate BLA approval of entolimod or result in any purchase by the U.S. government for this product.**

In July 2014, we met with the FDA regarding human dose-conversion of entolimod and based on the results of that meeting, we submitted a pre-EUA dossier in June 2015 in order to inform and expedite the FDA s issuance of an EUA, should one become necessary in the event of an emergency. The FDA does not have review deadlines with respect to pre-EUA submissions and, therefore, the timing of any approval of a pre-EUA submission is uncertain. If we submit a pre-EUA, the FDA may decide not to accept the data or may decide that our data are insufficient for pre-EUA. The FDA may require additional pre-clinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. Additionally, an authorization of our pre-EUA submission will not guarantee, and may not accelerate, BLA approval of entolimod as a radiation countermeasure. Further, even if our pre-EUA submission is authorized, there is no guarantee that such authorization will lead to procurement by the United States or other governments or any additional development funding as it is possible that the United States or other government may not be interested in our product or our proposed terms of sale for any number of reasons including, but not limited to, lack of available funding, potential lack of government co-sponsorship of our pre-EUA, perceptions about the safety and effectiveness of entolimod, the storage requirements for entolimod or one of our competitors receiving pre-EUA authorization for their product. If we are not successful in partnering entolimod or completing the development, licensure and commercialization of entolimod for its biodefense indication use, or if we are significantly delayed in doing so, our business may be materially harmed.

***Even if our drug candidates obtain regulatory approval, we will be subject to on-going government regulation.**

Even if our drug candidates obtain regulatory approval, our products will be subject to continuing regulation by the FDA, including record keeping requirements, submitting periodic reports to the FDA, reporting of any adverse experiences with the product and complying with Risk Evaluation and Mitigation Strategies and drug sampling and distribution requirements. In addition, updated safety and efficacy information must be maintained and provided to the FDA. We or our collaborative partners, if any, must comply with requirements concerning advertising and promotional labeling, including the prohibition against promoting non-FDA approved or off-label indications or products. Failure to comply with these requirements could result in significant enforcement action by the FDA, including warning letters, orders to pull the promotional materials and substantial fines.

After FDA approval of a product, the discovery of problems with a product or its class, or the failure to comply with requirements may result in restrictions on a product, manufacturer or holder of an approved marketing application. These include withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay or prevent further marketing. Newly discovered or developed safety or effectiveness data, including from other products in a therapeutic class, may require changes to a product s approved labeling, including the addition of new warnings and contraindications. Also, the FDA requires post-market clinical testing of products approved under

the Animal Rule at the time of a declared emergency and may require post-market clinical testing of other products. They may also require surveillance to monitor the product s safety or efficacy to evaluate long-term effects. It is also possible that rare but serious adverse events not seen in our drug candidates may be identified after marketing approval. This could result in withdrawal of our product from the market.

Compliance with post-marketing regulations may be time-consuming and costly and could delay or prevent us from generating revenue from the commercialization of our drug candidates.

If physicians and patients do not accept and use our drugs, we will not achieve sufficient product revenues and our business will suffer.

Even if we gain marketing approval of our drug candidates, government purchasers, physicians and/or patients may not accept and use them. Acceptance and use of these products may depend on a number of factors including:

perceptions by members of the government healthcare community, including physicians, about the safety and effectiveness of our drugs;

published studies demonstrating the safety and effectiveness of our drugs;

adequate reimbursement for our products from payors; and

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effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of our drugs, if approved for marketing, to gain acceptance in the market would harm our business and could require us to seek additional financing.

RISKS RELATED TO OUR DEPENDENCE ON U.S. AND FOREIGN GOVERNMENT CONTRACTS AND GRANTS

***If we are unable to procure additional government funding, we may not be able to fund future R&D and implement technological improvements, which would materially harm our financial conditions and operating results.**

For the six months ended June 30, 2015, we received 58.2% of our revenues from government contract development work in the Russian Federation. In 2014 and 2013, we received 0.6% and 26.8% of our revenues from U.S. government contract and grant development work, and 95.2% and 73.2% of our revenues from Russian government contract development work, respectively.

These revenues have funded some of our personnel and other R&D and G&A costs and expenses. It is possible that we may not choose to apply for or, if we do apply, be able to procure new grants and contracts that provide sufficient funding, or any funding at all. If we do submit proposals for new grants or contracts, the review of such proposals may take significant time. In addition, in the event of a positive review of one or more of our proposals, it may take significant time from the time we receive the positive review to the finalization of a new contract or grant. Additionally, a positive review of a proposal in no way indicates that we will ultimately receive a grant or contract award. Contract and grant awards are subject to a significant amount of uncertainty, including, but not limited to, successful negotiation and availability of funds. In addition, in our experience, contracts from Russian government entities require matching funds and posting of performance guarantees. Therefore, we expect that our acceptance of new contracts or grants from Russian government entities will also be subject to our ability to provide matching funds and to post performance guarantees.

As an example of the uncertainty of U.S. government contracting, in January 2014, we announced that the Biomedical Advanced Research and Development Authority, or BARDA, had terminated negotiations related to our proposal for further development of entolimod as a medical radiation countermeasure, noting that all such negotiations are subject to the availability of funds. In addition, we announced in January 2015 that we had received notice that our proposal application to support further development of entolimod as a medical radiation countermeasure has been recommended for funding subject to negotiations by the DoD. This proposal application aims to conduct additional animal studies to support submission of a BLA. Additionally, in April 2015, we announced that we had received notice that another of our proposal applications to support further development of entolimod as a medical radiation countermeasure was recommended for funding subject to negotiations by the DoD and office of CDMRP. This proposal application aims to conduct an additional clinical study to support submission of a BLA. There is no guarantee that either of these recommendations will quickly or ever lead to the funding by DoD of the related proposals. The Company s receipt of these awards is subject to successful negotiations and availability of funds. Additionally, with regard to our current Russian contracts, in each instance where we have been successful in receiving a contract, the contracts have been subject to matching funds and we have had to post performance guarantees, which have restricted our ability to use funds previously classified as operating funds.

If we are unable to obtain sufficient grants and contracts on a timely basis or if our current grants or contracts are terminated our ability to fund future R&D would be diminished, which would negatively impact our ability to compete in our industry and could materially and adversely affect our business, financial condition and results of operations.

Our future business may be harmed as a result of the foreign and U.S. government contracting process as it involves risks not present in the commercial marketplace.

We expect that a significant portion of the business that we will seek in the near future will be under government contracts or subcontracts, both U.S. and foreign, which may be awarded through competitive bidding. For example, as described above, we are seeking funding from the DoD to support further development of entolimod. Additionally, in the Russian federation we may seek additional funding from the Skolkovo Foundation or MPT. Competitive bidding for government contracts presents a number of risks that are not typically present in the commercial contracting process, which may include:

- the need to devote substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;

- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;

- the risk that the government will issue a request for proposal to which we would not be eligible to respond;

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the risk that third parties may submit protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal;

the expenses that we might incur and the delays that we might suffer if our competitors protest or challenge contract awards made to us pursuant to competitive bidding and the risk that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in termination, reduction or modification of the awarded contract; and

the risk that review of our proposal or award of a contract or an option to an existing contract could be significantly delayed for reasons including, but not limited to, the need for us to resubmit our proposal or limitations on available funds due to government budget cuts.

The U.S. government may choose to award future contracts for the supply of medical radiation countermeasures to our competitors instead of to us. If we are unable to win particular contracts, or if the government chooses not to fully exercise all options under contracts awarded to us, we may not be able to operate in the market for products that are provided under those contracts for a number of years. If we are unable to consistently win new contract awards, or if we fail to anticipate all of the costs and resources that will be required to secure such contract awards, our growth strategy and our business, financial condition and operating results could be materially adversely affected.

Additionally, government authorities have a high degree of discretion in Russia and have at times exercised their discretion selectively or arbitrarily, without hearing or prior notice, and sometimes in a manner that is perceived to be influenced, or may be influenced, by political or commercial considerations. The government also has the power, in certain circumstances, to interfere with the performance of, nullify or terminate contracts. Selective or arbitrary actions have included withdrawal of licenses, sudden and unexpected tax audits, criminal prosecutions and civil actions. Federal and local government entities have also used common defects in documentation as pretexts for court claims and other demands to invalidate and/or to void transactions, apparently for political purposes. We cannot assure you that regulators, judicial authorities or third parties will not challenge our compliance with applicable laws, decrees and regulations in Russia. Selective or arbitrary government action could have a material adverse effect on our business and on the value of our common stock.

The market for U.S. and other government funding is highly competitive.

We have submitted or plan to submit applications for funding of various research studies of our product candidates to the U.S. and other governments. There is no guarantee that any proposals that we have or plan to submit will be funded even if we receive positive reviews of such proposals as funding by the government is highly competitive and limited to the availability of funds. Failure to receive funding from U.S. and other government sources for the development of our product candidates could impair our ability to fund the development programs for our product candidates and thus could result in delays in development, or even stopping of development, of certain indications for our product candidates.

Notably, our biodefense product candidate, entolimod, faces significant competition for U.S. government funding for both development and procurement of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. In addition, we may not be able to compete effectively if entolimod does not satisfy procurement requirements of the U.S. government with respect to biodefense products. Our opportunities to succeed in the biodefense industry could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than any products that we may develop.

U.S. government agencies have special contracting requirements, which create additional risks.

We have historically entered into contracts with various U.S. government agencies. Due to these contracts with government agencies, we are subject to various federal contract requirements. Future sales to U.S. government agencies will depend, in part, on our ability to meet these requirements, certain of which we may not be able to satisfy.

U.S. government contracts typically contain unfavorable termination provisions and are subject to audit by the government at its sole discretion even after the end of the period of performance under the contract, which subjects us to additional risks. These risks include the ability of the U.S. government to unilaterally:

- suspend or prevent us for a set period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations;
- terminate our existing contracts;
- reduce the scope and value of our existing contracts;
- audit and object to our contract-related costs and fees, including allocated indirect costs;
- control and potentially prohibit the export of our products; and
- change certain terms and conditions in our contracts.

Pursuant to our government contracts, we are generally permitted to retain title to any patentable invention or discovery made while performing the contract. However, the U.S. government is generally entitled to receive a non-exclusive, non-transferable, irrevocable, paid-up license to the subject inventions throughout the world. In addition, our government contracts generally provide that the U.S. government retains unlimited rights in the technical data produced under such government contract.

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***Our business could be adversely affected by a negative audit by the U.S. government.**

As a U.S. government contractor, we may become subject to periodic audits and reviews by U.S. government agencies such as the Defense Contract Audit Agency, or the DCAA. These agencies review a contractor s performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. The DCAA also reviews the adequacy of, and a contractor s compliance with, its internal control systems and policies, including the contractor s accounting, purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, which such costs already reimbursed must be refunded.

Based on the results of these audits, the U.S. government may adjust our contract-related costs and fees, which have already been paid to us, including allocated indirect costs. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. In addition, under U.S. government purchasing regulations, some of our costs, including most financing costs, amortization of intangible assets, portions of our R&D costs and some marketing expenses, may not be reimbursable or allowed under our contracts. Further, as a U.S. government contractor, we may become subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities to which purely private sector companies are not.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

We rely upon licensed patents to protect our technology. We may be unable to obtain or protect such intellectual property rights and we may be liable for infringing upon the intellectual property rights of others.

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies and the proprietary technology of others with which we have entered into licensing agreements. We have entered into five separate exclusive license agreements to license our product candidates that are not owned by us and some product candidates are covered by up to three separate license agreements. Pursuant to these license agreements we maintain patents and patent applications covering our product candidates. We do not know whether any of these patent applications that are still in the approval process will ultimately result in the issuance of a patent with respect to the technology owned by us or licensed to us. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the United States Patent and Trademark Office use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others.

Our technology may be found in the future to infringe upon the rights of others or be infringed upon by others. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties patent rights. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief, which could effectively block our ability to further develop, commercialize and sell products. In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our products so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon

our technology and the technology exclusively licensed by us or developed with our collaborative partners. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

Moreover, the cost to us of any litigation or other proceeding relating to our patents and other intellectual property rights, even if resolved in our favor, could be substantial and the litigation would divert our management s efforts and our resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If we fail to comply with our obligations under our license agreement with third parties, we could lose our ability to develop our product candidates.

The manufacture and sale of any products developed by us may involve the use of processes, products or information, the rights to certain of which are owned by others. Although we have obtained exclusive licenses for our product candidates from The Cleveland Clinic and RPCI with regard to the use of patent applications as described above and certain processes, products and information of others, these licenses could be terminated or expire during critical periods and we may not be able to obtain licenses for other rights

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that may be important to us, or, if obtained, such licenses may not be obtained on commercially reasonable terms. Furthermore, some of our product candidates require the use of technology licensed from multiple third parties, each of which is necessary for the development of such product candidates. If we are unable to maintain and/or obtain licenses, we may have to develop alternatives to avoid infringing upon the patents of others, potentially causing increased costs and delays in product development and introduction or precluding the development, manufacture, or sale of planned products. Additionally, the patents underlying any licenses may not be valid and enforceable. To the extent any products developed by us are based on licensed technology, royalty payments on the licenses will reduce our gross profit from such product sales and may render the sales of such products uneconomical.

Our current exclusive licenses impose various development, royalty, diligence, record keeping, insurance, solvency and other obligations on us. If we breach any of these obligations and do not cure such breaches within the relevant cure period, the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology.

In addition, while we cannot currently determine the dollar amount of the royalty and other payments we will be required to make in the future under the license agreements, if any, the amounts may be significant. The dollar amount of our future payment obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any.

If we are not able to protect and control our unpatented trade secrets, know-how and other technology, we may suffer competitive harm.

We also rely on a combination of trade secrets, know-how, technology and nondisclosure and other contractual agreements and technical measures to protect our rights in the technology. However, trade secrets are difficult to protect and we rely on third parties to develop our products and thus must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements will typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. If any trade secret, know-how or other technology not protected by a patent or intellectual property right were disclosed to, or independently developed by, a competitor, our business, financial condition and results of operations could be materially adversely affected.

RISKS RELATING TO OUR INDUSTRY AND OTHER EXTERNAL FACTORS

The biopharmaceutical market in which we compete is highly competitive.

The biopharmaceutical industry is characterized by rapid and significant technological change. Our success will depend on our ability to develop and apply our technologies in the design and development of our product candidates and to establish and maintain a market for our product candidates. In addition, there are many companies, both public and private, including major pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions engaged in developing pharmaceutical and biotechnology products. Many of these

companies have substantially greater financial, technical, research and development resources and human resources than us. Competitors may develop products or other technologies that are more effective than those that are being developed by us or may obtain FDA or other governmental approvals for products more rapidly than us. If we commence commercial sales of products, we still must compete in the manufacturing and marketing of such products, areas in which we have no experience.

Our growth could be limited if we are unable to attract and retain key personnel and consultants.

We have limited experience in filing and prosecuting regulatory applications to obtain marketing approval from the FDA or other regulatory authorities. The loss of services of one or more of our key employees or consultants could have a negative impact on our business or our ability to expand our research, development and clinical programs. We depend on our scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. In addition, to the extent that we are unable to engage certain collaborators or advisors for certain periods of time due to lack of relevant work or lack of available funds, there is a risk that such collaborators or advisors will not be available to provide services in the future at such time when there is available work and/or funds. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial and marketing personnel, particularly as we expand our activities in clinical trials, the regulatory approval process, external partner solicitations and sales and manufacturing. We routinely enter into consulting agreements with our scientific and clinical collaborators and advisors, opinion leaders and heads of academic departments in the ordinary course of our business. We also enter into contractual agreements with physicians and institutions who recruit patients into our clinical trials

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on our behalf in the ordinary course of our business. In addition, as a result of our 2013 corporate restructuring and workforce reductions, we may face additional challenges in retaining our existing senior management and key employees and recruiting new employees to join our company as our business needs change. We face significant competition for this type of personnel and for employees from other companies, research and academic institutions, government entities and other organizations. We cannot predict our success in hiring or retaining the personnel we require for continued growth.

We may be subject to damages resulting from claims that we, our employees or our consultants have wrongfully used or disclosed alleged trade secrets of their former employers.

We engage as employees and consultants individuals who were previously employed at other biotechnology or pharmaceutical companies, including at competitors or potential competitors. Although no claims against us are currently pending, we may become subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and distract management.

We may incur substantial liabilities from any product liability and other claims if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if the product candidates are sold commercially. An individual may bring a product liability claim against us if one of the product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

decreased demand for our product candidates;

injury to our reputation;

withdrawal of clinical trial participants;

costs of related litigation;

diversion of our management s time and attention;

substantial monetary awards to patients or other claimants;

loss of revenues;

the inability to commercialize product candidates; and

increased difficulty in raising required additional funds in the private and public capital markets.

We currently have product liability insurance and intend to expand such coverage from coverage for clinical trials to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage that will be adequate to satisfy any liability that may arise.

From time to time, we may also become subject to litigation, such as stockholder derivative claims or securities fraud claims, which could involve our directors and officers as defendants. We currently have director and officer, or D&O, insurance to cover such risk exposure for our directors and officers. Our bylaws require us to indemnify our current and past directors and officers from reasonable expenses related to the defense of any action arising from their service to us. Our certificate of incorporation and by-laws include provisions to indemnify the directors and officers to the fullest extent permitted by the Delaware General Corporation Law, including circumstances under which indemnification is otherwise discretionary. If our D&O insurance were insufficient to cover all such expenses for all directors and officers, we would be obligated to cover any shortfall, which may be substantial. Such expenditure could have a material adverse effect on our results of operation, financial condition and liquidity. Further, if D&O insurance becomes prohibitively expensive to maintain in the future, we may be unable to renew such insurance on economic terms or unable renew such insurance at all. The lack of D&O insurance may make it difficult for us to retain and attract talented and skilled directors and officers to serve our company, which could adversely affect our business.

Our former laboratories used certain chemical and biological agents and compounds that may be deemed hazardous and we are subject to various safety and environmental laws and regulations. Our compliance with these laws and regulations may result in significant costs, which could materially reduce our ability to become profitable.

Until late 2013, we operated laboratories that used hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment and we currently sublease these laboratories for operation by other companies. As appropriate, we stored these materials and wastes resulting from their use at our laboratory facility pending their ultimate use or disposal and we currently require that our laboratory sub-lessors do the same. We contracted with a third party to properly dispose of these materials and wastes and our laboratory sub-lessors now manage such contracts. We were and continue to be subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. We may incur significant costs if we unknowingly failed to comply with environmental laws and regulations.

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We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

Political or social factors may delay or impair our ability to market our products.

Entolimod is being developed to treat ARS, which is a disease that may be caused by terrorist acts. The political and social responses to terrorism have been highly charged and unpredictable. Political or social pressures may delay or cause resistance to bringing our products to market or limit pricing of our products, which would harm our business. Changes to favorable laws, such as the Project BioShield Act, could have a material adverse effect on our ability to generate revenue and could require us to reduce the scope of or discontinue our operations.

We hope to receive funding from U.S. or foreign government agencies for the development of entolimod and our products. Changes in government budgets and agendas, however, have previously resulted in termination of our contract negotiations and may, in the future, result in future funding being decreased and de-prioritized. In addition, government contracts contain provisions that permit cancellation in the event that funds are unavailable to the government agency. Furthermore, we cannot be certain of the timing of any future funding and substantial delays or cancellations of funding could result from protests or challenges from third parties. If the U.S. government fails to continue to adequately fund R&D programs, we may be unable to generate sufficient revenues to continue development of entolimod or continue our other operations. Similarly, if our pre-EUA submission for entolimod is authorized by the FDA, but the U.S. government does not place sufficient orders for this product, our future business may be harmed.

Failure to comply with the United States Foreign Corrupt Practices Act and similar foreign laws could subject us to penalties and other adverse consequences.

We are required to comply with the United States Foreign Corrupt Practices Act, or FCPA, which prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business. Foreign companies, including some that may compete with us, are not subject to these prohibitions. Furthermore, foreign jurisdictions in which we operate may have laws that are similar to the FCPA to which we are or may become subject. This may place us at a significant competitive disadvantage. Corruption, extortion, bribery, pay-offs, theft and other fraudulent practices may occur from time to time in the foreign markets where we conduct business. Although we inform our personnel that such practices are illegal, we can make no assurance that our employees or other agents will not engage in illegal conduct for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA and similar foreign anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, such anti-bribery laws present particular challenges in the biotech or pharmaceutical industry, because, in many countries, hospitals are operated by the government and doctors and other hospital employees may be considered foreign officials.

RISKS RELATED TO CONDUCTING BUSINESS IN THE RUSSIAN FEDERATION

***Political, economic and governmental instability in Russia could materially adversely affect our operations and financial results.**

Political, ethnic, religious, historical and other differences have, on occasion, given rise to tensions within certain regions of Russia. Further, political and economic relations between Russia and the United States, two of the jurisdictions in which we operate, are complex. The current situation in Ukraine and Crimea along with the response of the governments of Russia, the United States, member states of the European Union, the European Union itself and other nations to this situation, have the potential to materially adversely affect our operations in Russia. In connection with the current situation in Ukraine, the United

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States, the European Union and certain other states have imposed a broad raft of sanctions against Russian and Crimean officials, Russian businesses and certain businessmen, including sectorial sanctions applicable to businesses operating in certain sectors of the economy, including energy and finance. Russia has responded with certain countermeasures, including limiting the import of certain goods from the United States and other countries. While we do not anticipate that the current sanctions will materially affect our business directly, if further sanctions are ordered by the European Union, the United States or other international interests, such sanctions may materially adversely affect our operations in Russia.

In addition to geopolitical events, other factors, including the steady fall in oil prices, the global strengthening of the U.S. dollar and the Russian Central Bank s reduction of currency rate support, have negatively affected the value of the Russian ruble relative to the U.S. dollar. Fluctuations in the rates at which the U.S. dollar are exchanged into Russian rubles may result in both foreign currency transaction and translation losses. We are subject to exchange rate fluctuations if we or one of our subsidiaries exchanges one currency into another, in order to conduct cross-border operations, and as we translate ruble denominated assets and liabilities that fluctuate from period-to-period. The former results in a transaction gain/loss that is reflected in our operating results. The later results in a translation gain/loss reflected in other comprehensive income/loss in equity. Presently, BioLab 612 and Panacela conduct most of their activities in the Russian Federation. As such we expect most of the foreign currency fluctuations to be related to ruble denominated asset and liability translations.

Even before the current events mentioned above, and since the early 1990s, Russia has sought to transform from a one-party state with a centrally planned economy to a democracy with a market economy. As a result of the sweeping nature of various reforms and the failure of some of them, the political system of Russia remains vulnerable to popular dissatisfaction, including demands for autonomy from particular regional and ethnic groups. Current and future changes in the Russian government, major policy shifts or lack of consensus between various branches of the government and powerful economic groups could disrupt or reverse economic and regulatory reforms. Furthermore, the Russian economy is vulnerable to market downturns and economic slowdowns elsewhere in the world, and has experienced periods of considerable instability. Although the Russian economy showed positive trends until 2008, including annual increases in the gross domestic product, a relatively stable currency, strong domestic demand, rising real wages and a reduced rate of inflation, these trends were interrupted by the global financial crisis in late 2008, in which Russia experienced adverse economic and financial effects including a substantial decrease in the growth rate of gross domestic product, depreciation of local currency and a decline in domestic and international demand for its products and services. Economic instability in Russia could materially adversely affect our business, financial condition and results of operations.

***Emerging markets, such as Russia, are subject to greater risks than more developed markets and financial turmoil in Russia could disrupt our business.**

Investors in emerging markets, such as Russia, should be aware that these markets are subject to greater risks than more developed markets, including significant economic risks. For example, the Russian economy has periodically experienced high rates of inflation and is experiencing increased rates of inflation at present. According to The World Bank, the annual inflation rate in Russia, as measured by the consumer price index, was 5.1% in 2012, 6.8% in 2013 and 7.8% in 2014. Periods of higher inflation may slow economic growth. Inflation also is likely to increase some of our costs and expenses including the costs for our subsidiaries and joint ventures to conduct business operations, including any outsourced product testing costs.

Prospective investors in our common stock should note that emerging markets are subject to rapid change and that the information set out in our filings with the SEC about our operations in Russia may become outdated relatively quickly.

Our subsidiary/joint venture research operations are conducted primarily in Russia, making them subject to political uncertainties relating to Russia and U.S.-Russian relations.

The majority of our subsidiary s and joint ventures research activities are in Russia. Given the unprecedented level of hostility between the United States and Russia since the dissolution of the Soviet Union, our operations may be negatively and materially impacted by escalation of measures and counter-measures taken by the United States against Russia and Russia against the United States and their respective citizens and persons organized under their laws, including the adoption of measures that could require us to reduce, suspend or terminate our operations in Russia. For example, the organizations funding our activities in Russia are highly regulated and, in many instances, are controlled by the Russian government so our funding could be delayed, reduced or even terminated under expanded sanction regimes.

***The legal system in Russia can create an uncertain environment for business activity, which could materially adversely affect our business and operations in Russia.**

The legal framework to support a market economy remains new and in flux in Russia and, as a result, its legal system can be characterized by: inconsistencies between and among laws and governmental, ministerial and local regulations, orders, decisions, resolutions and other acts; gaps in the regulatory structure resulting from the delay in adoption or absence of implementing regulations; selective enforcement of laws or regulations, sometimes in ways that have been perceived as being motivated by political

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or financial considerations; limited judicial and administrative guidance on interpreting legislation; relatively limited experience of judges and courts in interpreting recent commercial legislation; a perceived lack of judicial and prosecutorial independence from political, social and commercial forces; inadequate court system resources; a high degree of discretion on the part of the judiciary and governmental authorities; and underdeveloped bankruptcy procedures that are subject to abuse.

In addition, as is true of civil law systems generally, judicial precedents generally have no binding effect on subsequent decisions. Not all legislation and court decisions in Russia are readily available to the public or organized in a manner that facilitates understanding. Enforcement of court orders can in practice be very difficult. All of these factors make judicial decisions difficult to predict and effective redress uncertain. Additionally, court claims and governmental prosecutions may be used in furtherance of what some perceive to be political or commercial aims.

Effective August 6, 2014, the Supreme State Commercial (Arbitrazh) Court was merged into the Russian Supreme Court and now exits as a sub-division of the Russian Supreme Court, known as the Judicial Collegium for Economic Disputes of the Supreme Court. A draft law on full merger of the commercial courts and courts of general jurisdiction reportedly is being prepared; however, there is no current information regarding this draft law available. In addition, there have been no negative consequences of this merger process on the expeditious resolution of commercial disputes and stability of the prior decisions of the Supreme State Commercial (Arbitrazh) Court.

The untested nature of much of recent legislation in Russia and the rapid evolution of its legal system may result in ambiguities, inconsistencies and anomalies in the application and interpretation of laws and regulations. Any of these factors may affect our ability to enforce our rights under our contracts or to defend ourselves against claims by others, or result in our being subject to unpredictable requirements. These uncertainties also extend to property rights and the expropriation or nationalization of any of our entities, their assets or portions thereof, potentially without adequate compensation, could materially adversely affect our business, financial condition and results of operations.

***Changes in the tax system in Russia or the arbitrary or unforeseen application of existing rules could materially adversely affect our financial condition and results of operations.**

There have been significant changes to the taxation system in Russia in recent years as the authorities have gradually replaced legislation regulating the application of major taxes such as corporate income tax, value added tax, corporate property tax and other taxes with new legislation. Effective January 1, 2015, the Russian tax law was amended as part of the government s deoffshorization policy to, among other things, introduce a concept analogous to that of controlled foreign corporations found in other jurisdictions.

Tax authorities in Russia have also been aggressive in their interpretation of tax laws and their many ambiguities, as well as in their enforcement and collection activities. Technical violations of contradictory laws and regulations, many of which are relatively new and have not been subject to extensive application or interpretation, can lead to penalties. High-profile companies, particularly those operating in strategically sensitive sectors, can be perceived to be particularly vulnerable to aggressive application of unclear requirements. Many companies must negotiate their tax bills with tax inspectors who may demand higher taxes than applicable law appears to provide. Our Russian subsidiary s and joint ventures tax liabilities may become greater than the estimated amount that they have expensed to date and paid or accrued on the balance sheets, particularly if the tax benefits currently received in Russia are changed or removed. Any additional tax liability, as well as any unforeseen changes in tax laws, could materially adversely affect our future results of operations, financial condition or cash flows in a particular period.

In October 2006, the Supreme State Commercial (Arbitrazh) Court of Russia issued a ruling that introduced the concept of an unjustified tax benefit, which is a benefit that may be disallowed for tax purposes. Specific examples

cited by the court include benefits obtained under transactions lacking a business purpose (*i.e.*, when the only purpose of a deal or structure is to derive tax benefits). The tax authorities have actively sought to apply this concept when challenging tax positions taken by taxpayers. Although the intention of the ruling was to combat tax abuse, in practice there is no assurance that the tax authorities will not seek to apply this concept in a broader sense than may have been intended by the court. In addition, the tax authorities and the courts have indicated a willingness to interpret broadly the application of criminal responsibility for tax violations.

The tax system in Russia imposes additional burdens and costs on our operations there and complicate our tax planning and related business decisions. For example, the tax environment in Russia has historically been complicated by contradictions in Russian tax law and ambiguity in areas such as the deductibility of certain expenses. This uncertainty could result in a greater than expected tax burden and potentially exposes us to significant fines and penalties and enforcement measures, despite our best efforts at compliance. These factors raise the risk of a sudden imposition of arbitrary or onerous taxes on our operations in these countries. This could materially adversely affect our financial condition and results of operations.

Recently in an additional tax assessment case (*Oriflame Cosmetics LLC v. Moscow City Department of the Federal Tax Service*, case No. À40-138879/14) the court pierced corporate veil of the Russian limited liability company for tax reasons. The court agreed with the tax authorities that this company (albeit a separate legal entity under Russian law) is a *permanent establishment / dependent agent* of its foreign parent company and therefore the Russian LLC illegally understated its taxable base having used royalty payments which were paid by the LLC to its parent company under sub-concession agreement (which is quite a widespread scheme). As a result the Russian LLC has incurred additional taxes amounting to approx. to 0.5 billion Rubles. The case is unprecedented and may impact business schemes of foreign companies having business in Russia. In particular, any transactions between foreign parent company and its Russian subsidiary should be carefully reconsidered, for example when making lease payments, purchasing materials or equipment etc. Even though the resolution on the case was issued on June 11, 2015 by State Commercial Court of the Moscow Region, it should not be considered as binding for other courts. The resolution is currently being contested in the Supreme Court of the Russian Federation.

Selective or arbitrary government action may have an adverse effect on our business and the value of our common stock.

Government authorities have a high degree of discretion in Russia and have at times exercised their discretion selectively or arbitrarily, without hearing or prior notice, and sometimes in a manner that is perceived to be influenced, or may be influenced, by

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political or commercial considerations. The government also has the power, in certain circumstances, to interfere with the performance of, nullify or terminate contracts. Selective or arbitrary actions have included withdrawal of licenses, sudden and unexpected tax audits, criminal prosecutions and civil actions. Federal and local government entities have also used common defects in documentation as pretexts for court claims and other demands to invalidate and/or to void transactions, apparently for political purposes. We cannot assure you that regulators, judicial authorities or third parties will not challenge our compliance with applicable laws, decrees and regulations in Russia. Selective or arbitrary government action could have a material adverse effect on our business and on the value of our common stock.

***Shareholder liability under Russian legislation could cause us to become liable for the obligations of our subsidiaries and joint ventures.**

The Russian Civil Code and the Law on Limited Liability Companies generally provide that shareholders in a Russian limited liability company are not liable for the obligations of the company and bear only the risk of loss of their investment. This may not be the case, however, when one person, an effective parent, is capable of determining decisions made by another, an effective subsidiary. The effective parent bears joint and several responsibilities for transactions concluded by the effective subsidiary in carrying out these decisions in certain circumstances (i.e. transactions were made in fulfillment of mandatory instructions of parent company). However, the courts have developed a strict test for and generally are reluctant to hold parent companies liable. According to the court practice in most cases, claimants were unable to prove elements necessary to establish liability, e.g. to prove the right of the parent company (respondent) to give mandatory instructions to subsidiary or the fact that a particular transaction was made upon parent company s instruction.

Since September 1, 2014 the law was supplemented with a provision which allows holding a parent company liable for transactions of its subsidiary if such transactions were done upon consent (in addition to instructions) of the parent company. This rule is applicable to transactions made after September 1, 2014. However, it was further clarified in July 2015 that no liability will arise (1) if the parent company voted for such transaction in a general meeting of shareholders of the subsidiary or (2) if the parent s corporate body approved such transaction in the case that such approval procedure was stipulated in constitutional documents of the parent or the subsidiary company.

In addition, a parent may be secondarily liable for an effective subsidiary s debts if an effective subsidiary becomes insolvent or bankrupt as a result of the action or inaction of the parent. It is assumed that the subsidiary has become insolvent (bankrupt) as a result of the action or inaction of the parent, if one of the following circumstances is established by the court:

- One or several transactions of the subsidiary executed with the parent or in favor of the parent and/or approved by the parent violate the creditors rights; or

- Undue bookkeeping makes it substantially difficult to perform bankruptcy procedures (formation and sale of bankruptcy assets).

The latter is relevant only if the parent is in charge for bookkeeping for the subsidiary.

Accordingly, in CBLI s position as a parent, there is a risk that it could be held liable in certain limited circumstances for the debts of its effective subsidiaries consequently, it is possible that CBLI could face material liability in this regard in the future, which could materially adversely affect our business and our results of operations.

***Russia may depart from its international obligations in exceptional circumstances**

In July 2015 the Constitutional Court of the Russian Federation issued a resolution which introduced a mechanism for the Russian state bodies to avoid enforcement of decisions of the European Court of Human Rights (ECHR) in case such enforcement would contradict the Constitution of the Russian Federation.

Namely, if a Russian court or other governmental body comes to a conclusion that a resolution of ECHR, which is to be enforced by the Russian court / governmental body, is grounded on such interpretation of norms of the European Convention on Human Rights which leads to contradiction with the Constitution of the Russian Federation such court/body must apply to the Constitutional Court which will finally determine whether enforcement is permissible or not.

The resolution creates a risk for businesses and person who might seek legal recourse from the ECHR after failing to receive remedy in all Russian instances, albeit Russia signed and ratified the European Convention of Human Rights.

In addition, there is a risk that such interpretation could be extended to other obligations of the Russian Federation in the area of international law. Thus, one might face difficulties enforcing Russian awards obtained from other intergovernmental institutions or tribunals if Russian state authorities consider that an award is grounded on interpretation of international treaties in a way which is contrary to the norms of the Constitution of the Russian Federation.

***Our Russian subsidiary/joint ventures can be forced into liquidation on the basis of formal noncompliance with certain legal requirements.**

BioLab 612 and Panacela Labs, LLC, the wholly-owned Russian subsidiary of Panacela, were organized under the laws of the Russian Federation. Certain provisions of Russian law may allow a court to order the liquidation of a locally organized legal entity on the basis of its formal noncompliance with certain requirements during formation, reorganization or during its operations. Additionally, Russian corporate law allows the government to liquidate a company if its net assets fall below a certain threshold. Similarly, there have also been cases in Russia in which formal deficiencies in the establishment process of a legal entity or noncompliance with provisions of law have been used by courts as a basis for liquidation of a legal entity. Weaknesses in the legal systems of Russia create an uncertain legal environment, which makes the decisions of a court or a governmental authority difficult, if not impossible, to predict. If involuntary liquidation of either of the aforementioned entities were to occur, such liquidation could materially adversely affect our financial condition and results of operations.

Crime and corruption could disrupt our ability to conduct our business.

Political and economic changes in Russia in recent years have resulted in significant dislocations of authority. The local and international press has reported the existence of significant organized criminal activity, particularly in large metropolitan centers. In addition, the local and international press has reported high levels of corruption, including the bribing of officials for the purpose of initiating investigations by government agencies. Press reports have also described instances in which state officials have engaged in selective investigations and prosecutions to further the interests of the state and individual officials, as well as private businesses, including competitors and corporate raiders. Corruption in Russia is perceived to be pervasive and, in some cases, is worsening. The government in Russia has recently pursued a campaign against corruption. However, there is no assurance that such laws or other laws enacted elsewhere will be applied with any effectiveness by the local authorities and the continuing effects of corruption, money laundering and other criminal activity could have a negative effect on the Russian economy and could materially adversely affect our business in Russia.

RISKS RELATING TO OUR SECURITIES

***Our principal stockholder has the ability to control our business, which may be disadvantageous to other stockholders.**

As of the date of this filing, David Davidovich, a venture capital investor, or the Purchaser, beneficially owns or controls approximately 60.2% of the voting power of our outstanding common stock. As a result of his ability to control a majority of the voting power of our outstanding common stock, the Purchaser has the ability to control all matters requiring approval by our stockholders, including the election and removal of directors, amendments to our certificate of incorporation and bylaws, any proposed merger, consolidation or sale of all or substantially all of our assets and other corporate transactions. The Purchaser may have interests that are different from those of other stockholders. Moreover, this concentration of share ownership makes it impossible

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for other stockholders to replace directors and management without the consent of the Purchaser. In addition, this significant concentration of share ownership may adversely affect the price at which prospective buyers are willing to pay for our common stock because investors may perceive disadvantages in owning stock in companies with controlling stockholders.

***We are a controlled company within the meaning of the NASDAQ rules and, as a result, qualify for exemptions from certain corporate governance requirements. If we rely on these exemptions in the future, you will not have the same protections afforded to stockholders of companies that are subject to such requirements.**

Because the Purchaser holds common stock that represents a majority of the voting power of our outstanding common stock, we may be considered a controlled company within the meaning of the NASDAQ corporate governance standards. Under these rules, a company of which more than 50% of the voting power is held by an individual, group or another company is a controlled company and may elect not to comply with certain corporate governance requirements, including the requirements that:

- a majority of the board of directors consists of independent directors;
- we have a nominating and corporate governance committee that is composed entirely of independent directors; and
- we have a compensation committee that is composed entirely of independent directors.

We are not currently utilizing these exemptions. However, we may use these exemptions in the future, and as a result, we could choose not to have a majority of independent directors on our board of directors, or any of our board committees. If that were the case, you would not have the same protections afforded to stockholders of companies that are subject to all of the NASDAQ corporate governance requirements.

There is uncertainty regarding the application of the federal and state securities laws to our February 2015 offering of common stock and warrants, and there is a corresponding risk that we could be required to refund the purchase price of securities offered to purchasers who so elect.

We conducted an offering under a registration statement filed with the Securities and Exchange Commission and a concurrent private placement intended to comply with the requirements of Section 4(a)(2) under the Securities Act of 1933, as amended, and Rule 506(b) promulgated thereunder. Shares of common stock and warrants were offered and sold in combination. The shares of common stock and Series B pre-funded warrants were intended to be offered and sold in a transaction registered under the Securities Act, while the other warrants and shares of common stock issuable thereunder were intended to be offered and sold in a private placement exempt from the registration requirements of the Securities Act.

While we are aware of other transactions using a concurrent public/private offering approach, the SEC has not addressed whether concurrent public and private offerings and sales to the same prospective investors would adversely impact the public offering or preclude the private offering from satisfying the requirements of Rule 506(b). If the securities offered in our concurrent private placement do not satisfy the conditions of Rule 506(b), the offering would be a violation of Section 5 of the Securities Act and each purchaser would have the right to rescind its purchase of the securities, meaning that we would be required to refund the purchase price of the securities to each purchaser electing

rescission. If that were to occur, we would face severe financial demands and reputational harm that could adversely affect our business and operations. Additionally, if we did not in fact qualify for the exemptions upon which it has relied, we may become subject to significant fines and penalties imposed by SEC. It is also possible that additional remedies may be available to purchasers under applicable state law.

Significant stockholders or potential stockholders may attempt to effect changes to our company, which could adversely affect our corporate governance, results of operations and financial condition.

Stockholders may from time to time attempt to effect changes, engage in proxy solicitations or advance stockholder proposals. Responding to proxy contests and other actions by activist stockholders can generally be costly and time-consuming, disrupting our operations and diverting the attention of our board of directors and senior management from the pursuit of business strategies. Additionally, stockholder campaigns could result in corporate governance changes that could adversely affect our results of operations and financial condition.

***The price of our common stock has been and could remain volatile, which may in turn expose us to securities litigation.**

The market price of our common stock has historically experienced and may continue to experience significant volatility. From January 1, 2014 through June 30, 2015, the market price of our common stock, which is listed on the NASDAQ Capital Market, fluctuated from a high of $25.40 per share in the first quarter of 2014 to a low of $1.84 in the second quarter of 2015. The listing of our common stock on the NASDAQ Capital Market does not assure that a meaningful, consistent and liquid trading market will exist, and in recent years, the market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility in addition to volatility caused by the occurrence of industry and company specific events. Factors that could cause fluctuations include, but are not limited to, the following:

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our progress in developing and commercializing our products;

price and volume fluctuations in the overall stock market from time to time;

fluctuations in stock market prices and trading volumes of similar companies;

actual or anticipated changes in our earnings or fluctuations in our operating results or in the expectations of securities analysts;

general economic conditions and trends;

major catastrophic events;

sales of large blocks of our stock;

departures of key personnel;

changes in the regulatory status of our product candidates, including results of our pre-clinical studies and clinical trials;

status of contract and funding negotiations relating to our product candidates;

events affecting our collaborators;

events affecting our competitors;

announcements of new products or technologies, commercial relationships or other events by us or our competitors;

regulatory developments in the U.S. and other countries;

failure of our common stock to be listed or quoted on the NASDAQ Capital Market, other national market system or any national stock exchange;

changes in accounting principles; and

discussion of us or our stock price by the financial and scientific press and in online investor communities.

As a result of the volatility of our stock price, we could be subject to securities litigation, which could result in substantial costs and divert management s attention and company resources from our business.

***Issuance of additional equity may adversely affect the market price of our stock.**

We are currently authorized to issue 160,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of this filing, 10,729,123 shares of our common stock were issued and outstanding warrants to purchase 2,227,232 shares of our common stock at an average exercise price of $13.95 per share (exclusive of the Rusnano warrant described above as it was not exercisable at the time), and we had outstanding options to purchase 365,784 shares of our common stock at an average exercise price of $48.89 per share. To the extent we issue shares of common stock or our outstanding options and warrants are exercised, holders of our common stock will experience dilution.

On April 10, 2015, we filed a registration statement on Form S-1, or the April Form S-1, with the Securities and Exchange Commission for the sale of $10 million of common stock and warrants and Class B convertible preferred stock and warrants at terms to be negotiated. Presently, we have not taken further action regarding the April Form S-1 but may utilize the April S-1 to raise funds in the future. At this time we cannot confirm the total amount, timing, or terms of an equity raise, if any.

In the event of any other future issuances of equity securities or securities convertible into or exchangeable for, common stock, holders of our common stock may experience dilution. Furthermore, certain of our outstanding warrants, pre-funded warrants and convertible preferred stock contain provisions that, in certain circumstances, could result in the number of shares of common stock issuable upon the exercise of such securities to increase and/or the exercise price of such warrants to decrease.

Moreover, our board of directors is authorized to issue preferred stock without any action on the part of our stockholders. Our board of directors also has the power, without stockholder approval, to set the terms of any such preferred stock that may be issued, including voting rights, conversion rights, dividend rights, preferences over our common stock with respect to dividends or if we liquidate, dissolve or wind up our business and other terms. For example, on February 6, 2015, we issued 717.4 shares of Series A Convertible Preferred Stock convertible into 239,134 shares of our common stock at a conversion price of $3.00 per share. As of the date of this filing, the Series A Preferred Stock issued in the transaction are no longer outstanding. If we issue additional shares of preferred stock in the future, such as those contemplated by the April Form S-1, that have preference over our common stock with respect to the payment of dividends or upon our liquidation, dissolution or winding up, or if we issue preferred stock with voting rights that dilute the voting power of our common stock, the market price of our common stock could decrease. Additionally, the conversion of any preferred stock issued in the future into our common stock could result in significant dilution to the holders of our common stock.

We also consider from time to time various strategic alternatives that could involve issuances of additional shares of common stock or shares of preferred stock, including but not limited to acquisitions and business combinations.

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these reports and we currently do not have any industry analysts covering us. In

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the event we do regain analyst coverage, there can be no assurance that analysts will provide favorable coverage. Our stock price may be adversely impacted by our current lack of analyst coverage as we may have less visibility in the financial markets than other companies in our industry, which may cause declined trading volume and stock price.

We have no plans to pay dividends on our common stock and investors may not receive funds without selling their common stock.

We have not declared or paid any cash dividends on our common stock, nor do we expect to pay any cash dividends on our common stock for the foreseeable future. We currently intend to retain any additional future earnings to finance our operations and growth and, therefore, we have no plans to pay cash dividends on our common stock at this time. Any future determination to pay cash dividends on our common stock will be at the discretion of our board of directors and will be dependent on our earnings, financial condition, operating results, capital requirements, any contractual restrictions, regulatory and other restrictions on the payment of dividends by our subsidiaries to us and other factors that our board of directors deems relevant.

Accordingly, investors may have to sell some or all of their common stock in order to generate cash from your investment. Investors may not receive a gain on their investment when they sell our common stock and may lose the entire amount of their investment.

Provisions in our charter documents and Delaware law may inhibit a takeover or impact operational control of our company, which could adversely affect the value of our common stock.

Our certificate of incorporation and bylaws, as well as Delaware corporate law, contain provisions that could delay or prevent a change of control or changes in our management that a stockholder might consider favorable. These provisions include, among others, prohibiting stockholder action by written consent, advance notice for raising business or making nominations at meetings of stockholders and the issuance of preferred stock with rights that may be senior to those of our common stock without stockholder approval. These provisions would apply even if a takeover offer may be considered beneficial by some of our stockholders. If a change of control or change in management is delayed or prevented, the market price of our common stock could decline.

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

On July 9, 2015, we closed a private placement transaction with David Davidovich, a venture capital investor, pursuant to which we issued and sold to Mr. Davidovich an aggregate of 6,459,948 shares of our common stock, par value $0.005 per share, for an aggregate purchase price of approximately $25 million, or $3.87 per share, which we refer to as the Private Placement. We relied on the private placement exemption from registration provided by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D, promulgated by the Securities and Exchange Commission, and in reliance on similar exemptions under applicable state laws. On November 4, 2014, we entered into a letter agreement, as later amended, with Ladenburg Thalmann & Co. Inc., a subsidiary of Ladenburg Thalmann Financial Services Inc., or Ladenburg, which we refer to as the Placement Agency Agreement, pursuant to which we engaged Ladenburg to act as our exclusive book-runner in connection with the issuance and sale of our equity securities. Pursuant to the terms of the Placement Agency Agreement, we paid Ladenburg $685,000 in connection with the Private Placement. In addition, on June 3, 2015, we entered into a letter agreement, or the Fairness Opinion Advisory Agreement, with Ladenburg pursuant to which we engaged Ladenburg to render a fairness opinion with regard to the Private Placement. Pursuant to the terms of the Fairness Opinion Advisory Agreement, we paid Ladenburg a fairness opinion advisory fee of $300,000.

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	Amendment to Second Amended and Restated By-Laws of Cleveland BioLabs, Inc. (Incorporated by reference to Form 8-K filed on April 17, 2015)
10.1	First Amendment to Cleveland BioLabs, Inc. Employee Stock Purchase Plan (Incorporated by reference to Form 8-K filed on April 17, 2015)
10.2	Third Amendment to Cleveland BioLabs, Inc. Equity Incentive Plan (Incorporated by reference to Form 8-K filed on April 17, 2015)
10.3	Master Purchase Agreement dated April 29, 2015 by and among Cleveland BioLabs, Inc., Mikhail Mogutov and Incuron LLC (Incorporated by reference to Form 8-K filed on May 4, 2015)
10.4	Option Agreement dated April 29, 2015 by and between Cleveland BioLabs, Inc. and Mikhail Mogutov (Incorporated by reference to Form 8-K filed on May 4, 2015)
10.5	Royalty Agreement dated April 29, 2015 by and between Cleveland BioLabs, Inc. and Incuron LLC (Incorporated by reference to Form 8-K filed on May 4, 2015)
10.6	Fourth Amendment to Participation Agreement dated April 29, 2015 by and among Cleveland BioLabs, Inc., Bioprocess Capital Partners and Mikhail Mogutov (Incorporated by reference to Form 8-K filed on May 4, 2015)
10.7	Employment Agreement dated May 4, 2015 by and between Cleveland BioLabs, Inc. and Langdon Miller, M.D. (Incorporated by reference to Form 8-K filed on May 8, 2015)
10.8	Securities Purchase Agreement dated June 24, 2015 by and between Cleveland BioLabs, Inc. and David Davidovich (Incorporated by reference to Form 8-K filed on June 24, 2015)
31.1	Rule 13a-14(a)/15d-14(a) Certification of Yakov Kogan.
31.2	Rule 13a-14(a)/15d-14(a) Certification of C. Neil Lyons.
32.1	Certification pursuant to 18 U.S.C. Section 1350.
101.1	The following information from CBLI s Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of June 30, 2015 and December 31, 2014; (ii) Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2015 and 2014; (iii) Consolidated Statements of Comprehensive Loss for the Three and Six Months Ended June 30, 2015 and 2014; (iv) Consolidated Statements of Cash Flows for the Six Months ended June 30, 2015 and 2014; (v) Consolidated Statements of Stockholders Equity (Deficit) for the Six Months Ended June 30, 2015; and (vi) Notes to Consolidated Financial Statements.

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Signatures

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

CLEVELAND BIOLABS, INC.

Dated: August 12, 2015

By: /s/ YAKOV KOGAN
Yakov Kogan
Chief Executive Officer
(Principal Executive Officer)

Dated: August 12, 2015

By: /s/ C. NEIL LYONS
C. Neil Lyons
Chief Financial Officer
(Principal Financial Officer)