

CLEVELAND BIOLABS INC
Form 10-Q
August 09, 2011

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2011

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
(State or other jurisdiction of incorporation or organization)

20-0077155
(I.R.S. Employer Identification No.)

73 High Street, Buffalo, New York
(Address of principal executive offices)

14203
(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 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 No

Edgar Filing: CLEVELAND BIOLABS INC - Form 10-Q

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

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

As of August 5, 2011, there were 35,427,650 shares outstanding of registrant's common stock, par value \$0.005 per share.

CLEVELAND BIOLABS INC. AND SUBSIDIARY
 10-Q
 8/10/2011

TABLE OF CONTENTS

	PAGE
PART I - FINANCIAL INFORMATION	
ITEM 1:	Consolidated Financial Statements
	Consolidated Balance Sheets as of June 30, 2011 and December 31, 2010 3
	Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2011 and 2010 5
	Consolidated Statement of Stockholders' Equity from January 1, 2010 to December 31, 2010 and to June 30, 2011 6
	Consolidated Statement of Comprehensive Income/(Loss) for the Three and Six Months Ended June 30, 2011 and 2010 8
	Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2011 and 2010 9
	Consolidated Notes to Financial Statements 11
ITEM 2:	Management's Discussion and Analysis of Financial Condition and Results of Operations 17
ITEM 3:	Quantitative and Qualitative Disclosures About Market Risk 26
ITEM 4:	Controls and Procedures 26
PART II - OTHER INFORMATION	
ITEM 1:	Legal Proceedings 27
ITEM 1A:	Risk Factors 27
ITEM 2:	Unregistered Sales of Equity Securities and Use of Proceeds 28
ITEM 3:	Defaults Upon Senior Securities 28
ITEM 4:	Removed and Reserved 28
ITEM 5:	Other Information 28

ITEM 6:	Exhibits	28
	Signatures	29

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 subsidiary and the “Company,” “we,” “us” and “our” refer to Cleveland BioLabs, Inc. together with its consolidated subsidiary. Our common stock, par value \$0.005 per share, is referred to as “common stock.”

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

June 30, 2011 (unaudited) and December 31, 2010

	June 30 2011	December 31 2010
ASSETS		
CURRENT ASSETS		
Cash and equivalents	\$30,996,271	\$ 10,918,537
Short-term investments	712,357	459,364
Accounts receivable	140,409	5,382,121
Other current assets	1,209,511	991,062
Total current assets	33,058,548	17,751,084
EQUIPMENT		
Computer equipment	543,881	400,892
Lab equipment	1,579,233	1,528,066
Furniture	472,060	397,013
	2,595,174	2,325,971
Less accumulated depreciation	1,594,929	1,384,847
	1,000,245	941,124
OTHER ASSETS		
Intellectual property	1,488,908	1,162,287
Other long term assets	15,376	-
Deposits	33,697	32,108
	1,537,981	1,194,395
TOTAL ASSETS	\$35,596,774	\$ 19,886,603

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

June 30, 2011 (unaudited) and December 31, 2010

	June 30, 2011	December 31 2010
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable	\$655,180	\$1,261,493
Deferred revenue	201,556	349,111
Accrued expenses	241,121	136,163
Accrued bonuses	-	3,321,131
Accrued warrant liability	10,006,733	25,350,733
Total current liabilities	11,104,590	30,418,631
LONG TERM LIABILITIES		
Deferred revenue	2,107,236	1,968,107
Total long term liabilities	2,107,236	1,968,107
Commitments and contingencies - See Note 9		
STOCKHOLDERS' EQUITY (DEFICIT)		
Common stock, \$.005 par value		
Authorized - 80,000,000 shares at June 30, 2011 and December 31, 2010		
Issued and outstanding 35,373,096 and 28,959,176 shares at June 30, 2011 and December 31, 2010, respectively		
	176,866	144,796
Additional paid-in capital	107,298,224	80,241,717
Accumulated other comprehensive income (loss)	160,711	(30,544)
Accumulated deficit	(90,184,813)	(96,053,977)
Total Cleveland BioLabs, Inc. stockholders' equity (deficit)	17,450,988	(15,698,008)
Noncontrolling interest in stockholders' equity	4,933,960	3,197,873
Total stockholders' equity (deficit)	22,384,948	(12,500,135)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	\$35,596,774	\$19,886,603

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

Three and Six Months Ended June 30, 2011 and 2010 (unaudited)

	Three Months Ended		Six Months Ended	
	June 30	June 30	June 30	June 30
	2011	2010	2011	2010
REVENUES				
Grant and contract	\$569,049	\$4,210,763	\$3,043,031	\$8,381,111
	569,049	4,210,763	3,043,031	8,381,111
OPERATING EXPENSES				
Research and development	5,209,194	4,170,115	10,918,127	7,867,895
General and administrative	1,987,451	2,661,200	3,864,653	4,590,701
Total operating expenses	7,196,645	6,831,315	14,782,780	12,458,596
LOSS FROM OPERATIONS	(6,627,596)	(2,620,552)	(11,739,749)	(4,077,485)
OTHER (INCOME)/EXPENSE				
Interest income	(67,071)	(7,639)	(105,330)	(13,412)
Other income	(49,287)	(50,205)	(113,248)	(100,430)
Other expense	174,578	-	195,060	231,980
Change in value of warrant liability	(17,815,964)	(33,800)	(17,101,013)	1,697,296
Total other (income)/expense	(17,757,744)	(91,644)	(17,124,531)	1,815,434
NET INCOME/(LOSS)	\$11,130,148	\$(2,528,908)	\$5,384,782	\$(5,892,919)
LOSS ATTRIBUTABLE TO NONCONTROLLING INTERESTS	238,076	89,248	484,383	89,248
NET INCOME/(LOSS) ATTRIBUTABLE TO CLEVELAND BIOLABS, INC.	\$11,368,224	\$(2,439,660)	\$5,869,165	\$(5,803,671)
NET INCOME/(LOSS) AVAILABLE TO COMMON SHAREHOLDERS PER SHARE OF COMMON STOCK BASIC	\$0.38	\$(0.09)	\$0.20	\$(0.23)
NET INCOME/(LOSS) AVAILABLE TO COMMON SHAREHOLDERS PER SHARE OF COMMON STOCK DILUTED	\$0.30	\$(0.09)	\$0.16	\$(0.23)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATING NET INCOME/(LOSS) PER SHARE, BASIC	30,033,049	26,734,076	29,574,561	25,132,246
	37,588,006	26,734,076	36,685,508	25,132,246

**WEIGHTED AVERAGE NUMBER OF SHARES
USED IN CALCULATING NET INCOME/(LOSS)
PER SHARE, DILUTED**

See Notes to Consolidated Financial Statements

5

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

Period From January 1, 2010 to December 31, 2010 and to
June 30, 2011 (unaudited)

	Stockholders' Equity Common Stock		Preferred Stock	
	Shares	Amount	Series D Shares	Series D Amount
Balance at January 1, 2010	20,203,508	\$ 101,018	467	\$2
Issuance of options	-	-	-	-
Issuance of shares	461,196	2,306	-	-
Recapture of expense for nonvested options forfeited	-	-	-	-
Amortization of restricted stock awards	-	-	-	-
Exercise of options	336,674	1,683	-	-
Issuance of shares - February 2010 financing	1,538,462	7,692	-	-
Allocation of financing proceeds to fair value of warrants	-	-	-	-
Fees associated with February 2010 financing	-	-	-	-
Issuance of shares - December 2010 financing	1,400,000	7,000	-	-
Fees associated with December 2010 financing	-	-	-	-
Conversion of Series D preferred shares to common shares	4,576,979	22,885	(467)	(2)
Exercise of warrants	442,357	2,212	-	-
Warrant exercise fees	-	-	-	-
Noncontrolling interest capital contribution to Incuron, LLC	-	-	-	-
Net loss	-	-	-	-
Other comprehensive loss				
Foreign currency translation	-	-	-	-
Balance at December 31, 2010	28,959,176	\$ 144,796	-	\$-
Issuance of options	-	-	-	-
Issuance of shares	75,917	380	-	-
Recapture of expense for nonvested options forfeited	-	-	-	-
Exercise of options	184,092	920	-	-
Exercise of warrants	281,411	1,407	-	-
Warrant exercise fees	-	-	-	-
Noncontrolling interest capital contribution to Incuron, LLC	-	-	-	-
Issuance of shares - June 2011 financing	5,872,500	29,363	-	-
Allocation of financing proceeds to fair value of warrants	-	-	-	-
Fees associated with June 2011 financing	-	-	-	-
Net income/(loss)	-	-	-	-
Other comprehensive income				
Foreign currency translation	-	-	-	-
Balance at June 30, 2011	35,373,096	\$ 176,866	-	\$-

See Notes to Consolidated Financial Statements

6

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

Period From January 1, 2010 to December 31, 2010 and to
June 30, 2011 (unaudited)

	Stockholders' Equity					Total
	Additional Paid-in Capital	Accumulated Comprehensive Income (loss)	Other Accumulated Deficit	Noncontrolling Interests		
Balance at January 1, 2010	\$62,786,418	\$ -	\$(69,687,932)	\$ -	\$(6,800,494)	
Issuance of options	2,947,209	-	-	-	2,947,209	
Issuance of shares	1,716,785	-	-	-	1,719,091	
Recapture of expense for nonvested options forfeited	(39,483)	-	-	-	(39,483)	
Amortization of restricted stock awards	13,333	-	-	-	13,333	
Exercise of options	900,228	-	-	-	901,911	
Issuance of shares - February 2010 financing	4,992,310	-	-	-	5,000,002	
Allocation of financing proceeds to fair value of warrants	(2,629,847)	-	-	-	(2,629,847)	
Fees associated with February 2010 financing	(578,118)	-	-	-	(578,118)	
Issuance of shares - December 2010 financing	8,379,000	-	-	-	8,386,000	
Fees associated with December 2010 financing	(659,980)	-	-	-	(659,980)	
Conversion of Series D preferred shares to common shares	(22,883)	-	-	-	-	
Exercise of warrants	2,438,558	-	-	-	2,440,770	
Warrant exercise fees	(1,813)	-	-	-	(1,813)	
Noncontrolling interest capital contribution to Incuron, LLC	-	-	-	3,509,564	3,509,564	
Net loss	-	-	(26,366,045)	(305,812)	(26,671,857)	
Other comprehensive loss						
Foreign currency translation	-	(30,544)	-	(5,879)	(36,423)	
Balance at December 31, 2010	\$80,241,717	\$ (30,544)	\$(96,053,977)	\$ 3,197,873	\$(12,500,135)	
Issuance of options	4,678,166	-	-	-	4,678,166	
Issuance of shares	460,929	-	-	-	461,309	
Recapture of expense for nonvested options forfeited	(39,656)	-	-	-	(39,656)	
Exercise of options	521,339	-	-	-	522,259	
Exercise of warrants	1,978,261	-	-	-	1,979,668	
Warrant exercise fees	(34,448)	-	-	-	(34,448)	

Edgar Filing: CLEVELAND BIOLABS INC - Form 10-Q

Noncontrolling interest capital contribution to Incuron, LLC	176,092	-	-	2,164,282	2,340,374
Issuance of shares - June 2011 financing	23,460,637	-	-	-	23,490,000
Allocation of financing proceeds to fair value of warrants	(2,525,175)	-	-	-	(2,525,175)
Fees associated with June 2011 financing	(1,619,638)	-	-	-	(1,619,638)
Net income/(loss)	-	-	5,869,165	(484,383)	5,384,782
Other comprehensive income					
Foreign currency translation	-	191,255	-	56,188	247,443
Balance at June 30, 2011	\$107,298,224	\$ 160,711	\$(90,184,813)	\$ 4,933,960	\$22,384,948

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME/(LOSS)

Three and Six Months Ended June 30, 2011 and 2010 (unaudited)

	Three Months Ended		Six Months Ended	
	June 30	June 30	June 30	June 30
	2011	2010	2011	2010
Net income/(loss) including noncontrolling interests	\$ 11,130,148	\$(2,528,908)	\$ 5,384,782	\$(5,892,919)
Other comprehensive income (loss)				
Foreign currency translation adjustment	43,344	(119,591)	247,443	(119,591)
Comprehensive income/(loss) including noncontrolling interests	11,173,492	(2,648,499)	5,632,225	(6,012,510)
Comprehensive loss attributable to noncontrolling interests	227,591	108,551	428,195	108,551
Comprehensive income/(loss) attributable to Cleveland BioLabs, Inc.	\$ 11,401,083	\$(2,539,948)	\$ 6,060,420	\$(5,903,959)

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

Six Months Ended June 30, 2011 and 2010 (unaudited)

	June 30 2011	June 30 2010
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income/(loss)	\$5,384,782	\$(5,892,919)
Adjustments to reconcile net income/(loss) to net cash used in operating activities:		
Depreciation	210,068	192,996
Amortization	13,147	6,681
Noncash salaries and consulting expense	5,099,819	3,193,103
Warrant issuance costs	150,827	231,980
Change in value of warrant liability	(17,101,013)	1,697,296
Changes in operating assets and liabilities:		
Accounts receivable	5,241,712	(1,146,318)
Other current assets	(211,702)	42,021
Other long term assets	(15,376)	-
Deposits	(835)	-
Accounts payable	(614,846)	(133,040)
Deferred revenue	(8,426)	(8,357)
Accrued expenses	102,512	(951,944)
Accrued bonuses	(3,321,131)	-
Net cash used in operating activities	(5,070,462)	(2,768,501)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of short-term investments	(213,707)	(1,378,408)
Purchase of equipment	(269,017)	(250,199)
Costs of patents pending	(322,544)	(92,621)
Net cash used in investing activities	(805,269)	(1,721,228)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	23,490,000	5,000,002
Noncontrolling interest capital contribution to Incuron, LLC	2,340,374	3,509,402
Financing costs on common stock offering	(1,411,733)	(350,632)
Cash warrant issuance costs	(131,466)	(140,697)
Warrant exercise fees	(34,448)	-
Exercise of options	522,259	99,645
Exercise of warrants	984,241	86,744
Net cash provided by financing activities	25,759,227	8,204,464
Effect of exchange rate change on cash and equivalents	194,238	(119,591)
INCREASE IN CASH AND EQUIVALENTS	20,077,734	3,595,144
CASH AND EQUIVALENTS AT BEGINNING OF PERIOD	10,918,537	963,100

CASH AND EQUIVALENTS AT END OF PERIOD	\$30,996,271	\$4,558,244
---------------------------------------	--------------	-------------

See Notes to Consolidated Financial Statements

9

CLEVELAND BIOLABS, INC. AND SUBSIDIARY
 CONSOLIDATED STATEMENTS OF CASH FLOWS

Six Months Ended June 30, 2011 and 2010 (unaudited)

	June 30 2011	June 30 2010
Supplemental disclosures of cash flow information:		
Cash paid during the period for interest	\$-	\$-
Cash paid during the period for income taxes	\$-	\$-
Supplemental schedule of noncash financing activities:		
Issuance of options	\$4,678,166	\$1,952,271
Issuance of shares	\$461,309	\$1,272,989
Recapture of expense for nonvested options forfeited	\$(39,656)	\$(38,787)
Amortization of restricted stock awards	\$-	\$6,630
Conversion of warrant liability to equity upon warrant exercise	\$995,428	\$379,661
Noncash financing costs on common stock offering	\$277,206	\$227,486
Noncash warrant issuance costs	\$19,361	\$91,283

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization and Principles of Consolidation

Cleveland BioLabs, Inc. (“CBLI”) together with its subsidiary, Incuron, LLC (“Incuron”) (collectively, the “Company”) is a biotechnology company focused on developing biodefense, tissue protection and cancer treatment drugs based on the concept of modulation of cell death for therapeutic benefit. All intercompany balances and transactions have been eliminated in consolidation.

The Company’s financial statements have been prepared on the accrual basis of accounting in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and on a going concern basis which contemplates the realization of assets and the liquidation of liabilities in the ordinary course of business.

The Company believes it has sufficient cash and fully executed contracts to maintain ongoing operating activities beyond the next 12 months.

Note 2. Basis of Presentation

The information at June 30, 2011 and for the three and six months ended June 30, 2011 and June 30, 2010, has been prepared in accordance with GAAP for interim financial information and the rules and regulations of the U.S. Securities and Exchange Commission (the “SEC”) for quarterly reports on Form 10-Q. In the opinion of management, these financial statements have been prepared on a basis consistent with the Company’s annual audited financial statements and include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year. These financial statements should be read in conjunction with the Company’s audited financial statements and notes thereto for the year ended December 31, 2010, which were contained in the Company’s Annual Report on Form 10-K. All terms used but not defined elsewhere herein have the meaning ascribed to them in the Company’s Annual Report on Form 10-K filed on March 15, 2011.

Note 3. Noncontrolling Interests

On January 20, 2011 and March 14, 2011, Bioprocess Capital Ventures, our joint venture partner and the holder of the noncontrolling interest in Incuron, contributed 68,000,000 Russian Rubles (approximately \$2.3 million based on the current exchange rate) and 1,730,000 Russian Rubles (approximately \$0.1 million based on the current exchange rate), respectively, to Incuron, which increased their ownership percentage from 16.1% to 24.2% and decreased CBLI’s ownership percentage from 83.9% to 75.8%.

The following disclosure provides detail regarding the change in the noncontrolling interest of Incuron during the six months ended June 30, 2011:

Net income attributable to CBLI	\$5,869,165
Net loss attributable to noncontrolling interests	(484,383)
Increase in CBLI’s additional paid-in capital related to the issuance of additional membership interests to the noncontrolling interest of Incuron	176,092

Change due to net income/(loss) and issuance of additional membership interests in Incuron	\$5,560,874
---	-------------

Note 4. Equity Transactions

During June 2011, CBLI issued 5,872,500 shares of its common stock and warrants to purchase a total of 2,936,250 shares of its common stock to certain accredited investors for gross proceeds of \$23,490,000 (the “June 2011 Common Stock Equity Offering”). The common stock and warrants were sold in units, at a price of \$4.00 per unit, with each unit consisting of: (i) one share of common stock; (ii) a Series E Warrant to purchase 0.25 of a share of common stock, with an exercise price of \$4.50 per share; and (iii) a Series F Warrant to purchase 0.25 of a share of common stock, with an exercise price of \$5.00 per share. The Series E Warrants will be exercisable beginning six months following issuance and will expire on the twelve month anniversary of issuance. The Series F Warrants will be exercisable beginning six months following issuance and will expire on the five year anniversary of issuance. The number of shares issuable upon exercise of the warrants and the exercise price of the warrants are adjustable in the event of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. In total, there were 5,875,200 shares of common stock, 1,468,125 Series E Warrants and 1,468,125 Series F Warrants issued to investors in this offering.

The placement agent also received warrants to purchase up to 176,175 shares of common stock, equal to 3% of the aggregate number of shares of common stock sold in the offering. The placement agent's warrants have an exercise price of \$5.00 per share, an initial exercise date on the six month anniversary of issuance and an expiration date of June 17, 2015. The number of shares issuable upon exercise of the placement agent's warrants and the exercise price of such warrants are adjustable in the event of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

The Series F warrants contain provisions that could require the Company to settle the warrants in cash. Accordingly, the Series F warrants have been classified as liability instruments since their issuance. The fair value of the Series F warrants at the issuance date amounted to \$2,525,175 and was determined based on the following assumptions using the Black-Scholes valuation model.

Stock price	\$4.45
Exercise price	\$5.00
Term in years	2.50
Volatility	69.36 %
Annual rate of quarterly dividends	-
Discount rate- bond equivalent yield	0.53 %

Immediately after the completion of the June 2011 Common Stock Equity Offering, pursuant to weighted-average anti-dilution provisions of the Series B Warrants, the Series C Warrants and the warrants issued in March 2010, the following adjustments were made:

- the exercise price of CBLI's Series B Warrants was reduced from \$5.99 to approximately \$5.28 per share and the aggregate number of shares of common stock issuable upon exercise of the Series B Warrants was increased from 3,918,376 to 4,445,276 shares;
- the exercise price of the CBLI's Series C Warrants was reduced from \$6.32 to approximately \$5.54 per share and the aggregate number of shares of common stock issuable upon exercise of the Series C Warrants was increased from 464,852 to 530,297 shares; and
- the exercise price of CBLI's warrants issued in March 2010 was decreased from \$4.50 to \$4.00 per share.

Note 5. Equity Incentive Plan

During the three months ended June 30, 2011, the Company issued 252,962 stock options and 30,556 shares of common stock under the Company's Equity Incentive Plan (the "Plan") as follows:

- 102,962 stock options were issued to employees and consultants under the Company's incentive bonus plan;
 - 50,000 stock options were issued to three new employees as part of their compensation;
- 100,000 stock options were issued to two consultants for payment of corporate strategy consulting services rendered;
- 6,480 shares of common stock valued at \$32,950 were issued to two new employees as part of their compensation;
- 19,276 shares of common stock valued at \$108,005 were issued to four consultants for payment of corporate strategy consulting services rendered; and
- 4,800 shares of common stock valued at \$36,420 were issued to two consultants for payment of financial consulting services rendered.

Edgar Filing: CLEVELAND BIOLABS INC - Form 10-Q

During the six months ended June 30, 2011, the Company issued 1,013,635 stock options and 58,970 shares of common stock under the Plan as follows:

- 198,199 stock options were issued to employees and consultants under the Company's incentive bonus plan;
 - 110,000 stock options were issued to five new employees as part of their compensation;
 - 7,000 stock options were issued to a consultant for payment of accounting services rendered;
- 598,436 stock options were issued to the executive management team for the 2010 Executive Compensation Plan;
- 100,000 stock options were issued to two consultants for payment of corporate strategy consulting services rendered;
- 6,480 shares of common stock valued at \$32,950 were issued to two new employees as part of their compensation;

- 45,565 shares of common stock valued at \$299,766 were issued to five consultants for payment of corporate strategy consulting services rendered; and
- 6,925 shares of common stock valued at \$51,423 were issued to two consultants for payment of financial consulting services rendered.

Note 6. Stock-Based Compensation

During the three months ended June 30, 2011 and 2010, the Company granted 252,962 and 702,404 stock options, respectively. The Company recognized a total of \$1,030,657 and \$614,025 in expense related to stock options for the three months ended June 30, 2011 and 2010, respectively. The Company also recaptured \$23,430 and \$0 of previously recognized expense due to the forfeiture of non-vested stock options during the three months ended June 31, 2011 and 2010, respectively.

During the six months ended June 30, 2011 and 2010, the Company granted 1,013,635 and 846,433 stock options, respectively. The Company recognized a total of \$1,685,986 and \$944,271 in expense related to stock options for the six months ended June 30, 2011 and 2010, respectively. The Company also recaptured \$17,953 and \$0 of previously recognized expense for stock options awarded under the 2010 Executive Compensation Plan during the six months ended June 30, 2011 and 2010, respectively. The Company also recaptured \$39,656 and \$38,787 of previously recognized expense due to the forfeiture of non-vested stock options during the six months ended June 30, 2011 and 2010, respectively.

The weighted average of the estimated grant date fair values of stock options granted during the three months ended June 30, 2011 and 2010 were \$5.19 and \$2.32, respectively.

The assumptions used to value option grants using the Black-Scholes option valuation model are as follows:

	For the six months ended June 30, 2011		For the six months ended June 30, 2010	
Risk-free interest rate	1.89-2.61	%	1.98-2.75	%
Expected dividend yield	0	%	0	%
Expected life	5-6 years		5-6 Years	
Expected volatility	84.28-88.69	%	84.23-89.55	%

The following tables summarize the stock option activity for the six months ended June 30, 2011 and 2010, respectively.

	Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)
Outstanding, December 31, 2010	3,264,440	\$ 5.10	
Granted	1,013,635	\$ 7.27	
Exercised	(184,092)	\$ 2.84	
Forfeited, Canceled	(55,314)	\$ 3.61	
Outstanding, June 30, 2011	4,038,669	\$ 5.76	7.92

Edgar Filing: CLEVELAND BIOLABS INC - Form 10-Q

Exercisable, June 30, 2011	3,635,352	\$	5.56	7.89
----------------------------	-----------	----	------	------

	Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)
Outstanding, December 31, 2009	2,517,007	\$ 5.46	
Granted	846,433	\$ 3.39	
Exercised	(63,541)	\$ 1.57	
Forfeited, Canceled	(64,427)	\$ 7.47	
Outstanding, June 30, 2010	3,235,472	\$ 4.95	8.15
Exercisable, June 30, 2010	2,963,097	\$ 4.72	8.16

Note 7. Fair Value of Financial Instruments

The Company values its financial instruments in accordance with the Codification on fair value measurements and disclosures which establishes a hierarchy for the inputs used to measure fair value. The fair value hierarchy prioritizes the valuation inputs into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs in which little or no market data exists, therefore requiring a company to develop its own assumptions. The Company does not have any significant assets or liabilities measured at fair value using Level 1 or Level 2 inputs as of June 30, 2011 and December 31, 2010.

The Company used Level 3 inputs for valuation of the Company's outstanding warrants that are accounted for as derivative instruments. Fair values were determined using the Black-Scholes valuation model based on the following assumptions as of June 30, 2011:

	Series D Private Placement Warrant Value at June 30, 2011	March 2010 Common Stock Equity Offering Warrant Value at June 30, 2011	June 2011 Common Stock Equity Offering Series F Warrant Value at June 30, 2011	June 2011 Common Stock Equity Offering Agent Warrant Value at June 30, 2011
Stock price	\$ 3.41	\$ 3.41	\$ 3.41	\$ 3.41
Exercise price	\$ 1.60	\$ 4.00	\$ 5.00	\$ 5.00
Term in years	2.37	1.84	2.48	1.98
Volatility	69.46 %	56.77 %	70.37 %	61.36 %
Annual rate of quarterly dividends	-	-	-	-
Discount rate- bond equivalent yield	0.58 %	0.44 %	0.62 %	0.44 %

The following table shows the fair value measurements for the financial instruments as of June 30, 2011:

Liabilities	Fair Value As of June 30, 2011	Fair Value Measurements at June 30, 2011 Using Fair Value Hierarchy		
		Level 1	Level 2	Level 3
Series D Private Placement	\$ 7,494,492	\$-	\$-	\$7,494,492
March 2010 Common Stock Equity Offering	795,077	-	-	795,077

Edgar Filing: CLEVELAND BIOLABS INC - Form 10-Q

June 2011 Series F and Placement Agent Warrants	1,717,164	-	-	1,717,164
Total	\$ 10,006,733	\$-	\$-	\$10,006,733

The following tables set forth a summary of changes in the fair value of the Company's Level 3 fair value measurements for the three months and six months ended June 30, 2011.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3) For the Three Months

	Ended June 30, 2011			
	June 2011 Series F and			
	Series D Private Placement	March 2010 Common Stock Equity Offering	Placement Agent Warrants	Total
Beginning balance	\$ 21,526,268	\$ 3,591,878	\$ -	\$ 25,118,146
Total gains or losses (realized/unrealized)				
Included in earnings as Change in value of warrant liability	(13,983,887)	(2,796,801)	(1,035,277)	(17,815,964)
Issuances	-	-	2,752,441	2,752,441
Settlements	(47,890)	-	-	(47,890)
Ending balance	\$ 7,494,492	\$ 795,077	\$ 1,717,164	\$ 10,006,733

The amount of total gains or losses for the period included in earnings as Change in value of warrant liability attributable to the change in unrealized gains or losses relating to assets still held at the reporting date

	\$ (13,978,098)	\$ (2,796,801)	\$ (1,035,277)	\$ (17,810,176)
--	------------------	-----------------	-----------------	------------------

Fair Value Measurements Using Significant Unobservable Inputs (Level 3) For the Six Months

	Ended June 30, 2011			
	June 2011 Series F and			
	Series D Private Placement	March 2010 Common Stock Equity Offering	Placement Agent Warrants	Total
Beginning balance	\$ 21,223,779	\$ 4,126,954	\$ -	\$ 25,350,733
Total gains or losses (realized/unrealized)				
Included in earnings as Change in value of warrant liability	(13,113,611)	(2,952,125)	(1,035,277)	(17,101,013)
Issuances	-	-	2,752,441	2,752,441
Settlements	(615,676)	(379,752)	-	(995,428)
Ending balance	\$ 7,494,492	\$ 795,077	\$ 1,717,164	\$ 10,006,733

The amount of total gains or losses for the period included in earnings as Change in value of warrant liability attributable to the change in unrealized gains or losses relating to assets still held at the reporting date

	\$ (13,104,467)	\$ (2,927,755)	\$ (1,035,277)	\$ (17,067,499)
--	------------------	-----------------	-----------------	------------------

The Company does not have any other non-recurring assets and liabilities that are required to be presented on the balance sheets at fair value.

Note 8. Net Income (Loss) Per Share

Basic and diluted earnings (loss) per share has been computed using the weighted-average number of shares of common stock outstanding for the period. The following table presents the calculation of basic and diluted earnings (loss) per share for the three and six months ended June 30, 2011 and 2010:

15

Edgar Filing: CLEVELAND BIOLABS INC - Form 10-Q

	Three Months Ended June 30, 2011	Three Months Ended June 30, 2010	Six Months Ended June 30, 2011	Six Months Ended June 30, 2010
Income Available to Common Shareholders	\$ 11,368,224	\$ (2,439,660)	\$ 5,869,165	\$ (5,803,671)
Weighted Average Number of Common Shares Outstanding	30,033,049	26,734,076	29,574,561	25,132,246
Adjustments for Dilutive Securities:				
- Stock Options	1,127,015	-	1,000,176	-
- Warrants	6,427,942	-	6,110,771	-
Adjusted Weighted Average Number of Common Shares Outstanding	37,588,006	26,734,076	36,685,508	25,132,246
Basic Earnings/(Loss) Per Share	\$ 0.38	\$ (0.09)	\$ 0.20	\$ (0.23)
Diluted Earnings/(Loss) Per Share	\$ 0.30	\$ (0.09)	\$ 0.16	\$ (0.23)

The dilutive securities above represent only those stock options and warrants whose exercise prices were less than the average market price of the Company's common stock during the respective periods and therefore were dilutive. Stock options to purchase 1,796,635 shares of common stock and warrants to purchase 225,000 shares of common stock are not included in the diluted calculation during the six months ended June 30, 2011. These options and warrants were excluded from the diluted earnings per share calculation as their exercise prices exceeded the average market price of the stock during the respective periods and, hence, would be anti-dilutive.

Note 9. Commitments and 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 is not a party to any pending material litigation or other material legal proceedings.

The Company has issued warrants to strategic partners, consultants and investors with exercise prices ranging from \$1.60 to \$9.19. The warrants expire between one and seven years from the date of grant, subject to the terms applicable in the agreement. A list of the total warrants awarded and exercised for the six months ended June 30, 2011 and 2010 appears below:

	Number of Warrants	Weighted Average Exercise Price	Number of Common Shares Exercisable Into
Outstanding at December 31, 2010	7,530,689	\$ 3.79	9,450,633
Granted	3,112,425	4.76	3,112,425
Exercise Price Adjustment	-	(0.70)	591,501
Exercised	(301,895)	3.96	(371,206)
Outstanding at June 30, 2011	10,341,219	\$ 3.86	12,783,353

Number of Weighted Average Number of Common

	Warrants	Exercise Price	Shares Exercisable Into
Outstanding at December 31, 2009	6,956,673	\$ 3.71	8,641,893
Granted	1,138,461	4.50	1,138,461
Exercise Price Adjustment	-	(0.14)	272,127
Exercised	(208,939)	1.52	(243,144)
Forfeited, Canceled	(3,973)	1.39	(5,718)
Outstanding at June 30, 2010	7,882,222	\$ 3.88	9,803,619

Note 10. Subsequent Events

The Company has analyzed its operations subsequent to June 30, 2011 through the date the financial statements were submitted to the SEC and has determined that it does not have any additional material subsequent events to disclose in these financial statements.

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. Our actual results could differ materially from those anticipated by the forward-looking information. 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, 2010. See also the Risk Factors discussed under Part II, Item 1A. of this Form 10-Q and Item 1A. of our Annual Report on Form 10-K for the year ended December 31, 2010. 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 in our Annual Report on Form 10-K for the year ended December 31, 2010.

GENERAL OVERVIEW

Cleveland BioLabs, Inc. ("CBLI") together with its subsidiary, Incuron, LLC ("Incuron") (collectively, the "Company") is a biotechnology company focused on developing biodefense, tissue protection and cancer treatment drugs based on the concept of modulation of cell death for therapeutic benefit. CBLI was incorporated in Delaware and commenced business operations in June 2003. We have devoted substantially all of our resources to the identification, development and commercialization of new types of drugs for protection of normal tissues from exposure to radiation and other stresses, such as toxic chemicals and cancer treatments. Our pipeline includes products from two primary families of compounds: protectans and curaxins. We are developing protectans as drug candidates that protect healthy tissues from acute stresses such as radiation, chemotherapy and ischemia (pathologies that develop as a result of blocking blood flow to a part of the body) as well as act as direct anticancer agents by inducing the immune system to attack cancer cells. Curaxins are being developed by Incuron, our majority-owned Russian subsidiary, as anticancer agents that could act as mono-therapy drugs or in combination with other existing anticancer therapies. Our common stock is listed on the NASDAQ Capital Market under the symbol "CBLI."

Technology

Our development efforts are based on discoveries made in connection with the investigation of the cell-level process known as apoptosis. Apoptosis is a highly specific and tightly regulated form of cell death that can occur in response to external events such as exposure to radiation or toxic chemicals or internal stresses. Apoptosis is a major determinant of tissue damage caused by a variety of medical conditions including cerebral stroke, heart attack and acute renal failure. Conversely, apoptosis is also an important protective mechanism that allows the body to shed itself of defective cells, which otherwise can cause cancerous growth.

Research has demonstrated that apoptosis is sometimes suppressed naturally. For example, most cancer cells develop resistance to apoptotic death caused by drugs or natural defenses of the human body. Our research is geared towards identifying the means by which apoptosis can be affected and manipulated depending on the need.

If the need is to protect healthy tissues against an external event such as exposure to radiation, we focus our research efforts on attempting to temporarily and reversibly suppress apoptosis in those healthy tissues, thereby imitating the apoptotic-resistant tendencies displayed by cancer cells. A drug with this effect would also be useful in ameliorating the toxicities of anticancer drugs and radiation that cause collateral damage to healthy tissues during cancer treatment. Because the severe toxicities of anticancer drugs and radiation often limit their dosage in cancer patients, an apoptosis suppressant drug may enable a more aggressive treatment regimen using chemo- and radiation therapy of cancer and thereby increase their effectiveness. In addition, the same mechanisms that suppress apoptosis may trigger an innate immune system response to cancers and, thus, have a direct anticancer effect.

On the other hand, if the need is to destroy cancerous cells, we focus our research efforts on restoring apoptotic mechanisms that are suppressed in tumors, so that those cancerous cells will once again become vulnerable to apoptotic death. In this regard, we believe that our drug candidates could have significant potential for improving, and becoming vital to, the treatment of cancer patients.

Through our research and development ("R&D"), and our strategic partnerships, we have established a technological foundation for the development of new pharmaceuticals and their rapid preclinical evaluation.

We have acquired rights to develop and commercialize the following prospective drugs:

- Protectans - modified factors of microbes that protect cells from apoptosis, and which, therefore, have a broad spectrum of potential applications. The potential applications include both non-medical applications such as protection from exposure to radiation, whether as a result of military or terrorist action or as a result of a nuclear accident, as well as medical applications such as reducing cancer treatment toxicities inducing the immune system to attack cancer cells.

- Curaxins - small molecules designed to kill tumor cells by simultaneously targeting two regulators of apoptosis. Initial test results indicate that curaxins can be effective against a number of malignancies, including hormone-refractory prostate cancer, renal cell carcinoma ("RCC") (a highly fatal form of kidney cancer), and soft-tissue sarcoma.

In the area of radiation protection and cancer treatment, we have achieved high levels of efficacy in numerous animal models. With respect to cancer treatment, the biology of cancer is such that there is no single drug that can be successfully used to treat a significant proportion of the large number of different cancers and there is wide variability in individual responses to most therapeutic agents. This means there is a continuing need for additional anticancer drugs for most cancers.

Our drug candidates demonstrate the value of our scientific foundation. Based on the accelerated review and approval status currently available for drugs qualifying for Fast Track status, we believe that our most advanced drug candidate, Protectan CBLB502 may be approved for treatment of acute radiation syndrome within 18 - 24 months. Another drug candidate, Curaxin CBLC102, demonstrated activity and safety in a Phase IIa clinical trial concluded in late 2008. In November 2010, the first patient was dosed in an ongoing multi-center clinical trial of Curaxin CBLC102 on patients with liver tumors in the Russian Federation.

RESEARCH AND DEVELOPMENT

We are highly dependent on the success of our R&D efforts and, ultimately, upon regulatory approval and market acceptance of our products under development.

There are significant risks and uncertainties inherent in the preclinical and clinical studies associated with our R&D projects. As a result, the costs to complete such projects, as well as the period in which net cash outflows from such programs are expected to be incurred, may not be reasonably estimated. From our inception to June 30, 2011, we spent \$84,647,562 on R&D. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations— Three Months Ended June 30, 2011 Compared to June 30, 2010—Operating Expenses" for a more detailed discussion of our R&D spending.

Our ability to complete our R&D on schedule is, however, subject to a number of risks and uncertainties. In addition, we have sustained losses from operations in each fiscal year since our inception in June 2003, and we may exhaust our financial resources and be unable to complete the development of our products due to the substantial investment in R&D that will be required for the next several years. We expect to spend substantial additional sums on the continued R&D of proprietary products and technologies with no certainty that losses will not increase or that we will ever become profitable as a result of these expenditures.

The marketing of any product for use in the U.S. will require approval from the U.S. Food and Drug Administration ("FDA"). We cannot predict with any certainty the amount of time necessary to obtain such FDA approval and whether any such approval will ultimately be granted. Preclinical studies and 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 or terminated. Moreover, obtaining approval for certain products may require testing on human subjects of substances whose effects on humans are not fully understood or documented. 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 the product's potential commercial success and on our business, prospects, financial condition and results of operations. In addition, 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 U.S. that perform roles similar to that of the FDA, uncertainties

similar to those stated above will also exist.

PRODUCTS IN DEVELOPMENT

Protectans

We are exploring a new natural source of factors that temporarily suppress the programmed cell death (apoptosis) response in human cells, which can be rapidly developed into therapeutic products. These inhibitors, known as protectans, are anti-apoptotic factors developed by microorganisms of human microflora throughout millions of years of co-evolution with mammalian hosts. We have established a technological process for screening of these factors and their rapid preclinical evaluation. These inhibitors may be used as protection from cancer treatment toxicities and antidotes against injuries induced by radiation and other stresses associated with severe pathologies (i.e., heart attack or stroke).

We have accumulated preclinical data in numerous mouse and rat transplanted cancer models suggesting that the same mechanisms that suppress apoptosis may trigger an innate immune system response to cancers and, thus, have a direct anticancer effect. In one of the animal models using transplanted colon cancer, treatment with Protectan CBLB502, our lead protectan drug candidate, resulted in the complete tumor regression with no recurrence of the disease in a large percentage of animals. Experimental results suggest that Protectan CBLB502's anticancer effect involves tissue-specific activation of an innate immune system response mediated by Protectan CBLB502's interaction with its receptor, TLR5. In addition, experimental results suggest that antitumor effects of Protectan CBLB502 largely depend on the expression of TLR5 by the tumor. However, in the case of tumors residing in the liver, the organ which has been identified as the natural primary target site for Protectan CBLB502 activity, experimental results suggest that tumors become effectively suppressed as a result of host immune system attack regardless of their TLR5 status. This characteristic may make liver metastasis a favorable target for potential anticancer applications of Protectan CBLB502.

During the three months ended June 30, 2011, the Company received notices of allowance from the United States Patent and Trademark Office (the "USPTO") and the Japan Patent Office for patent applications 11/722,682 and 2006-542849, respectively, covering Protectan CBLB502. Allowed claims of the U.S. Patent Application number 11/722,682, titled "Flagellin Related Polypeptides and Uses Thereof," cover composition of matter and use of Protectan CBLB502 for protecting a mammal from radiation. Allowed claims for the Japanese Patent Application cover the method of protecting a mammal from radiation using flagellin or its derivatives, including Protectan CBLB502. In addition, the Company received a notice of allowance from the USPTO for the Company's Protectan CBLB612 patent application number 11/917,494 titled "Methods of Protecting against Apoptosis using Lipopeptides." Allowed claims cover the various properties of Protectan CBLB612 and related compounds, including composition of matter and methods of use for protecting against apoptosis.

On June 23, 2011, a modification (the "Modification") to the existing contract, awarded on September 16, 2010 (the "2010 DoD Contract"), between CBLI and the United States Department of Defense ("DoD") Chemical Biological and Medical Systems Medical Identification and Treatment Systems (CBMS-MITS) was awarded. The Modification provides for an increased scope of work relating to service items under the 2010 DoD Contract for the advanced development of Protectan CBLB502 and project management in respect thereof, for an aggregate increase in funding of \$1.3 million. In addition, as part of the Modification, a new option for \$0.2 million was added to the 2010 DoD Contract. As a result of the Modification, the 2010 DoD Contract, as modified, is valued at up to \$46.5 million, including all options provided thereunder.

For the three months ended June 30, 2011 and 2010, we spent \$4,340,497 and \$3,733,742, respectively, on R&D for protectans. For the six months ended June 30, 2011 and 2010, we spent \$8,868,199 and \$7,326,313, respectively, on R&D for protectans. From our inception to June 30, 2011, we spent \$63,437,363 on R&D for protectans. The increase is mainly due to the increase in expenditures supporting the development of Protectan CBLB502, including an increase in employee compensation expense due to the hiring of additional drug development, regulatory affairs and quality assurance personnel.

For the three months ended June 30, 2011 and 2010, we spent \$4,329,981 (all for non-medical applications) and \$3,733,742 (all for non-medical applications), respectively, on R&D for Protectan CBLB502. For the six months ended June 30, 2011 and 2010, we spent \$8,857,683 (\$8,834,913 for non-medical applications and \$22,770 for medical applications) and \$7,326,313 (all for non-medical applications), respectively, on R&D for Protectan CBLB502. From our inception to June 30, 2011, we spent \$60,284,766 (\$58,428,939 for non-medical applications and \$1,855,827 for medical applications) on R&D for Protectan CBLB502.

For the three months ended June 30, 2011 and 2010, we spent \$10,516 and \$0, respectively, on R&D for Protectan CBLB612. For the six months ended June 30, 2011 and 2010, we spent \$10,516 and \$0, respectfully, on R&D for

Protectan CBLB612. From our inception to June 30, 2011, we spent \$3,152,597 on R&D for Protectan CBLB612. Further development and extensive testing will be required to determine its technical feasibility and commercial viability.

Curaxins

Curaxins are small molecules that are intended to destroy tumor cells by simultaneously targeting two regulators of apoptosis. Our initial test results indicate that curaxins may be effective against a number of malignancies, including RCC, soft-tissue sarcoma, and hormone-refractory prostate cancer.

For the three months ended June 30, 2011 and 2010, we spent \$858,231 and \$333,458, respectively, on R&D for curaxins. For the six months ended June 30, 2011 and 2010, we spent \$1,979,859 and \$404,462, respectively, on R&D for curaxins. From our inception to June 30, 2011, we spent \$15,786,770 on R&D for curaxins. The increase is mainly due to the increase in expenditures supporting the clinical development of Curaxin CBLC102 and the formal preclinical development of Curaxin CBLC137.

For the three months ended June 30, 2011 and 2010, we spent \$602,130 and \$166,729, respectively, on R&D for Curaxin CBLC102. For the six months ended June 30, 2011 and 2010, we spent \$1,417,495 and \$201,930, respectively, on R&D for Curaxin CBLC102. From our inception to June 30, 2011, we spent \$8,545,682 on R&D for Curaxin CBLC102. The increase is mainly due to the increase in expenditures supporting the multi-center clinical trial of Curaxin CBLC102 in patients with liver tumors.

For the three months ended June 30, 2011 and 2010, we spent \$256,101 and \$166,729, respectively, on R&D for other curaxins. For the six months ended June 30, 2011 and 2010, we spent \$562,364 and \$202,532 respectively, on R&D for other curaxins. From our inception to June 30, 2011, we spent \$7,241,088 on R&D for other curaxins.

General R&D

General R&D includes R&D expenses, such as overhead, shared project expenses and other expenses that are not considered part of the curaxin or protectan classes of research.

For the three months ended June 30, 2011 and 2010 we spent \$10,466 and \$102,915, respectively on general R&D expenses. For the six months ended June 30, 2011 and 2010 we spent \$70,069 and \$137,120, respectively, on general R&D expenses. From our inception to June 30, 2011 we spent \$5,423,429 on general R&D expenses.

FINANCIAL OVERVIEW

Including several non-cash items, our net income increased from a net loss of \$2,528,908 for the three months ended June 30, 2010 to net income of \$11,130,148 for the three months ended June 30, 2011, an increase of \$13,659,056 or 540.1%. We incurred non-cash charges of depreciation and amortization of \$111,912 and \$98,953, non-cash salaries and consulting fees of \$1,184,603 and \$1,274,180 and a change in the value of warrants of (\$17,815,964) and (\$33,800) for the three months ended June 30, 2011 and 2010, respectively. Excluding these non-cash charges, our net loss increased \$4,198,816 or 353.0% from \$1,189,575 for the three months ended June 30, 2010 to \$5,389,301 for the three months ended June 30, 2011. This increase was primarily related to higher R&D costs due to an increase in expenditures to support preclinical animal studies as well as a reduction in revenue. In addition, our consolidated subsidiary, Incuron, also incurred higher costs in the three months ended June 30, 2011 as compared to the three months ended June 30, 2010 due to increased activity resulting from Incuron's operations being established only in the second quarter of 2010, including the increase of expenditures supporting clinical development of Curaxin CBLC102 and formal preclinical development of Curaxin CBLC137.

Including several non-cash items, our net income increased from a net loss of \$5,892,919 for the six months ended June 30, 2010 to net income of \$5,384,782 for the six months ended June 30, 2011, an increase of \$11,277,701 or 191.4%. We incurred non-cash charges of depreciation and amortization of \$223,215 and \$199,677, non-cash salaries and consulting fees of \$2,107,639 and \$2,210,871 and a change in the value of warrants of (\$17,101,013) and \$1,697,296 for the six months ended June 30, 2011 and 2010, respectively. Excluding these non-cash charges, our net loss increased \$7,600,302 or 425.8% from \$1,785,075 for the six months ended June 30, 2010 to \$9,385,377 for the six months ended June 30, 2011. This increase was primarily related to higher R&D costs due to an increase in expenditures to support preclinical animal studies, an increase in employee compensation due to the hiring of additional drug development, regulatory affairs and quality assurance personnel, as well as a reduction in revenue. In addition, our consolidated subsidiary, Incuron, also incurred higher costs in the six months ended June 30, 2011 as compared to the six months ended June 30, 2010 due to increased activity resulting from Incuron's operations being established only in the second quarter of 2010, including the increase of expenditures supporting clinical development of Curaxin CBLC102 and formal preclinical development of Curaxin CBLC137.

Our total cash and equivalents, short-term investments and accounts receivable increased from \$16,760,022 at December 31, 2010 to \$31,849,037 at June 30, 2011. This increase of \$15,089,015 or 90.0% was primarily due to the proceeds from the June 2011 financing, capital contributions to Incuron from our joint venture partner, Bioprocess Capital Ventures, and cash proceeds from the exercise of warrants and options, partially offset by our operating losses.

Recent Developments

On June 22, 2011, CBLI issued 5,872,500 shares of its common stock and warrants to purchase a total of 2,936,250 shares of its common stock to certain accredited investors for gross proceeds of \$23,490,000. The common stock and warrants were sold in units, at a price of \$4.00 per unit, with each unit consisting of: (i) one share of common stock; (ii) a Series E Warrant to purchase 0.25 of a share of common stock, with an exercise price of \$4.50 per share; and (iii) a Series F Warrant to purchase 0.25 of a share of common stock, with an exercise price of \$5.00 per share. The Series E Warrants will be exercisable beginning six months following issuance and will expire on the twelve month anniversary of issuance. The Series F Warrants will be exercisable beginning six months following issuance and will expire on the five year anniversary of issuance. The number of shares issuable upon exercise of the warrants and the exercise price of the warrants are adjustable in the event of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. In total, there were 5,875,200 shares of common stock, 1,468,125 Series E Warrants and 1,468,125 Series F Warrants issued to the investors in this offering.

In addition, the placement agent also received warrants to purchase up to 176,175 shares of common stock, equal to 3% of the aggregate number of shares of common stock sold in the offering. The placement agent's warrants have an exercise price of \$5.00 per share, an initial exercise date on the six month anniversary of issuance and an expiration date of June 17, 2015. The number of shares issuable upon exercise of the placement agent's warrants and the exercise price of such warrants are adjustable in the event of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

Immediately after the completion of this offering, pursuant to anti-dilution provisions of the Series B Warrants, the Series C Warrants and the warrants issued in March 2010, the following adjustments were made:

- the exercise price of CBLI's Series B Warrants was reduced from \$5.99 to approximately \$5.28 per share, and the aggregate number of shares of common stock issuable upon exercise of the Series B Warrants was increased from 3,918,376 to 4,445,276;
- the exercise price of CBLI's Series C Warrants was reduced from \$6.32 to approximately \$5.54 per share, and the aggregate number of shares of common stock issuable upon exercise of the Series C Warrants was increased from 464,852 to approximately 530,297; and
- the exercise price of CBLI's warrants issued in March 2010 decreased from \$4.50 to \$4.00 per share.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues, expenses and other reported disclosures. We believe that we consistently apply these judgments and estimates and the financial statements and accompanying notes fairly represent all periods presented. However, any differences between these judgments and estimates and actual results could have a material impact on our statements of income and financial position. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances.

While all decisions regarding accounting policies are important, we believe that our policies regarding revenue recognition, R&D expenses, intellectual property related costs, stock-based compensation expense and fair value measurements could be considered critical. For a discussion of our "Critical Accounting Policies and Estimates," refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2010. There have been no material changes to our critical accounting policies since December 31, 2010.

Results of Operations

The following table sets forth our statement of operations data for the three and six months ended June 30, 2011 and 2010 and the years ended December 31, 2010 and 2009 and should be read in conjunction with our financial statements and the related notes appearing elsewhere in this filing and in our annual report on Form 10-K for the year ended December 31, 2010.

Three Months Ended June 30, 2011 (unaudited)	Three Months Ended June 30, 2010 (unaudited)	Six Months Ended June 30, 2011 (unaudited)	Six Months Ended June 30, 2010 (unaudited)	Year Ended December 31, 2010	Year Ended December 31, 2009
---	---	---	---	------------------------------------	------------------------------------

Edgar Filing: CLEVELAND BIOLABS INC - Form 10-Q

Revenues	\$ 569,049	\$ 4,210,763	\$ 3,043,031	\$ 8,381,111	\$ 15,331,567	\$ 14,345,908
Operating expenses	7,196,645	6,831,315	14,782,780	12,458,596	26,068,765	20,728,837
Other expense (income)	(17,690,673)	(84,005)	(17,019,201)	1,828,846	16,033,770	6,463,208
Net interest expense (income)	(67,071)	(7,639)	(105,330)	(13,412)	(99,111)	(19,728)
Net income (loss)	\$ 11,130,148	\$ (2,528,908)	\$ 5,384,782	\$ (5,892,919)	\$ (26,671,857)	\$ (12,826,409)

The following table summarizes R&D expenses for the three and six months ended June 30, 2011 and 2010 and the years ended December 31, 2010 and 2009 and since inception:

Edgar Filing: CLEVELAND BIOLABS INC - Form 10-Q

	Three Months Ended June 30, 2011 (unaudited)	Three Months Ended June 30, 2010 (unaudited)	Six Months Ended June 30, 2011 (unaudited)	Six Months Ended June 30, 2010 (unaudited)	Year Ended December 31, 2010	Year Ended December 31, 2009	Total Since Inception (unaudited)
Research and development	\$ 5,209,194	\$ 4,170,115	\$ 10,918,127	\$ 7,867,895	\$ 16,141,040	\$ 14,331,673	\$ 84,647,562
General	\$ 10,466	\$ 102,915	\$ 70,069	\$ 137,120	\$ 246,730	\$ -	\$ 5,423,429
Protectan CBLB502 - non-medical applications	\$ 4,329,981	\$ 3,733,742	\$ 8,834,913	\$ 7,326,313	\$ 14,316,540	\$ 13,676,289	\$ 58,428,939
Protectan CBLB502 - medical applications	\$ -	\$ -	\$ 22,770	\$ -	\$ -	\$ 56,127	\$ 1,855,827
Protectan CBLB612	\$ 10,516	\$ -	\$ 10,516	\$ -	\$ 5,140	\$ 6,567	\$ 3,152,597
Curaxin CBLC102	\$ 602,130	\$ 166,729	\$ 1,417,495	\$ 201,930	\$ 399,068	\$ 262,637	\$ 8,545,682
Other Curaxins	\$ 256,101	\$ 166,729	\$ 562,364	\$ 202,532	\$ 1,173,562	\$ 330,053	\$ 7,241,088

Three Months Ended June 30, 2011 Compared to Three Months Ended June 30, 2010

Revenue

Revenue decreased from \$4,210,763 for the three months ended June 30, 2010 to \$569,049 for the three months ended June 30, 2011, representing a decrease of \$3,641,714 or 86.5% resulting primarily from a decrease in revenue from various federal grants and contracts including the DoD, NIH and the Biomedical Advanced Research and Development Authority of the Department of Health and Human Services (“BARDA”) contracts.

See the table below for further details regarding the sources of our government grant and contract revenue:

Agency	Program	Amount	Period of Performance	Revenue 2011 (April 1 thru June 30) (unaudited)	Revenue 2010 (April 1 thru June 30) (unaudited)	Revenue 2010
DOD	CBMS-MITS Contract	\$ 14,800,000	09/2010-03/2013	\$ 46,718	\$ -	\$ 623,975
DTRA	DTRA Contract	\$ 1,589,106	01/2011-05/2012	\$ 518,118	\$ -	\$ -
HHS	BARDA Contract	\$ 15,600,000	09/2008-02/2011	\$ -	\$ 3,468,372	\$ 9,968,445
AFRRI	Subcontractor	\$ 69,878	02/2010-11/2010	\$ -	\$ -	\$ 69,878
NY State/RPCI	Sponsored Research Agreement	\$ 3,000,000	03/2007-02/2012	\$ 4,213	\$ 4,213	\$ 12,398
DoD	DOD Contract	\$ 9,590,000	05/2008-09/2010	\$ -	\$ 112,533	\$ 564,432
NIH	NIAID Grant	\$ 1,232,695	09/2008-02/2010	\$ -	\$ -	\$ 560

Edgar Filing: CLEVELAND BIOLABS INC - Form 10-Q

NIH	NIAID GO Grant	\$ 5,329,543	09/2009-09/2011	\$ -	\$ 625,645	\$ 4,091,879
				\$ 569,049	\$ 4,210,763	\$ 15,331,567

We anticipate our revenue over the next year to be derived mainly from government grants and contracts. In addition, it is common in our industry for companies to enter into licensing agreements with large pharmaceutical companies. To the extent we enter into such licensing arrangements, we may receive additional revenue from licensing fees.

Operating Expenses

Operating expenses have historically consisted of costs relating to R&D and general and administrative expenses. R&D expenses have consisted mainly of supporting our R&D teams, process development, sponsored research at the Roswell Park Cancer Institute and Cleveland Clinic, clinical trials and consulting fees. General and administrative expenses include all corporate and administrative functions that serve to support our current and future operations while also providing an infrastructure to support future growth. Major items in this category include management and staff salaries, rent/leases, professional services and travel-related expenses. We anticipate these expenses to increase as a result of increased legal and accounting fees anticipated in connection with our compliance with ongoing reporting and accounting requirements of the SEC and the expansion of our business.

Operating expenses increased from \$6,831,315 for the three months ended June 30, 2010 to \$7,196,645 for the three months ended June 30, 2011, representing an increase of \$365,330 or 5.4%. We recognized a total of \$1,184,603 of non-cash, stock-based compensation for the three months ended June 30, 2011 compared to \$1,274,180 for the three months ended June 30, 2010. If these non-cash, stock-based compensation expenses were excluded, operating expenses would have increased from \$5,557,135 for the three months ended June 30, 2010 to \$6,012,042 for the three months ended June 30, 2011. This represents an increase in operating expenses of \$454,907 or 8.2% as explained below.

Research and development costs increased from \$4,170,115 for the three months ended June 30, 2010 to \$5,209,194 for the three months ended June 30, 2011. This represents an increase of \$1,039,079 or 24.9%. We recognized a total of \$604,928 of R&D non-cash, stock based compensation for the three months ended June 30, 2011 compared to \$204,634 for the three months ended June 30, 2010. Without the non-cash, stock-based compensation, the R&D expenses increased from \$3,965,481 for the three months ended June 30, 2010 to \$4,604,266 for the three months ended June 30, 2011, representing an increase of \$638,785 or 16.1%. The higher research and development expenses were a result of increased R&D efforts by Incuron for curaxins and increases in expenditures to support preclinical animal studies for Protectan CBLB502.

General and administrative costs decreased from \$2,661,200 for the three months ended June 30, 2010 to \$1,987,451 for the three months ended June 30, 2011. This represents a decrease of \$673,749 or 25.3%. We recognized a total of \$579,675 of non-cash, stock-based compensation under general and administrative costs for the three months ended June 30, 2011 compared to \$1,069,546 for the three months ended June 30, 2010. Without the non-cash, stock-based compensation, the general and administrative expenses decreased from \$1,591,654 for the three months ended June 30, 2010 to \$1,407,776 for the three months ended June 30, 2011, representing a decrease of \$183,878 or 11.6%. This decrease is primarily due to cost containment efforts.

Until we introduce a product to the market, we expect these expenses in the categories mentioned above will be the largest categories in our income statement.

Other Income

Other income increased from \$91,644 to \$17,757,744 for the three months ended June 30, 2011, representing an increase of \$17,666,100. This increase in other income is primarily attributable to a decrease in the warrant liability of \$17,815,964 for the three months ended June 30, 2011 as compared to a decrease in the warrant liability of \$33,800 during the three months ended June 30, 2010.

Six Months Ended June 30, 2011 Compared to Six Months Ended June 30, 2010

Revenue

Revenue decreased from \$8,381,111 for the six months ended June 30, 2010 to \$3,043,031 for the six months ended June 30 2011, representing a decrease of \$5,338,080 or 63.7% resulting primarily from a decrease in revenue from various federal grants and contracts including the DoD, NIH and BARDA contracts.

See the table below for further details regarding the sources of our government grant and contract revenue:

Agency	Program	Amount	Period of Performance	Revenue 2011 (thru June 30) (unaudited)	Revenue 2010 (thru June 30) (unaudited)	Revenue 2010
CBMS-MITS						
DOD	Contract	\$ 14,800,000	09/2010-03/2013	\$ 1,921,852	\$ -	\$ 623,975
DTRA	DTRA Contract	\$ 1,589,106	01/2011-05/2012	\$ 875,005	\$ -	\$ -
HHS	BARDA Contract	\$ 15,600,000	09/2008-02/2011	\$ 237,748	\$ 6,441,224	\$ 9,968,445
AFRRI	Subcontractor	\$ 69,878	02/2010-11/2010	\$ -	\$ -	\$ 69,878
NY State/RPCI	Sponsored Research	\$ 3,000,000	03/2007-02/2012	\$ 8,426	\$ 8,357	\$ 12,398

Edgar Filing: CLEVELAND BIOLABS INC - Form 10-Q

Agreement							
DoD	DOD Contract	\$ 9,590,000	05/2008-09/2010	\$ -	\$ 495,655	\$ 564,432	
NIH	NIAID Grant	\$ 1,232,695	09/2008-02/2010	\$ -	\$ 560	\$ 560	
NIH	NIAID GO Grant	\$ 5,329,543	09/2009-09/2011	\$ -	\$ 1,435,315	\$ 4,091,879	
				\$ 3,043,031	\$ 8,381,111	\$ 15,331,567	

We anticipate our revenue over the next year to be derived mainly from government grants and contracts. In addition, it is common in our industry for companies to enter into licensing agreements with large pharmaceutical companies. To the extent we enter into such licensing arrangements, we may receive additional revenue from licensing fees.

Operating Expenses

Operating expenses have historically consisted of costs relating to R&D and general and administrative expenses. R&D expenses have consisted mainly of supporting our R&D teams, process development, sponsored research at the Roswell Park Cancer Institute and Cleveland Clinic, clinical trials and consulting fees. General and administrative expenses include all corporate and administrative functions that serve to support our current and future operations while also providing an infrastructure to support future growth. Major items in this category include management and staff salaries, rent/leases, professional services and travel-related expenses. We anticipate these expenses to increase as a result of increased legal and accounting fees anticipated in connection with our compliance with ongoing reporting and accounting requirements of the SEC and the expansion of our business.

Operating expenses increased from \$12,458,596 for the six months ended June 30, 2010 to \$14,782,780 for the six months ended June 30, 2011, representing an increase of \$2,324,184 or 18.7%. We recognized a total of \$2,107,639 of non-cash, stock-based compensation for the six months ended June 30, 2011 compared to \$2,210,871 for the six months ended June 30, 2010. If these non-cash, stock-based compensation expenses were excluded, operating expenses would have increased from \$10,247,725 for the six months ended June 30, 2010 to \$12,675,141 for the six months ended June 30, 2011. This represents an increase in operating expenses of \$2,427,416 or 23.7% as explained below.

Research and development costs increased from \$7,867,895 for the six months ended June 30, 2010 to \$10,918,127 for the six months ended June 30, 2011. This represents an increase of \$3,050,232 or 38.8%. We recognized a total of \$1,139,206 of R&D non-cash, stock based compensation for the six months ended June 30, 2011 compared to \$344,825 for the six months ended June 30, 2010. Without the non-cash, stock-based compensation, the R&D expenses increased from \$7,523,070 for the six months ended June 30, 2010 to \$9,778,921 for the six months ended June 30, 2011, representing an increase of \$2,255,851 or 30.0%. The higher research and development expenses were a result of increased R&D efforts by Incuron for curaxins and increases in expenditures to support preclinical animal studies for Protectan CBLB502.

General and administrative costs decreased from \$4,590,701 for the six months ended June 30, 2010 to \$3,864,653 for the six months ended June 30, 2011. This represents a decrease of \$726,048 or 15.8%. We recognized a total of \$968,433 of non-cash, stock-based compensation under general and administrative costs for the six months ended June 30, 2011 compared to \$1,866,046 for the six months ended June 30, 2010. Without the non-cash, stock-based compensation, the general and administrative expenses increased from \$2,724,655 for the six months ended June 30, 2010 to \$2,896,220 for the six months ended June 30, 2011, representing an increase of \$171,565 or 6.3%. This increase is primarily due to the general and administrative expenses incurred by Incuron.

Until we introduce a product to the market, we expect these expenses in the categories mentioned above will be the largest categories in our income statement.

Other Income/Expense

Other income increased from an expense of \$1,815,434 to income of \$17,124,531 for the six months ended June 30, 2011, representing an increase of \$18,939,965 or 1,043.3%. This increase in other income is primarily attributable to an increase in the income resulting from a decrease in the warrant liability of \$17,101,013 for the six months ended June 30, 2011 as compared to an expense due to an increase in the warrant liability of \$1,697,296 during the six months ended June 30, 2010.

Liquidity and Capital Resources

We have incurred annual operating losses since our inception, and, as of June 30, 2011, we had an accumulated deficit of \$90,184,813. Our principal sources of liquidity have been cash provided by sales of our securities, government grants and contracts and licensing agreements. Our principal uses of cash have been R&D and working capital. We expect our future sources of liquidity to be primarily government contracts and grants, equity financing, licensing fees and milestone payments in the event we enter into licensing agreements with third parties, and research collaboration fees in the event we enter into research collaborations with third parties.

Net cash used in operating activities totaled \$5,070,462 for the six months ended June 30, 2011, compared to \$2,768,501 used in operating activities for the six months ended June 30, 2010. This increase in cash used in operating activities resulted from increased activities on the part of our consolidated subsidiary, Incuron for curaxins and extensive animal studies for Protectan CBLB502 combined with a reduction in revenue collections for the period.

Net cash used in investing activities was \$805,269 for the six months ended June 30, 2011, compared to net cash used in investing activities of \$1,771,228 for the six months ended June 30, 2010. The decrease in cash used in investing activities resulted primarily from larger purchases of short-term investments in the first six months of 2010 as compared to the first six months of 2011.

Net cash provided by financing activities totaled \$25,759,227 for the six months ended June 30, 2011, compared to net cash provided by financing activities of \$8,204,464 for the six months ended June 30, 2010. This increase in cash provided by financial activities was primarily attributed to the June 2011 equity offering that took place in the first six months of 2011 as compared to the March 2010 equity offering that took place in the first six months of 2010.

Under our exclusive license agreement with CCF, we may be responsible for making milestone payments to CCF in amounts ranging from \$50,000 to \$4,000,000. The milestones and corresponding payments for Protectan CBLB502 and Curaxin CBLC102 are set forth above in our Annual Report on Form 10-K for the year ended December 31, 2010 under “Item 1 – Description of Business – Collaborative Research Agreements – Cleveland Clinic Foundation.”

Our agreement with CCF also provides for payment by us to CCF of royalty payments calculated as a percentage of the net sales of the drug candidates ranging from 1-2%, and sublicense royalty payments calculated as a percentage of the royalties received from the sublicenses ranging from 5-35%. However, any royalty payments and sublicense royalty payments assume that we will be able to commercialize our drug candidates, which are subject to numerous risks and uncertainties, including those associated with the regulatory approval process, our R&D process and other factors. Accrued milestone payments, royalty payments and sublicense royalty payments are payable upon achievement of the milestone.

We believe that although existing cash resources will be sufficient to finance our currently planned operations beyond the next twelve months, these amounts will not be sufficient to meet our longer-term cash requirements, including our cash requirements for the commercialization of certain of our drug candidates currently in development. We may be required to issue equity or debt securities or enter into other financial arrangements, including relationships with corporate and other partners, in order to raise additional capital. Depending upon market conditions, we may not be successful in raising sufficient additional capital for our long-term requirements. In such event, our business, prospects, financial condition and results of operations could be materially adversely affected.

Impact of Inflation

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

Impact of Exchange Rate Fluctuations

We believe that our results of operations are somewhat dependent upon changes in foreign currency exchange rates. We have entered into agreements with foreign third parties to produce one of our drug compounds and are required to make payments in the foreign currency. As a result, our financial results could be affected by changes in foreign currency exchange rates. As of June 30, 2011, we are obligated to make payments under these agreements of 994,179 Euros.

Off-Balance Sheet Arrangements

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

Item 3: Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks, including changes to interest rates, foreign currency exchange rates and equity investment prices. To reduce the volatility related to these exposures, we may enter into various derivative hedging transactions pursuant to our investment and risk management policies. There are inherent risks that may only be partially offset by our hedging programs should there be unfavorable movements in interest rates, foreign currency exchange rates, or equity investment prices.

There has been no significant change in our exposure to market risk during the first six months of 2011. 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, 2010.

Item 4: Controls and Procedures

Effectiveness of Disclosure

Our management, with the participation of our Chief Executive Officer and Interim 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, 2011. 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, 2011, our Chief Executive Officer and Interim 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 Interim 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, 2011, 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

As of June 30, 2011, we were not a party to any litigation or other legal proceeding.

Item 1A. Risk Factors

Other than as discussed below, there have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the period ended December 31, 2010. For a further discussion of our Risk Factors, refer to the "Risk Factors" discussion contained in our Annual Report on Form 10-K for the period ended December 31, 2010.

Certain risks related to our business include the following:

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

The testing and, marketing and manufacturing of any product for use in the U.S. will require approval from the FDA. We cannot predict with any certainty the amount of time necessary to obtain such FDA approval and whether any such approval will ultimately be granted. Preclinical studies and 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. Moreover, obtaining approval for certain products may require testing on human subjects of substances whose effects on humans are not fully understood or documented.

The receipt of FDA approval may be delayed for reasons other than the results of preclinical and clinical trials. For example, the IND application for Protectan CBLB502 for biodefense applications was recently transferred within the FDA from the Division of Biologic Oncology Products (DBOP) to the Division of Medical Imaging Products (DMIP). As a result of this transfer, we are in the process of familiarizing DMIP with the IND for Protectan CBLB502 and updating DMIP on the results of the Phase I studies as well as other data from preclinical studies. We are working towards reaching an agreement with FDA on the scope and design of our remaining developmental program for Protectan CBLB502. However, there can be no guarantee that we will reach a satisfactory agreement in a timely manner, or at all.

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.

If we lose our funding from R&D contracts and grants or 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.

In 2010, we received 100% of our revenues from government contract and grant development work in connection with grants from the DoD, NIH, and BARDA. In 2009 and 2008, we received 88.5% and 97.4% of our revenues from government contract and grant development work.

These revenues have funded some of our personnel and other R&D and General and Administrative costs and expenses. However, it is possible that awards that have been granted are not funded in their entirety. It is also the case that we may not be able to procure new grants and contracts that provide sufficient funding, or at all. In addition, the finalization of new contracts and grants may require a significant time from the initial request and negotiations for

such contracts and grants are subject to a significant amount of uncertainty.

For example, on May 31, 2011, we announced that we had concluded advanced stages of contract negotiation with BARDA for the funding of certain development activities relating to Protectan CBLB502 in our 2010 proposal to BARDA. BARDA has indicated that further contract-related negotiations will require clarification of the development path for Protectan CBLB502 with the FDA, which is in the process of actively reviewing our investigational new drug (“IND”) application for Protectan CBLB502 for biodefense applications. BARDA has indicated that we may resubmit an updated proposal upon confirmation from the FDA that they do not have any objections to us proceeding with our development plan as a result of this review. We are actively working toward obtaining this confirmation in the shortest time period possible. However, as with any federal contract proposal, there is no assurance that our new proposal will result in an award from BARDA.

If we are unable to obtain sufficient grants and contracts on a timely basis or if our existing grants and contracts are not funded, our ability to fund future R&D and implement technological improvements 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.

In addition, 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 U.S. that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Removed and Reserved

Item 5. Other Information

None.

Item 6. Exhibits

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

Exhibit Number	Description of Document
4.1	Form of Warrants (incorporated by reference to Exhibit 4.1 to CBLI's Current Report on Form 8-K filed on June 21, 2011).
10.1	Consulting Agreement, dated January 1, 2010, between Cleveland BioLabs, Inc. and Andrei Gudkov (incorporated by reference to Exhibit 10.1 to CBLI's Current Report on Form 8-K filed on June 13, 2011).
10.2	First Amendment to Consulting Agreement, dated June 10, 2011, between Cleveland BioLabs, Inc. and Andrei Gudkov (incorporated by reference to Exhibit 10.1 to CBLI's Current Report on Form 8-K filed on June 13, 2011).
10.3	Engagement letter, dated as of June 16, 2011, by and between Cleveland BioLabs, Inc. and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.1 to CBLI's Current Report on Form 8-K filed on June 21, 2011).
10.4	Form of Securities Purchase Agreement, dated June 17, 2011, by and between Cleveland BioLabs, Inc. and the investors in the Offering (incorporated by reference to Exhibit 10.1 to CBLI's Current Report on Form 8-K filed on June 21, 2011).
10.5	Amendment of Solicitation/Modification of Contract, effective as of June 23, 2011, between Cleveland BioLabs, Inc. and the U.S. Army Space and Missile Defense Command/Army Forces Strategic Command (incorporated by reference to Exhibit 10.1 to CBLI's Current Report on Form 8-K filed on

June 29, 2011).

- 31.1 Certification of Michael Fonstein, Chief Executive Officer, pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
- 31.2 Certification of Michael Fonstein, Interim Chief Financial Officer, pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
- 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, 2011 formatted in XBRL: (i) Unaudited Consolidated Statements of Operations for the three and six months ended June 30, 2011 and 2010; (ii) Consolidated Balance Sheets as of June 30, 2011 (Unaudited) and December 31, 2010; (iii) Unaudited Consolidated Statements of Stockholders' Equity as of June 30, 2011; (iv) Unaudited Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2011; (v) Unaudited Consolidated Statements of Cash Flows for the six months ended June 30, 2011 and 2010; and (v) Notes to Unaudited Consolidated Financial Statements tagged as blocks of text.**

** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

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 9, 2011

By:

/s/ MICHAEL FONSTEIN
Michael Fonstein
Chief Executive Officer and Interim Chief
Financial Officer
(Principal Executive Officer)
(Principal Financial Officer)