CLEVELAND BIOLABS INC
Form 10-Q
November 09, 2011

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 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	20-0077155
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
73 High Street, Buffalo, New York	14203
(Address of principal executive offices)	(Zip Code)

(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 x
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 x

As of November 5, 2011, there were 35,511,651 shares outstanding of registrant's common stock, par value $0.005 per share.

CLEVELAND BIOLABS INC. AND SUBSIDIARY
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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 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

	September 30, 2011 (unaudited)	December 31, 2010
ASSETS		
CURRENT ASSETS		
Cash and equivalents	$ 25,260,037	$ 10,918,537
Short-term investments	31,372	459,364
Accounts receivable	412,537	5,382,121
Other current assets	963,233	991,062
Total current assets	26,667,179	17,751,084
EQUIPMENT		
Computer equipment	557,223	400,892
Lab equipment	1,754,085	1,528,066
Furniture	522,696	397,013
	2,834,004	2,325,971
Less accumulated depreciation	1,709,790	1,384,847
	1,124,214	941,124
OTHER ASSETS		
Intellectual property	-	1,162,287
Other long-term assets	332,533	32,108
	332,533	1,194,395
TOTAL ASSETS	$ 28,123,926	$ 19,886,603
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable	$ 1,329,026	$ 1,261,493
Deferred revenue	-	349,111
Accrued expenses	634,502	136,163
Accrued bonuses	-	3,321,131
Accrued warrant liability	6,013,294	25,350,733
Total current liabilities	7,976,822	30,418,631
LONG-TERM LIABILITIES		
Deferred revenue	-	1,968,107
Commitments and contingencies - See Note 1	-	-
STOCKHOLDERS' EQUITY (DEFICIT)		
Common stock, $.005 par value		
Authorized - 80,000,000 shares, issued and outstanding		
35,477,531 and 28,959,176 shares at September 30, 2011 and		

December 31, 2010, respectively	177,388	144,796
Additional paid-in capital	108,258,416	80,241,717
Accumulated other comprehensive loss	(81,857)	(30,544)
Accumulated deficit	(92,876,154)	(96,053,977)
Total Cleveland BioLabs, Inc. stockholders' equity (deficit)	15,477,793	(15,698,008)
Noncontrolling interest in stockholders' equity	4,669,311	3,197,873
Total stockholders' equity (deficit)	20,147,104	(12,500,135)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 28,123,926	$ 19,886,603

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	Three months ended		Nine months ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
REVENUES				
Grants and contracts	$3,801,267	$ 3,189,488	$6,844,298	$ 11,570,599
OPERATING EXPENSES				
Research and development	6,522,904	3,083,665	17,441,031	10,951,560
General and administrative	4,239,687	1,073,528	8,104,340	5,664,229
Total operating expenses	10,762,591	4,157,193	25,545,371	16,615,789
LOSS FROM OPERATIONS	(6,961,324)	(967,705)	(18,701,073)	(5,045,190)
OTHER (INCOME)/EXPENSE				
Interest income	52,776	49,448	158,106	62,860
Other income/(expense)	36,555	40,966	(45,257)	(90,584)
Change in value of warrant liability	3,993,439	(6,408,248)	21,094,452	(8,105,544)
Total other income/(expense)	4,082,770	(6,317,834)	21,207,301	(8,133,268)
NET INCOME/(LOSS)	(2,878,554)	(7,285,539)	2,506,228	(13,178,458)
LOSS ATTRIBUTABLE TO NONCONTROLLING INTERESTS	187,213	82,246	671,596	171,494
NET INCOME/(LOSS) ATTRIBUTABLE TO CLEVELAND BIOLABS, INC.	$(2,691,341)	$ (7,203,293)	$3,177,824	$ (13,006,964)
NET INCOME/(LOSS) AVAILABLE TO COMMON SHAREHOLDERS PER SHARE OF COMMON STOCK				
BASIC	$(0.08)	$ (0.27)	$0.10	$ (0.51)
DILUTED	$(0.08)	$ (0.27)	$0.09	$ (0.51)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATING NET INCOME/(LOSS) PER SHARE				
BASIC	35,447,032	26,984,059	31,553,562	25,756,300
DILUTED	35,447,032	26,984,059	36,802,952	25,756,300

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
Nine months ended September 30, 2011
(unaudited)

	Shares	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Noncontrolling Interests	Total
Balance at January 1, 2011	28,959,176	$144,796	$80,241,717	$(30,544)	$(96,053,977)	$3,197,873	$(12,500,135)
Stock based compensation	-	-	5,314,294	-	-	-	5,314,294
Issuance of compensatory shares	178,354	892	740,472	-	-	-	741,364
Exercise of options	186,090	930	526,204	-	-	-	527,134
Exercise of warrants	281,411	1,407	1,943,813	-	-	-	1,945,220
Noncontrolling interest capital contribution to Incuron, LLC	-	-	176,092	-	-	2,164,282	2,340,374
Issuance of common stock net of offering costs of $1,619,638	5,872,500	29,363	21,840,999	-	-	-	21,870,362
Allocation of financing proceeds to fair value of warrants	-	-	(2,525,175)	-	-	-	(2,525,175)
Net income/(loss)	-	-	-	-	3,177,824	(671,596)	2,506,228
Other comprehensive income							
Foreign currency translation	-	-	-	(51,313)	-	(21,249)	(72,562)
Balance at September 30, 2011	35,477,531	$177,388	$108,258,416	$(81,857)	$(92,876,154)	$4,669,311	$20,147,104

See Notes to Consolidated Financial Statements

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

	Three months ended		Nine months ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
Net income/(loss) including noncontrolling interests	$(2,878,554)	$ (7,285,539)	$2,506,228	$ (13,178,458)
Other comprehensive income (loss)				
Foreign currency translation adjustment	(320,005)	95,947	(72,562)	(23,643)
Comprehensive income/(loss) including noncontrolling interests	(3,198,559)	(7,189,592)	2,433,666	(13,202,101)
Comprehensive loss attributable to noncontrolling interests	264,650	66,759	692,845	175,310
Comprehensive income/(loss) attributable to Cleveland BioLabs, Inc.	$(2,933,909)	$ (7,122,833)	$3,126,511	$ (13,026,791)

See Notes to Consolidated Financial Statements

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

	Nine months ended September 30,	
	2011	2010
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income/(loss)	$ 2,506,228	$ (13,178,458)
Adjustments to reconcile net income/(loss) to net cash used in operating activities:		
Depreciation	324,950	290,426
Amortization	13,147	10,801
Noncash compensation	3,063,477	2,782,951
Warrant issuance costs	150,827	231,980
Change in value of warrant liability	(21,094,452)	8,105,544
Patent costs	1,481,318	-
Changes in operating assets and liabilities:		
Accounts receivable	4,969,584	436,109
Other current assets	57,763	(126,372)
Other long-term assets	(890)	(8,689)
Accounts payable	65,753	(882,961)
Deferred revenue	(2,317,218)	(12,570)
Accrued expenses	499,006	(35,019)
Accrued bonuses	(328,951)	-
Net cash used in operating activities	(10,609,458)	(2,386,258)
CASH FLOWS FROM INVESTING ACTIVITIES		
Sale of short-term investments	407,842	-
Issuance of note to Panacela Labs, LLC	(300,000)	-
Purchase of equipment	(508,128)	(384,424)
Investment in patents	(322,544)	(127,074)
Net cash used in investing activities	(722,830)	(511,498)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from issuance of common stock	21,946,801	4,508,673
Noncontrolling interest capital contribution to Incuron, LLC	2,340,374	3,509,402
Exercise of options	527,134	264,079
Exercise of warrants	949,793	86,743
Net cash provided by financing activities	25,764,102	8,368,897
Effect of exchange rate change on cash and equivalents	(90,314)	(22,435)
INCREASE IN CASH AND EQUIVALENTS	14,341,500	5,448,705
CASH AND EQUIVALENTS AT BEGINNING OF PERIOD	10,918,537	963,100
CASH AND EQUIVALENTS AT END OF PERIOD	$ 25,260,037	$ 6,411,805

Supplemental schedule of noncash financing activities:		
Conversion of warrant liability to equity upon warrant exercise	$ 995,428	$ 626,775
Noncash financing costs on common stock offering	$ 207,905	$ 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
(UNAUDITED)

1. Summary of significant accounting policies

Basis of presentation and consolidation

Cleveland BioLabs, Inc. ("CBLI") is a clinical-stage biotechnology company focused on developing biodefense, tissue protection and cancer treatment drugs based on modulation of cell death for therapeutic benefit. The accompanying unaudited consolidated financial statements include the accounts of CBLI and its majority-owned subsidiary, Incuron, LLC ("Incuron") (collectively, the "Company"). All significant intercompany balances and transactions have been eliminated in consolidation.

The unaudited consolidated financial statements included herein have been prepared in accordance with U.S. generally accepted accounting principles 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. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles 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, 2010, as filed with the Securities and Exchange Commission.

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 September 30, 2011, results of operations for the three and nine month periods ended September 30, 2011 and 2010, and cash flows for the nine month periods ended September 30, 2011 and 2010. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Intellectual property

During the quarter ended September 30, 2011, the Company performed its periodic review of capitalized patent costs and incorporated a more restrictive standard of capitalization widely utilized in the biotechnology industry, which includes a prerequisite of the U.S. Food and Drug Administration ("FDA") marketability approval as one of several factors needed to justify the continued capitalization of costs associated with securing patents. Given that the Company is currently developing requisite data towards submission to the FDA of new drug applications on its existing drug candidates, capitalized patent costs of approximately $1.5 million were expensed as general and administrative expenses during the three months ended September 30, 2011. This item has been treated as a change in estimate in the accompanying financial statements.

Revenue recognition

Our revenue sources consist of government grants and government contracts. Under cost reimbursement grants, revenue is recognized during the period that the costs are incurred. Under fixed-cost grants, revenue is recognized using a percentage-of-completion method. The assumptions and estimates used in determination of the percentage-of-completion are developed in coordination with the principal investigator performing the work.

We recognize revenue related to the funds received under a sponsored research agreement with the Roswell Park Cancer Institute as allowable costs are incurred. As of September 30, 2011, all grant revenue available to us under this sponsored research agreement was recognized.

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.

Earnings 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 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 the diluted net loss per common share because the inclusion of such securities would be anti-dilutive.

The following table presents the calculation of basic and diluted earnings (loss) per share for the three and nine months ended September 30, 2011 and 2010:

	Three months ended September 30, 2011	Three months ended September 30, 2010	Nine months ended September 30, 2011	Nine months ended September 30, 2010
Income Available to Common Shareholders	$ (2,691,341)	$ (7,203,293)	$ 3,177,824	$ (13,006,964)
Weighted Average Number of Common Shares Outstanding	35,447,032	26,984,059	31,553,562	25,756,300
Adjustments for Dilutive Securities:				
- Stock Options	-	-	684,765	-
- Warrants	-	-	4,564,625	-
Adjusted Weighted Average Number of Common Shares Outstanding	35,447,032	26,984,059	36,802,952	25,756,300
Basic Earnings Per Share	$ (0.08)	$ (0.27)	$ 0.10	$ (0.51)
Diluted Earnings per Share	$ (0.08)	$ (0.27)	$ 0.09	$ (0.51)

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 nine months ended September 30, 2011and therefore were dilutive. Stock options to purchase 1,086,199 shares of common stock and warrants to purchase 225,000 shares of common stock are not included in the diluted calculation during the nine months ended September 30, 2011 because their exercise prices exceeded the average market price of the stock during the respective periods and, hence, the inclusion of such options and warrants would be anti-dilutive.

Accounting for stock-based compensation

As of September 30, 2011, the Company has a stock-based compensation plan, the 2006 Equity Incentive Plan, as amended (the "Plan"), under which the Company is authorized to grant options to purchase common stock and restricted stock units. The Company determines the fair value of restricted stock units using the closing market price of the Company's common stock on the day prior to the date of grant. The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted. The fair value of each option is estimated on the date of grant. 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:

	Nine months ended September 30, 2011	Nine months ended September 30, 2010
Risk-free interest rate	0.96-2.61 %	1.46-2.75 %
Expected dividend yield	0 %	0 %
Expected life	5-6 years	5-6 Years

Expected volatility	84.28-90.14 %	84.23-89.55 %

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

Expected volatility — 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.

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

Expected average life of options — the period of time that options granted are expected to remain outstanding, based primarily on the use of the Simplified (Safe Harbor) Method.

Comprehensive income (loss)

Comprehensive income (loss) is comprised of net income (loss) attributable to the Company and other changes in equity that are excluded from net income (loss) attributable to the Company. The Company includes gains and losses incurred when converting its subsidiary's financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income (loss).

Reclassifications

Certain amounts presented in the prior year financial statements have been reclassified to conform with the current year presentation.

2. Fair value of financial instruments

The Company measures and records cash equivalents and 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 include:

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 Company used Level 3 inputs for valuation of the outstanding warrants. Fair value was determined using the Black-Scholes valuation model based on the following assumptions as of September 30, 2011:

	Accrued Warrant Liability Value at September 30, 2011	
Stock price	$ 2.53	
Exercise price	$ 2.89	
Term in years	2.18	
Volatility	67.59	%
Annual rate of quarterly dividends	-	
Discount rate- bond equivalent yield	0.28	%

As of September 30, 2011, approximately $6.0 million of accrued warrant liability was measured using Level 3 inputs.

The following table sets forth a summary of changes in the fair value measurements using significant unobservable inputs (Level 3):

Accrued Warrant Liability	Three months ended	Nine months ended

	September 30, 2011	September 30, 2011
Beginning balance	$ 10,006,733	$ 25,350,733
Total gains or losses (realized/unrealized) including in earnings as change in value of warrant liability	(3,993,439)	(21,060,938)
Total amount of realized gains/(losses)	-	(33,514)
Issuances	-	2,752,441
Settlements	-	(995,428)
Ending balance	$ 6,013,294	$ 6,013,294
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 liabilities still held at the reporting date	$ (3,993,439)	$ (21,060,938)

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis, as documented above, from those measured at fair value on a nonrecurring basis. As of September 30, 2011 and December 31, 2010, the Company had no assets or liabilities that were measured at fair value on a nonrecurring basis.

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

3. Noncontrolling Interests

On January 20, 2011 and March 14, 2011, Bioprocess Capital Ventures, the noncontrolling interest in Incuron, contributed 68.0 million Russian Rubles (approximately $2.3 million) and 1.73 million Russian Rubles (approximately $0.1 million), 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%.

4. Stockholders' Equity

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 $23.5 million (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 5,872,500 shares of common stock, 1,468,125 Series E Warrants and 1,468,125 Series F Warrants issued to investors in this offering.

In addition, the placement agent 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.

In addition, the Series F warrants contain provisions that could require the Company to settle the warrants in cash, and accordingly, have been classified as a liability. The fair value of the Series F warrants at issuance 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 $5.28 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 $5.54 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.

The Company has granted options to purchase shares of common stock and has granted restricted stock units under the Plan. As of September 30, 2011, an aggregate of 7.0 million shares of common stock are authorized for issuance under the Plan, of which a total of approximately 1.2 million shares of common stock remain available for future awards to be made to plan participants. The maximum number of shares subject to awards that may be granted per year under the 2006 Plan to a single participant is 400,000. The exercise price of each option must not be less than 100% of the fair market value of the shares underlying such option on the date of grant. 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 determined by the Company's compensation committee, which administers the Plan. Each equity award granted under the Plan vests as specified in the relevant agreement.

The following is a summary of option award activity under the Plan during the nine months ended September 30, 2011:

	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	1,410,159	$ 5.91	
Exercised	(186,090)	$ 2.83	
Forfeited, Canceled	(55,314)	$ 3.61	
Outstanding, September 30, 2011	4,433,195	$ 5.46	7.87
Exercisable, September 30, 2011	3,999,795	$ 5.34	7.79

During the three months ended September 30, 2011 and 2010, the Company granted 396,524 and 175,499 stock options under the Plan, respectively. The Company recognized a total of $675,784 and $387,490 in net expense related to stock options for the three months ended September 30, 2011 and 2010, respectively. The Company granted 102,437 and 40,054 shares of stock under the Plan and recognized a total of $280,054 and $169,224 in expense during the three months ended September 30, 2011 and 2010, respectively.

During the nine months ended September 30, 2011 and 2010, the Company granted 1,410,159 and 1,021,932 stock options under the Plan, respectively. The Company recognized a total of $2,304,162 and $1,292,974 in net expense related to stock options for the nine months ended September 30, 2011 and 2010, respectively. The Company granted 161,407 and 306,919 shares of stock under the Plan and recognized a total of $664,194 and $1,097,808 in expense during the nine months ended September 30, 2011 and 2010, respectively. In addition, the Company granted 11,947 and 34,000 shares of stock and recognized a total of $77,058 and $112,540 in expense related to shares issued during the nine months ended September 30, 2011 and 2010 that were outside of the Plan, respectively.

5. Warrants

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. The following is a summary of warrant activity for the nine months ended September 30, 2011:

	Number of warrants	Weighted average exercise price	Number of common shares exerciseable 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)	592,341
Exercised	(301,895)	3.96	(371,206)
Forfeited, Canceled	(170,000)	8.70	(170,000)

Outstanding at September 30, 2011	10,171,219	$ 3.77	12,614,193

6. Subsequent Events

On October 4, 2011, the Company consummated the transactions contemplated by the Investment Agreement, dated as of September 19, 2011 (the "Investment Agreement"), with Panacela Labs, Inc., a Delaware corporation ("Panacela"), and an open joint stock company organized under the laws of the Russian Federation ("Rusnano"), to provide funding to Panacela for the Project (as defined below). Panacela was incorporated on March 18, 2011 in anticipation of the transactions contemplated by the Investment Agreement and, in particular, to carry out a complete cycle of development, research, performance of clinical trials, production and sales of a line of pharmaceutical drugs for the treatment of oncological, infectious or other diseases (collectively, the "Project").

Pursuant to the Investment Agreement, (i) the Company invested $3.0 million and, together with certain third-party owners, assigned and/or provided exclusive licenses, as applicable, to Panacela in respect of certain intellectual property necessary for the Project and (ii) Rusnano provided $9.0 million to Panacela with additional amounts of up to $17.0 million to be provided by Rusnano upon the achievement of certain development milestones as set forth in the Investment Agreement. The Company and Rusnano also received warrants in Panacela that will provide them with an option to increase their respective investments at two and four years following the initial investment.

Following the closing, the Company has an initial ownership stake of approximately 55% in Panacela. It is anticipated that the Company will retain an ownership stake of approximately 51% in Panacela after giving effect to all subsequent investments by Rusnano, the exercise of all the warrants and the completion of the third party investment. As a result, subsequent to the closing, Panacela became a consolidated subsidiary of the Company.

As of September 30, 2011, the Company had advanced $300,000 to Panacela, which was classified as Other Long-Term Assets on the Balance Sheet. On October 4, 2011, an additional $2.7 million investment was made by the Company in satisfaction of its obligation to invest $3.0 million as referenced above.

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 Item 1A. of our Annual Report on Form 10-K for the year ended December 31, 2010 and our Quarterly Report on Form 10-Q for the period ended June 30, 2011. 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”) is a clinical-stage 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 (a circulatory obstruction). Curaxins are being developed by Incuron, LLC, our majority-owned Russian subsidiary (“Incuron”), as anticancer agents that could act as monotherapy 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 primarily 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, 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.

Severe toxicities of anticancer drugs and radiation and the resulting collateral damage to healthy tissues often limit their use and/or dosage in cancer patients. A drug, which can ameliorate such toxicities, may enable a more aggressive treatment regimen using anticancer drugs and radiation and thereby increase their effectiveness. Our preclinical studies demonstrated that that our drug candidates could temporarily and reversibly suppress apoptosis, which thereby increased resistance of normal tissues to cancer treatment without a decrease of its effect to cancer cells. We also have accumulated animal data suggesting that the same mechanisms utilized by our drug candidates to suppress apoptosis may trigger an innate immune system response to cancers and, thus, have a direct anticancer effect.

Given that our drug candidates appear to suppress apoptotic death of normal cells under stress from radiation and chemotherapy, along with the stimulation of an autoimmune response leading to direct anti-cancer activity, we believe that our drug candidates could have broad clinical potential for 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 defense 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. And as mentioned above, preliminary results suggest that some protectans may also have direct anticancer properties.

- Curaxins - small molecules designed to kill tumor cells by simultaneously targeting two regulators of apoptosis. Initial test results indicate that curaxins may 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, we have achieved high levels of protection in 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. Our most advanced drug candidate, Protectan CBLB502, is under development for acute radiation syndrome targeting approval under the animal rule of the U.S. Food and Drug Administration ("FDA") and has qualified for "Fast Track" status. Curaxin CBLC102 demonstrated activity and safety in a Phase IIa clinical trial concluded in late 2008. A multi-center clinical trial of Curaxin CBLC102 in patients with gastrointestinal and liver tumors in the Russian Federation continues to enroll patients and is expected to report data in 2012.

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 September 30, 2011, we recognized $91,170,466 in R&D expenses. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Financial Overview" 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. We expect to spend substantial additional sums on the continued R&D of proprietary products and technologies with no certainty that we will ever become profitable as a result of our efforts.

The testing, 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 or terminated. Delays in obtaining necessary regulatory approvals for any of our proposed products 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 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 these factors that provides for

rapid preclinical evaluation. We believe these inhibitors may be used as protection from cancer treatment toxicities and antidotes against injuries induced by radiation and other stresses associated with ischemic injury (i.e., heart attack or stroke) or other pathologies.

Our lead protectan drug candidate, Protectan CBLB502, is a rationally designed bio-engineered derivative of a microbial protein that potentially reduces injury from acute stresses, such as radiation and chemotherapy, by mobilizing several natural cell protective mechanisms, including inhibition of apoptosis, reduction of oxidative damage, and induction of regeneration-promoting cytokines. Protectan CBLB502 is being developed under the FDA's Animal Efficacy Rule for reducing the risk of or preventing death following total body irradiation during or after a radiation disaster and was granted Fast Track and Orphan Drug designations from the FDA for this indication. We are currently in discussions with the FDA to determine the scope and design of remaining development steps required to complete a Biologic License Application. In addition, we have recently opened an Investigational New Drug application (“IND”) for clinical testing of Protectan CBLB502 in a variety of oncologic patients.

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 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 that we have 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, and is the focus of our recently announced clinical trial in patients with advanced cancers.

We recently announced the pre-publication of a study in the International Journal of Radiation Oncology, Biology and Physics demonstrating Protectan CBLB502's ability to provide protection against local radiation toxicity in mice and to inhibit tumor growth in mouse tumor models. This work provides the first demonstration of CBLB502's potential radioprotective efficacy in a model of localized irradiation of cancer and shows that it potentially has direct anticancer properties as well.

We also recently announced the publication of a study in The Journal of Immunology demonstrating that CBLB502 may inhibit acute renal ischemic failure. Ischemia-reperfusion injury continues to be a major clinical problem causing significant morbidity and mortality in transplantation as well as in other surgeries. This study and previously collected data on Protectan CBLB502's efficacy against tourniquet-induced injury in animal models further reinforces our belief that Protectan CBLB502 may be efficacious in protecting against ischemic injury.

Curaxins

Curaxins are small molecules that are intended to destroy tumor cells by simultaneously targeting two regulators of apoptosis. A multi-center, Phase I single-dose ascending trial of Curaxin CBLC102 in patients with gastrointestinal and liver tumors in the Russian Federation is expected to be concluded in 2012. A Phase I clinical trial of the oral formulation of next generation Curaxin CBLC137 in solid tumors is planned to start in 2012 in the Russian Federation. An intravenous formulation of the compound is currently being developed to further optimize the bioavailability of CBLC137, with plans to initiate a Phase I trial in the United States as soon as formal preclinical toxicology and other preparations supporting an IND filing are completed.

In August, we announced the publication of findings regarding the mechanisms of action of curaxins in Science Translational Medicine. The findings highlighted by this publication introduce the possibility of both a novel anticancer target and a new class of DNA intercalators that may exert their function without genotoxic effects.

Recent Developments

On October 4, 2011, the Company consummated the transactions contemplated by the Investment Agreement, dated as of September 19, 2011 (the “Investment Agreement”), with Panacela Labs, Inc., a Delaware corporation (“Panacela”), and an open joint stock company organized under the laws of the Russian Federation (“Rusnano”), to provide funding to Panacela for the Project (as defined below). Panacela was incorporated on March 18, 2011 in anticipation of the transactions contemplated by the Investment Agreement and, in particular, to carry out a complete cycle of development, research, performance of clinical trials, production and sales of a line of pharmaceutical drugs for the treatment of oncological, infectious or other diseases (collectively, the “Project”).

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Pursuant to the Investment Agreement, (i) the Company invested $3.0 million and, together with certain third-party owners, assigned and/or provided exclusive licenses, as applicable, to Panacela in respect of certain intellectual property necessary for the Project and (ii) Rusnano provided $9.0 million to Panacela with additional amounts of up to $17.0 million to be provided by Rusnano upon the achievement of certain development milestones as set forth in the Investment Agreement. The Company and Rusnano also received warrants in Panacela that will provide them with an option to increase their respective investments at two and four years following the initial investment.

Following the closing, the Company has an initial ownership stake of approximately 55% in Panacela. It is anticipated that the Company will retain an ownership stake of approximately 51% in Panacela after giving effect to all subsequent investments by Rusnano, the exercise of all the warrants and the completion of the third party investment. As a result, subsequent to the closing, Panacela is a consolidated subsidiary of the Company.

FINANCIAL OVERVIEW

The following table sets forth our statement of operations data for the three and nine months ended September 30, 2011 and 2010 and should be read in conjunction with our financial statements and the related notes appearing elsewhere in this filing.

	Three months ended September 30, 2011	Three months ended September 30, 2010	Nine months ended September 30, 2011	Nine months ended September 30, 2010
Revenues	$ 3,801,267	$ 3,189,488	$ 6,844,298	$ 11,570,599
Operating expenses	10,762,591	4,157,193	25,545,371	16,615,789
Other expense (income)	(4,029,994)	6,367,282	(21,049,195)	8,196,128
Net interest expense (income)	(52,776)	(49,448)	(158,106)	(62,860)
Net loss	$ (2,878,554)	$ (7,285,539)	$ 2,506,228	$ (13,178,458)

Critical Accounting Policies

We prepare our financial statements in conformity with accounting principles generally accepted in the United States. Such accounting principles require that our management make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Our actual results could differ materially from those estimates. The items in our financial statements that have required us to make significant estimates and judgments are as follows:

Revenue recognition

Our primary revenue sources consist of government grants and government contracts. Under cost reimbursement grants, revenue is recognized during the period that the costs are incurred. Under fixed-cost grants, revenue is recognized using a percentage-of-completion method. The assumptions and estimates used in determination of the percentage-of-completion are developed in coordination with the principal investigator performing the work.

Costs of pre-clinical studies and clinical trials

We accrue estimated costs for pre-clinical studies and clinical trials conducted by contract research organizations and participating hospitals. These costs are a significant component of R&D expenses. We accrue costs for pre-clinical studies and clinical trials performed by contract research organizations based on estimates of work performed under the contracts. Costs of setting up hospital sites for participation in trials are accrued immediately. Hospital costs related to patient enrollment are accrued as patients are entered in the trial.

Share-based payment

We account for share-based compensation based on the estimated grant date fair value of the award using the Black-Scholes option-pricing model. The estimated grant date fair value is recognized over the requisite service period. Determining the appropriate fair value model and calculating the fair value of share-based payment awards require the input of highly subjective assumptions, including the expected life of the share-based payment awards and stock price volatility. Since our historical data is limited, the expected life was determined in accordance with SEC Staff Accounting Bulletin No. 107 guidance for "plain vanilla" options. We estimated the expected volatility based on closing prices of our common stock for a period consistent with the expected life of the option. In those cases where the expected life of the option exceeds the trading history of the Company then the volatility of the common stock of comparable companies is layered in with that of the Company. The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future. See Note 1 to the consolidated financial statements for a further discussion on stock-based compensation and the relative ranges of our historical, underlying assumptions.

Research and development

We expense R&D costs as they are incurred. Our R&D expenses consist primarily of:

- personnel-related expenses;
- fees to professional service providers for, among other things, preclinical and analytical testing, independently monitoring our clinical trials and acquiring and evaluating data from our clinical trials and non-clinical studies;
- costs of contract manufacturing services for clinical trial material;
- costs of materials used in clinical trials and R&D;
- depreciation of capital assets used to develop our products; and
- facility operational costs.

We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to be in a position to realize the potential of our product candidates. We expect that spending for our product pipeline will increase as our product development activities continue based on ongoing advancement of our product candidates, and as we prepare for regulatory submissions and other regulatory activities. We expect that the magnitude of any increase in our R&D spending will be dependent upon such factors as the results from our ongoing preclinical studies and clinical trials, the size, structure and duration of any follow-on clinical programs that we may initiate, and costs associated with manufacturing our product candidates on a large-scale basis.

General and administrative

General and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, sales and marketing, business development, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in R&D expense and professional fees for accounting and legal services, including the legal costs in support of our intellectual property applications.

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

Revenue

Revenue increased from $3,189,488 for the three months ended September 30, 2010 to $3,801,267 for the three months ended September 30 2011, representing an increase of $611,779 or 19.2%. This increase was due to an increase in research sponsored by the U.S. Department of Defense (“DoD”) of $655,726, and an increase in research sponsored by the Roswell Park Cancer Institute (“RPCI”) of $2,304,579, partially offset by a decrease in research sponsored by the U.S. Biomedical Advanced Research Development Authority (“BARDA”) of $2,348,526.

Operating Expenses

Operating expenses increased from $4,157,193 for the three months ended September 30, 2010 to $10,762,591 for the three months ended September 30, 2011, representing an increase of $6,605,398 or 158.9%. We recognized a total of $933,589 of non-cash, stock-based compensation for the three months ended September 30, 2011 compared to $560,049 for the three months ended September 30, 2010. We recognized a total of $114,939 in depreciation and amortization charges for the three months ended September 30, 2011 compared to $101,550 for the three months ended September 30, 2010. We recognized $1,481,318 in expense in connection with our change in estimates on capitalized patents for the three months ended September 30, 2011 compared to $0 for the three months ended September 30, 2010, as more fully described in Note 1 to the consolidated financial statements. If these non-cash expenses were excluded, operating expenses would have increased from $3,495,594 for the three months ended

September 30, 2010 to $8,232,745 for the three months ended September 30, 2011. This would have represented an increase in operating expenses of $4,737,206 or 135.5% as explained below.

R&D costs increased from $3,083,665 for the three months ended September 30, 2010 to $6,522,904 for the three months ended September 30, 2011. This represents an increase of $3,439,239 or 111.5%. We recognized a total of $250,792 of R&D non-cash, stock based compensation for the three months ended September 30, 2011 compared to $291,879 for the three months ended September 30, 2010. We recognized a total of $94,217 in R&D depreciation and amortization charges for the three months ended September 30, 2011 compared to $80,205 for the three months ended September 30, 2010. Without the non-cash expenses, the R&D expenses would have increased from $2,711,582 for the three months ended September 30, 2010 to $6,177,895 for the three months ended September 30, 2011, representing an increase of $3,466,313 or 127.8%. The higher R&D expenses primarily resulted from increased R&D efforts by Incuron for a multi-center clinical trial with Curaxin CBLC102 that commenced patient enrollment towards the end of 2010, increases in expenditures to support preclinical animal studies for Protectan CBLB502 for defense applications and for Protectan CBLB612, increases in expenditures relating to manufacturing of Protectan CBLB502, and increases in expenditures relating to preparation for initiation of clinical studies for medical applications of Protectan CBLB502.

	Three months ended September 30, 2011	Three months ended September 30, 2010	Increase (Decrease)
General R&D	$ 332,144	$ 64,356	$ 267,788
Protectan CBLB502 - Defense applications	5,549,454	2,689,779	2,859,675
Protectan CBLB502 - medical applications	111,086	-	111,086
Protectan CBLB612	243,168	5,103	238,065
Curaxin CBLC102	146,144	86,131	60,013
Other Curaxins	140,908	238,296	(97,388)
Total R&D	$ 6,522,904	$ 3,083,665	$ 3,439,239

General and administrative costs increased from $1,073,528 for the three months ended September 30, 2010 to $4,239,687 for the three months ended September 30, 2011. This represents an increase of $3,166,159 or 294.9%. We recognized a total of $682,797 of non-cash, stock-based compensation under general and administrative costs for the three months ended September 30, 2011 compared to $268,170 for the three months ended September 30, 2010. We recognized a total of $20,722 in depreciation and amortization charges under general and administrative costs for the three months ended September 30, 2011 compared to $17,225 for the three months ended September 30, 2010. We recognized $1,481,318 in expense for the change in estimates on patents for the three months ended September 30, 2011 compared to $0 for the three months ended September 30, 2010. Without the non-cash expenses, the general and administrative expenses would have increased from $784,012 for the three months ended September 30, 2010 to $2,054,850 for the three months ended September 30, 2011, representing an increase of $1,270,838 or 162.1%. This increase is due to expenses arising from an increase and change in the timing of our investor relations activities resulting from the challenging financial market environment of approximately $250,000; a tax credit recognized in 2010 of approximately $240,000; costs associated with the prosecution of patents, which the Company no longer capitalizes as referenced above and costs associated with the consummation of the Panacela transaction, referenced above, both totaling approximately $221,000; an increase in personnel related expenses, including personnel for Incuron, of approximately $165,000; expenses relating to severance and outside consulting services in connection with our chief financial officer transition of approximately $135,000; and other cost increases of approximately $260,000.

Other Income

Other income increased from an expense of $6,317,834 to income of $4,082,770 for the three months ended September 30, 2011, representing an increase of $10,400,604 or 164.6%. This increase was primarily attributable to the periodic fair vauluation of the Company's warrant liability which was a non-cash expense of $6,408,248 for the three months ended Septmeber 30, 2010 as compared to a non-cash gain of $3,993,439 for the three months ended September 30, 2011.

Nine Months Ended September 30, 2011 Compared to Nine Months Ended September 30, 2010

Revenue

Revenue decreased from $11,570,599 for the nine months ended September 30, 2010 to $6,844,298 for the nine months ended September 30 2011, representing a decrease of $4,726,301 or 40.8%. This resulted from a decrease in research sponsored by BARDA of $8,552,002, which was partially offset by an increase in research sponsored by DoD of $1,521,053, and an increase in research sponsored by RPCI of $2,304,648.

Operating Expenses

Operating expenses increased from $16,615,789 for the nine months ended September 30, 2010 to $25,545,371 for the nine months ended September 30, 2011, representing an increase of $8,929,582 or 53.7%. We recognized a total of $3,063,477 of non-cash, stock-based compensation for the nine months ended September 30, 2011 compared to $3,753,152 for the nine months ended September 30, 2010. We recognized a total of $338,097 in depreciation and amortization charges for the nine months ended September 30, 2011 compared to $301,227 for the nine months ended September 30, 2010. We recognized $1,481,318 in expense for the change in estimates on patents for the three months ended September 30, 2011 compared to $0 for the three months ended September 30, 2010, as more fully described in Note 1 to the consolidated financial statements. If these non-cash expenses were excluded, operating expenses would have increased from $12,561,410 for the nine months ended September 30, 2010 to $20,662,479 for the nine months ended September 30, 2011. This would have represented an increase in operating expenses of $8,101,069 or 64.5% as explained below.

R&D costs increased from $10,951,560 for the nine months ended September 30, 2010 to $17,441,031 for the nine months ended September 30, 2011. This represents an increase of $6,489,471 or 59.3%. We recognized a total of $1,412,248 of R&D non-cash, stock based compensation for the nine months ended September 30, 2011 compared to $648,735 for the nine months ended September 30, 2010. We recognized a total of $265,070 in R&D depreciation and amortization charges for the nine months ended September 30, 2011 compared to $238,320 for the nine months ended September 30, 2010. Without the non-cash expenses, the R&D expenses would have increased from $10,064,505 for the nine months ended September 30, 2010 to $15,763,713 for the nine months ended September 30, 2011, representing an increase of $5,669,208 or 56.6%. The higher R&D expenses primarily resulted from increased R&D efforts by Incuron for a multi-center clinical trial with Curaxin CBLC102 that commenced patient enrollment towards the end of 2010, increases in expenditures to support preclinical animal studies for Protectan CBLB502 for defense applications and for Protectan CBLB612, increases in expenditures relating to manufacturing of Protectan CBLB502, and increases in expenditures relating to preparation for initiation of clinical studies for medical applications of Protectan CBLB502.

	Nine months ended September 30, 2011	Nine months ended September 30, 2010	Increase (Decrease)
General R&D	$ 657,467	$ 201,477	$ 455,990
Protectan CBLB502 - Defense applications	14,463,477	10,016,092	4,447,385
Protectan CBLB502 - medical applications	133,857	-	133,857
Protectan CBLB612	253,684	5,103	248,581
Curaxin CBLC102	1,229,275	288,061	941,214
Other Curaxins	703,271	440,827	262,444
Total R&D	$ 17,441,031	$ 10,951,560	$ 6,489,471

General and administrative costs increased from $5,664,229 for the nine months ended September 30, 2010 to $8,104,340 for the nine months ended September 30, 2011. This represents an increase of $2,440,111 or 43.1%. We recognized a total of $1,651,229 of non-cash, stock-based compensation under general and administrative costs for the nine months ended September 30, 2011 compared to $2,134,216 for the nine months ended September 30, 2010. We recognized a total of $73,027 in depreciation and amortization charges under general and administrative costs for the nine months ended September 30, 2011 compared to $62,907 for the nine months ended September 30, 2010. We recognized $1,481,318 in expense for the change in estimates on patents for the nine months ended September 30, 2011 compared to $0 for the three months ended September 30, 2010. Without the non-cash expenses, the general and administrative expenses would have increased from $3,467,106 for the nine months ended September 30, 2010 to $4,898,766 for the nine months ended September 30, 2011, representing an increase of $1,431,661 or 41.3%. This increase is due to an increase in personnel related expenses of approximately $269,000 for Incuron which commenced operations in May 2010 and approximately $402,000 for CBLI; costs associated with the prosecution of patents, which the Company no longer capitalizes as referenced above and costs associated with the creation of Panacela and the consummation of the Panacela transaction, as described above, both totaling approximately $270,000; a tax credit recognized in 2010 of approximately $240,000; expenses related to severance and outside consulting services in connection with our chief financial officer transition of approximately $135,000; expenses related to an increase in our year-to-date investor relations activities resulting from the challenging financial market environment of approximately $90,000; and other cost increases of approximately $26,000.

Other Income/Expense

Other income increased from an expense of $8,133,268 to income of $21,207,301 for the nine months ended September 30, 2011, representing an increase of $29,340,569 or 360.7%. This increase in other income was primarily attributable to the periodic fair valuation of the Company's warrant liability which was a non-cash expense of $8,105,544 for the nine months ended September 30, 2010 as compared to a non-cash gain of $21,094,452 for the nine months ended September 30, 2011.

Liquidity and Capital Resources

Our total cash and equivalents, short-term investments and accounts receivable increased from $16,760,022 at December 31, 2010 to $25,703,946 at September 30, 2011. This increase of $8,943,924 or 53.4% 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.

We have incurred annual operating losses since our inception, and, as of September 30, 2011, we had an accumulated deficit of $92,876,154. 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 $10,609,438 for the nine months ended September 30, 2011, compared to $2,386,259 used in operating activities for the nine months ended September 30, 2010. This increase in cash used in operating activities resulted from increased activities on the part of our consolidated subsidiary, Incuron for a milti-center clinical trial with Curaxin CBLC102 that commenced patient enrollment towards the end of 2010, pre-clinical animal studies for Protectan CBLB502 for defense applications and Protectan CBLB612, increases in expenditures relating to manufacturing of Protectan CBLB502, and increases in expenditures relating to preparation for initiation of clinical studies for medical applications of Protectan CBLB502, combined with a reduction in sponsored research funding by BARDA.

Net cash used in investing activities was $722,830 for the nine months ended September 30, 2011, compared to net cash used in investing activities of $511,499 for the nine months ended September 30, 2010. The increase in cash used in investing activities resulted from increased investment in equipment and intellectual property in the first nine months of 2010 as compared to the first nine months of 2010, a loan to Panacela's as more fully described in Note 6 to the consolidated financial statements, partially offset by a reduction in our short-term investments..

Net cash provided by financing activities totaled $25,764,102 for the nine months ended September 30, 2011, compared to net cash provided by financing activities of $8,368,897 for the nine months ended September 30, 2010. This increase in cash provided by financial activities was primarily attributed to the larger June 2011 equity offering that took place in the first nine months of 2011 as compared to the March 2010 equity offering that took place in the first nine months of 2010.

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

From time-to-time our operations are somewhat dependent upon changes in foreign currency exchange rates, however at September 30, 2011, we were not obligated to make payments in foreign currencies.

Off-Balance Sheet Arrangements

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

Item 3: Quantitative and Qualitative Disclosures About Market Risk

There has been no significant change in our exposure to market risk during the first nine 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 and Part II, Item 1.A. of our Quarterly Report on Form 10-Q for the period ended June 30, 2011.

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

Item 1A. Risk Factors

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 and our previously filed Quarterly Reports on Form 10-Q. 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 and Part II, Item 1.A. of our Quarterly Report on Form 10-Q for the period ended June 30, 2011.

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
10.1	Investment Agreement, dated September 19, 2011, by and among Panacela Labs, Inc., the Registrant and Open Joint Stock Company Rusnano.
10.2	Exclusive License and Option Agreement, dated September 23, 2011, by and between Children’s Cancer Institute Australia for Medical Research and Panacela Labs, Inc.†
10.3	Second Amendment to Exclusive License Agreement, dated September 22, 2011, by and between The Cleveland Clinic Foundation and the registrant.†
10.4	Exclusive License and Option Agreement, dated September 23, 2011, by and between Health Research, Inc., Roswell Park Institute Division, Roswell Park Cancer Institute Corporation, and Panacela Labs, Inc.†
10.5	

	Amended and Restated Exclusive Sublicense Agreement, dated September 23, 2011, by and between the registrant and Panacela Labs, Inc.
10.6	Exclusive Sublicense Agreement, dated September 23, 2011, by and between the registrant and Panacela Labs, Inc.
10.7	Assignment Agreement, dated September 23, 2011, by and between Panacela Labs, Inc. and the registrant.
31.1	Certification of Michael Fonstein, Chief Executive Officer, pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
31.2	Certification of C. Neil Lyons, 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 September 30, 2011 formatted in XBRL: (i) Unaudited Consolidated Statements of Operations for the three and nine months ended September 30, 2011 and 2010; (ii) Consolidated Balance Sheets as of September 30, 2011 (Unaudited) and December 31, 2010; (iii) Unaudited Consolidated Statements of Stockholders' Equity as of September 30, 2011; (iv) Unaudited Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2011; (v) Unaudited Consolidated Statements of Cash Flows for the nine months ended September 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.

† Confidential treatment has been requested from the Securities and Exchange Commission as to certain portions of this document.

Signatures

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

CLEVELAND BIOLABS, INC.

Dated: November 9, 2011	By:	/s/ MICHAEL FONSTEIN Michael Fonstein Chief Executive Officer (Principal Executive Officer)
Dated: November 9, 2011	By:	/s/ C. NEIL LYONS C. Neil Lyons Chief Financial Officer (Principal Financial Officer)