CLEVELAND BIOLABS INC
Form 10-Q
May 10, 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 March 31, 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 ¨ 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 May 5, 2011, there were 29,403,640 shares outstanding of registrant's common stock, par value $0.005 per share.

CLEVELAND BIOLABS INC. AND SUBSIDIARY
10-Q
5/10/2011

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

March 31, 2011 (unaudited) and December 31, 2010

	March 31 2011	December 31 2010
ASSETS		
CURRENT ASSETS		
Cash and equivalents	$12,018,806	$ 10,918,537
Short-term investments	1,934,644	459,364
Accounts receivable	2,252,969	5,382,121
Other current assets	629,289	991,062
Total current assets	16,835,708	17,751,084
EQUIPMENT		
Computer equipment	453,696	400,892
Lab equipment	1,576,711	1,528,066
Furniture	463,686	397,013
	2,494,093	2,325,971
Less accumulated depreciation	1,488,364	1,384,847
	1,005,729	941,124
OTHER ASSETS		
Intellectual property	1,288,560	1,162,287
Other long term assets	14,812	-
Deposits	33,570	32,108
	1,336,942	1,194,395
TOTAL ASSETS	$19,178,379	$ 19,886,603

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

March 31, 2011 (unaudited) and December 31, 2010

	March 31 2011	December 31 2010
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$1,281,125	$1,261,493
Deferred revenue	365,963	349,111
Accrued expenses	136,605	136,163
Accrued bonuses	-	3,321,131
Accrued warrant liability	25,118,146	25,350,733
Total current liabilities	26,901,838	30,418,631
LONG TERM LIABILITIES		
Deferred revenue	1,947,042	1,968,107
Total long term liabilities	1,947,042	1,968,107
Commitments and contingencies - See Note 4		
STOCKHOLDERS' EQUITY		
Common stock, $.005 par value		
Authorized - 80,000,000 shares at March 31, 2011 and December 31, 2010		
Issued and outstanding 29,377,293 and 28,959,176 shares at March 31, 2011 and December 31, 2010, respectively	146,887	144,796
Additional paid-in capital	86,446,246	80,241,717
Accumulated other comprehensive income (loss)	127,852	(30,544)
Accumulated deficit	(101,553,037)	(96,053,977)
Total Cleveland BioLabs, Inc. stockholders' equity	(14,832,052)	(15,698,008)
Noncontrolling Interest in stockholders' equity	5,161,551	3,197,873
Total stockholders' equity	(9,670,501)	(12,500,135)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$19,178,379	$19,886,603

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

Three Months Ended March 31, 2011 and 2010 (unaudited)

	Three Months Ended	
	March 31 2011	March 31 2010
REVENUES		
Grant and contract	$2,473,982	$4,170,348
	2,473,982	4,170,348
OPERATING EXPENSES		
Research and development	5,708,933	3,697,780
Selling, general and administrative	1,877,202	1,929,501
Total operating expenses	7,586,135	5,627,281
LOSS FROM OPERATIONS	(5,112,153)	(1,456,933)
OTHER INCOME		
Interest income	38,259	5,773
Other income	63,961	50,225
Total other income	102,220	55,998
OTHER EXPENSE		
Other expense	20,482	231,980
Change in value of warrant liability	714,951	1,731,096
Total other expense	735,433	1,963,076
NET LOSS	$(5,745,366)	$(3,364,011)
LOSS ATTRIBUTABLE TO NONCONTROLLING INTERESTS	(246,307)	-
NET LOSS ATTRIBUTABLE TO CLEVELAND BIOLABS, INC.	$(5,499,059)	$(3,364,011)
NET LOSS AVAILABLE TO COMMON SHAREHOLDERS PER SHARE OF COMMON STOCK - BASIC AND DILUTED	$(0.19)	$(0.14)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATING NET LOSS PER SHARE, BASIC AND DILUTED	29,110,979	23,512,617

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

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

	Stockholders' Equity			
	Common Stock		Preferred Stock Series D	
	Shares	Amount	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 offering	-	-	-	-
Issuance of shares – December 2010 financing	1,400,000	7,000	-	-
Fees associated with December 2010 offering	-	-	-	-
Conversion of Series D Preferred Shares to Common	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	45,361	227	-	-
Recapture of expense for nonvested options forfeited	-	-	-	-
Exercise of options	113,369	567	-	-
Exercise of warrants	259,387	1,297	-	-
Warrant exercise fees	-	-	-	-
Noncontrolling interest capital contribution to Incuron, LLC	-	-	-	-
Net Loss	-	-	-	-

Other comprehensive income						
Foreign currency translation	-		-	-		-
Balance at March 31, 2011	29,377,293	$	146,887	-	$	-

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

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

	Stockholders' Equity				
	Additional Paid-in Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Equity	Noncontrolling Interests	Total
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 offering	(578,118)	-	-	-	(578,118)
Issuance of shares - December 2010 financing	8,379,000	-	-	-	8,386,000
Fees associated with December 2010 offering	(659,980)	-	-	-	(659,980)
Conversion of Series D Preferred Shares to Common	(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	3,647,509	-	-	-	3,647,509
Issuance of shares	283,706	-	-	-	283,933
Recapture of expense for nonvested options forfeited	(16,227)	-	-	-	(16,227)
Exercise of options	306,778	-	-	-	307,345
Exercise of warrants	1,837,877	-	-	-	1,839,174

Warrant exercise fees	(31,207)	-	-	-	(31,207)
Noncontrolling interest capital contribution to Incuron, LLC	176,092	-	-	2,164,282	2,340,374
Net Loss	-	-	(5,499,059)	(246,307)	(5,745,366)
Other comprehensive income					
Foreign currency translation	-	158,396	-	45,703	204,099
Balance at March 31, 2011	$86,446,246	$ 127,852	$(101,553,037)	$ 5,161,551	$(9,670,501)

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Three Months Ended March 31, 2011 and 2010 (unaudited)

	Three Months Ended	
	March 31 2011	March 31 2010
Net loss including noncontrolling interests	$(5,745,366)	$(3,364,011)
Other comprehensive income		
Foreign currency translation adjustment	204,099	-
Comprehensive loss including noncontrolling interests	(5,541,267)	(3,364,011)
Comprehensive loss attributable to noncontrolling interests	(200,604)	-
Comprehensive loss attributable to Cleveland BioLabs, Inc.	$(5,340,663)	$(3,364,011)

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

Three Months Ended March 31, 2011 and 2010 (unaudited)

	March 31 2011 (unaudited)	March 31 2010 (unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(5,745,366)	$(3,364,011)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	103,501	98,307
Amortization	6,892	2,417
Noncash salaries and consulting expense	3,915,215	936,690
Warrant issuance costs	-	231,980
Change in value of warrant liability	714,951	1,731,096
Changes in operating assets and liabilities:		
Accounts receivable	3,129,152	677,848
Other current assets	364,824	(114,326)
Other long term assets	(14,812)	-
Deposits	(816)	-
Accounts payable	11,202	(349,285)
Deferred revenue	(4,213)	(4,144)
Accrued expenses	(1,623)	(5,366)
Accrued bonuses	(3,321,131)	-
Net cash used in operating activities	(842,224)	(158,794)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of short-term invesments	(1,442,189)	-
Purchase of equipment	(167,966)	(145,225)
Costs of patents pending	(120,215)	(35,905)
Net cash used in investing activities	(1,730,370)	(181,130)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	-	5,000,002
Noncontrolling interest capital contribution to Incuron, LLC	2,340,374	-
Financing costs on common stock offering	-	(350,632)
Cash warrant issuance costs	-	(140,697)
Exercise of options	307,345	52,837
Warrant exercise fees	(31,207)	-
Exercise of warrants	891,635	29,601
Net cash provided by financing activities	3,508,147	4,591,111
Effect of exchange rate change on cash and equivalents	164,716	-
INCREASE IN CASH AND EQUIVALENTS	1,100,269	4,251,187

CASH AND EQUIVALENTS AT BEGINNING OF PERIOD	10,918,537	963,100
CASH AND EQUIVALENTS AT END OF PERIOD	$12,018,806	$5,214,287

See Notes to Consolidated Financial Statements

CLEVELAND BIOLABS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

Three Months Ended March 31, 2011 and 2010 (unaudited)

	March 31 2011 (unaudited)	March 31 2010 (unaudited)
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	$3,647,509	$330,246
Issuance of shares	$283,933	$641,898
Recapture of expense for nonvested options forfeited	$(16,227)	$(38,787)
Conversion of warrant liability to equity upon warrant exercise	$947,538	$64,615
Noncash financing costs on common stock offering	$-	$227,486
Noncash warrant issuance costs	$-	$91,283
Amortization of restricted stock awards	$-	$3,333

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 (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 under the laws of the State of Delaware on June 5, 2003 and is headquartered in Buffalo, New York.

The consolidated financial statements include the accounts of CBLI’s majority-owned, Russian subsidiary, Incuron, LLC (“Incuron”), a limited liability company formed on January 31, 2010 in the Russian Federation. All intercompany balances and transactions have been eliminated in consolidation.

In May 2010, CBLI contributed certain intellectual property rights to Incuron in exchange for an 83.9% membership interest. The minority partner, Bioprocess Capital Ventures (“BCV”), contributed a total of 105,840,000 Russian Rubles (approximately $3.7 million based on the current exchange rate) during April and June of 2010 in exchange for the remaining 16.1% membership interest. Incuron was formed to develop CBLI’s curaxin technology for certain medical applications including oncology. On January 20, 2011, BCV contributed 68,000,000 Russian Rubles (approximately $2.4 million based on the current exchange rate) and on March 14, 2011 the remaining initial capital contribution of 1,730,000 Russian Rubles (approximately $0.1 million based on the current exchange rate) was made by BCV which increased their ownership percentage to 24.2% and decreased CBLI’s ownership percentage to 75.8%.

As of March 31, 2011, the participation agreement between CBLI and BCV entered in December 2009 and amended in April 2010 required (i) further contributions up to 373,927,000 Russian Rubles (approximately $13.2 million based on the current exchange rate) by BCV contingent on the achievement of pre-determined scientific milestones, and (ii) contingent contributions by CBLI to preserve CBLI’s intended ultimate membership interest in Incuron of 50.1%. Incuron commenced operations in May 2010 and the results of its research and development efforts have been included in the Company’s results of operations since that date.

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 in the foreseeable future.

Note 2. Summary of Significant Accounting Policies

A. Basis of Presentation - The information at March 31, 2011 and for the three months ended March 31, 2011 and March 31, 2010, is unaudited. 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 for the year ended December 31, 2010, which were contained in the Company’s Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC").

B. Cash and Equivalents - The Company considers highly liquid investments with a maturity date of three months or less to be cash equivalents.

C. Short-term Investments – The Company's short-term investments are classified as held to maturity given the intent and ability to hold the investments to maturity. Accordingly, these investments are carried at amortized cost. As of March 31, 2011 and December 31, 2010, short-term investments classified as held-to-maturity totaled $1,934,644 and $459,364, respectively, and consisted of certificates of deposit with maturity dates beyond three months and less than one year.

D. Accounts Receivable - The Company extends unsecured credit to customers under normal trade agreements, which generally require payment within 30 days. Management estimates an allowance for doubtful accounts which is based upon management's review of delinquent accounts and an assessment of the Company's historical evidence of collections. There is no allowance for doubtful accounts as of March 31, 2011 and December 31, 2010.

E. Equipment - Equipment and furniture is stated at cost and depreciated over the estimated useful lives of the assets (generally five years) using the straight-line method. Expenditures for maintenance and repairs are charged to expense as incurred. Major expenditures for renewals and betterments are capitalized and depreciated. Depreciation expense was $103,501 and $98,307 for the three months ended March 31, 2011 and 2010, respectively.

F. Impairment of Long-Lived Assets - Long-lived assets to be held and used, including equipment and intangible assets subject to depreciation and amortization, are reviewed for impairment at least annually and whenever events or changes in circumstances indicate that the carrying amounts of the assets or related asset group may not be recoverable. Determination of recoverability is based on an estimate of discounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset or asset group, the carrying amount of the asset is written down to its estimated net realizable value.

G. Intellectual Property - The Company capitalizes the costs associated with the preparation, filing, and maintenance of patent applications relating to intellectual property. If the patent applications are approved, costs paid by the Company associated with the preparation, filing, and maintenance of the patents are amortized on a straight-line basis over the shorter of 20 years from the date of the initial application or the anticipated useful life of the patent. If the patent application is not approved, the costs associated the patent application are expensed as part of selling, general and administrative expenses at that time.

A portion of the Company's intellectual property is owned by the Cleveland Clinic Foundation ("CCF") and granted to the Company through an exclusive licensing agreement. As part of the licensing agreement, the Company agreed to bear the costs associated with the preparation, filing and maintenance of patent applications relating to the intellectual property being developed. Gross capitalized patents and patents pending costs relating to the CCF patents were $954,489 and $886,418 for eleven patent applications as of March 31, 2011 and December 31, 2010, respectively. Three of the CCF patent applications were approved by several nations and are being amortized on a straight-line basis over the weighted average estimated remaining life of approximately fourteen years. Related amortization expense amounted to $6,892 and $2,417 for the three months ended March 31, 2011 and 2010, respectively. The remainder of the CCF patent applications are pending approval.

The Company has also submitted patent applications as a result of intellectual property exclusively developed and owned by the Company. Gross capitalized patents pending costs were $208,233 and $197,757 for three patent applications as of March 31, 2011 and December 31, 2010, respectively. The patent applications are pending approval. During 2010, one patent application was combined with another patent application submitted in collaboration with the Roswell Park Cancer Institute ("RPCI").

The Company and RCPI have also submitted five patent applications as a result of the collaborative research agreement with RPCI. As part of this collaborative agreement, the Company agreed to bear the costs associated with the preparation, filing and maintenance of patent applications for three of these patent applications and RPCI agreed to bear the costs of the other two patent applications. Gross capitalized patents pending costs for the Company were $155,154 and $100,536 for three patent applications as of March 31, 2011 and December 31, 2010, respectively.

Below is a summary of the major identifiable intangible assets and weighted average amortization periods for each identifiable asset.

	As of March 31, 2011			
Intangible Assets	Cost	Accumulated Amortization	Net Intangible Asset	Weighted Average Amortization Period (Years)
Patents	$ 388,704	$ 29,316	$ 359,388	13.7
Patent applications	929,172	-	929,172	n.a.
	$ 1,317,876	$ 29,316	$ 1,288,560	

The estimated amortization expense for the next five years for approved patents is as follows:

2011	$26,267
2012	$26,267
2013	$26,267
2014	$26,267
2015	$26,267

H. Line of Credit - The Company has a working capital line of credit that is fully secured by cash equivalents and short-term investments. The working capital line of credit carries an interest rate of prime minus 1%, a borrowing limit of $600,000, and expires on May 31, 2011. At March 31, 2011 and December 31, 2010 there were no outstanding borrowings under this credit facility.

I. Accrued Warrant Liability – The Company issued warrants as part of the Series D Private Placement (as defined in Note 3) and as part of the March 2010 Common Stock Equity Offering (as defined in Note 3). The warrants are accounted for as derivative instruments in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("Codification") on derivatives and hedging as the warrant holders maintain full-ratchet anti-dilution protection and therefore the warrants are not considered indexed to CBLI's stock. The warrants are initially recorded as accrued warrant liabilities based on their fair values on the date of issuance. Subsequent changes in the value of the warrants are shown in the statements of operations as "Change in value of warrant liability."

The Series D Private Placement warrants carry a seven-year term, expire on February 12, 2016, March 19, 2016 and March 26, 2016 and are exercisable for common shares of the Company at $1.60 per share. The Company has a balance in accrued warrant liability of $21,526,268 and $21,223,779 for these warrants at March 31, 2011 and December 31, 2010, respectively.

The March 2010 Common Stock Equity Offering warrants carry a five-year term, expire on March 2, 2015 and are exercisable for common shares of the Company at $4.50 per share. The Company has a balance in accrued warrant liability of $3,591,878 and $4,126,954 for these warrants at March 31, 2011 and December 31, 2010, respectively.

The Company's remaining outstanding warrants that were not issued in connection with the Series D Private Placement or the March 2010 Common Stock Equity Offering were treated as equity upon issuance and continue to be treated as equity since these remaining warrants do not contain any mandatory redemption features or other provisions that would require classifications of these warrant instruments outside of permanent equity. Furthermore, these warrants do not contain any contingent exercise provisions or anti-dilution provisions that impact the fair value of a fixed-for-fixed option, and accordingly, the warrants are considered indexed to CBLI's stock.

J. Foreign Currency Translation - The Company translates all assets and liabilities of its foreign subsidiary, where the functional currency is the Russian Ruble, at the period-end exchange rate and translates income and expenses at the average exchange rates in effect during the period. The net effect of this translation is recorded in the consolidated financial statements as accumulated other comprehensive income (loss).

K. Fair Value of Financial Instruments – The carrying amount of financial instruments, including cash and equivalents, short-term investments, accounts receivable, accounts payable and accrued expenses, approximate fair value as of March 31, 2011 and December 31, 2010.

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 March 31, 2011 and December 31, 2010.

The Company used Level 3 inputs for valuation of the Series D Private Placement and March 2010 Common Stock Equity Offering warrants, and their fair values were determined using the Black-Scholes option pricing model based on the following assumptions as of March 31, 2011:

	Series D Private Placement Warrant Value at March 31, 2011		March 2010 Common Stock Equity Offering Warrant Value at March 31, 2011	
Stock price	$ 7.50		$ 7.50	
Exercise price	$ 1.60		$ 4.50	
Term in years	2.49		1.96	
Volatility	83.61	%	61.00	%
Annual rate of quarterly dividends	-		-	
Discount rate- bond equivalent yield	1.04	%	0.78	%

The following table shows the fair value measurements for the financial instruments as of March 31, 2011.

Liabilities	Fair Value As of March 31, 2011	Fair Value Measurements at March 31, 2011 Using Fair Value Hierarchy Level 1	Level 2	Level 3
Series D Private Placement	$ 21,526,268	$ -	$ -	$ 21,526,268
March 2010 Common Stock Equity Offering	3,591,878	-	-	3,591,878
Total	$ 25,118,146	$ -	$ -	$ 25,118,146

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 ended March 31, 2011.

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) For the Three Months Ended March 31, 2011		
	Series D Private Placement	March 2010 Common Stock Equity Offering	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	870,275	(155,324)	714,951
Purchases, issuances, sales and settlements, net	(567,786)	(379,752)	(947,538)
Ending balance	$ 21,526,268	$ 3,591,878	$ 25,118,146
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	$ 873,631	$ (130,954)	$ 742,677

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.

L. Use of Estimates - The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company bases its estimates on historical experience and on various other assumptions that the Company believes to be reasonable under these circumstances. Actual results could differ from those estimates.

M. Revenue Recognition - Revenue sources consist of government grants, government contracts and commercial development contracts.

Revenues from government grants and contracts are for research and development purposes and are recognized in accordance with the terms of the award and the government agency. Grant revenue is recognized in one of two different ways depending on the grant. Cost reimbursement grants require us to submit proof of costs incurred that are invoiced by us to the government agency, which then pays the invoice. In this case, grant revenue is recognized during the period that the costs were incurred according to the terms of the government grant. Fixed cost grants require no proof of costs at the time of invoicing, but proof is required for audit purposes and grant revenue is recognized during the period that the costs were incurred according to the terms of the government grant. The grant revenue under these fixed costs grants is recognized using a percentage-of-completion method, which uses assumptions and estimates. These assumptions and estimates are developed in coordination with the principal investigator performing the work under the government fixed-cost grants to determine key milestones, expenses incurred, and deliverables to perform a percentage-of-completion analysis to ensure that revenue is appropriately recognized. Critical estimates involved in this process include total costs incurred and anticipated to be incurred during the remaining life of the grant.

Government contract revenue is recognized as allowable research and development expenses are incurred during the period and according to the terms of the government contract.

The Company recognizes revenue related to the funds received from the State of New York under the sponsored research agreement with RPCI. This results in the recognition of revenue as allowable costs are incurred. The Company recognizes revenue on research laboratory services and the subsequent use of related equipment. The amount paid as a payment toward future services related to the equipment is recognized as a prepaid asset and will be recognized as revenue ratably over the useful life of the asset and as the prepaid asset is recognized as expense. The amount of the prepaid asset was $72,770 and $75,465 at March 31, 2011 and December 31, 2010, respectively.

Commercial revenue is recognized when the service or development is delivered or upon complying with the relevant terms of the commercial agreement.

N. Deferred Revenue - Deferred revenue for the Company relates to funds received from the State of New York under the sponsored research agreement with RPCI.

For the three months ended March 31, 2011, the Company recognized $4,213 as revenue resulting in a balance of deferred revenue of $2,313,005 at March 31, 2011. At December 31, 2010, the balance in deferred revenue was $2,317,218.

The following tables summarize deferred revenue activity for the three months ended March 31, 2011.

Balance at December 31, 2010	$2,317,218
Funds recognized as revenue	(4,213)
Balance at March 31, 2011	$2,313,005

The remaining balance of deferred revenue is expected to be recognized during the years 2011 through 2013 based on the schedule of collaborations planned with RPCI over the life of the sponsored research agreement. Accordingly, $1,947,042 of the deferred revenue is classified as long-term as of March 31, 2011.

O. Research and Development - Research and development expenses consist primarily of costs associated with salaries and related expenses for personnel, costs of materials used in research and development, costs of facilities, and costs incurred in connection with third-party efforts. Expenditures relating to research and development are expensed as incurred.

P. Noncontrolling Interests - The following disclosure provides detail regarding the change in the noncontrolling ownership interest of Incuron during the quarter ended March 31, 2011:

Net loss attributable to CBLI	$(5,499,059)
Net loss attributable to noncontrolling interests	(246,307)
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 loss and issuance of additional membership interests in Incuron	$(5,569,274)

Q. Equity Incentive Plan – On May 26, 2006, the Company's Board of Directors adopted the 2006 Equity Incentive Plan ("Plan" and as amended to date, the "Amended Plan") to attract and retain persons eligible to participate in the Plan, motivate participants to achieve long-term Company goals, and further align

participants' interests with those of the Company's other stockholders. The Plan was to expire on May 26, 2016 and the aggregate number of shares of stock to be delivered under the Plan was not to exceed 2,000,000 shares. On February 14, 2007, these 2,000,000 shares were registered with the Securities and Exchange Commission (“SEC”) by filing a Form S-8 registration statement. On April 29, 2008, the stockholders of the Company approved an amendment and restatement of the Plan that clarified certain aspects of the Plan, contained updates that reflect changes and developments in federal tax laws, and reset the expiration date at April 29, 2018. On June 8, 2010, the stockholders of the Company approved an additional amendment to the Plan increasing the total shares that could be awarded under the Amended Plan to 7,000,000. As of March 31, 2011, there were 4,427,256 stock options and 811,455 shares granted under the Amended Plan and 157,119 options forfeited, leaving 1,918,408 shares of stock available to be awarded under the Amended Plan.

During the three months ended March 31, 2011, the Company issued 760,673 stock options and 28,414 shares of common stock for the following:

- 95,237 stock options issued to employees and consultants under the Company's incentive bonus plan.
- 60,000 stock options to two new employees as part of their compensation.
- 7,000 stock options to a consultant for payment of accounting services rendered.
- 598,436 stock options to the executive management team for the 2010 Executive Compensation Plan.
- 26,289 shares of common stock valued at $191,762 to five consultants for payment of corporate strategy consulting services rendered.
- 2,125 shares of common stock valued at $15,003 to a consultant for payment of financial consulting services rendered.

During the year ended December 31, 2010, the Company issued 1,175,930 stock options and 336,509 shares of common stock for the following:

- 339,930 stock options issued to employees and consultants under the Company's incentive bonus plan.
- 200,000 stock options to seven new employees as part of their compensation.
- 46,000 stock options to two consultants for payment of corporate strategy consulting services rendered.
- 20,000 stock options to an employee as an award for a performance bonus.
- 10,000 stock options to two consultants for payment of accounting services rendered.
- 140,000 stock options to outside board members as part of their compensation.
- 420,000 stock options to the executive management team for the 2009 Executive Compensation Plan.
- 59,717 shares of common stock valued at $196,076 to outside board members as part of their compensation.
- 8,000 shares of common stock valued at $57,600 to a new employee as part of their compensation.
- 200,602 shares of common stock valued at $790,867 to seven consultants for payment of corporate strategy consulting services rendered.
- 68,190 shares of common stock valued at $250,137 to four consultants for payment of financial consulting services rendered.

R. Executive Compensation Plan - On May 11, 2007, the Compensation Committee of the Board of Directors ("Compensation Committee") approved an executive compensation program ("ECP") designed to reward each of the Company's Chief Executive Officer, Chief Operating Officer, Chief Financial Officer and Chief Scientific Officer ("Executive Officers") for the achievement of certain pre-determined milestones. The purpose of the program is to link each Executive Officer's compensation to the achievement of key Company milestones that the Compensation Committee believes have a strong potential to create long-term stockholder value. For the three months ended March 31, 2011, no accrual was deemed necessary for the 2011 ECP.

S. Stock-Based Compensation - The Company recognizes and values stock-based compensation under the provisions of the Codification on stock compensation.

The fair value of each stock option granted is estimated on the grant date. The Black Scholes model is used for standard stock options, but if market conditions are present within the stock options, the Company utilizes Monte Carlo simulation to value the stock options. The assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect the Company's experience. The Company uses a risk-free rate published by the St. Louis Federal Reserve at the time of the option grant, assumes a forfeiture rate of zero, assumes an expected dividend yield rate of zero based on the Company's intent not to issue a dividend in the foreseeable future, uses an expected life based on the simplified method and computes an expected volatility based on the volatility of the Company's common stock and on the common stock of similar high-growth, publicly-traded, biotechnology companies. The Company has elected to use the simplified method for expected life due to the limited period of time

its equity shares have been publicly traded. In 2008, the Company began to include the use of its own common stock in the volatility calculation and is layering in the volatility of the common stock of the Company with that of common stock of comparable companies since there is not adequate trading history to rely solely on the volatility of the Company. The Company recognizes the fair value of stock-based compensation in net income on a straight-line basis over the requisite service period.

During the three months ended March 31, 2011 and March 31, 2010, the Company granted 760,673 and 144,029 stock options, respectively. The Company recognized a total of $673,282 and $330,246 in expense related to stock options for the three months ended March 31, 2011 and March 31, 2010, respectively. The Company also recaptured $17,953 of previously recognized expense for stock options awarded under the 2010 Executive Compensation Plan. These options were originally expensed based on the December 31, 2010 assumptions, but were not issued until March 21, 2011. The change in dates resulted in a difference in valuation assumptions used in the Black-Scholes model causing a reduction in the grant date fair value. This reduction in the grant date fair value from $5.00 to $4.97 per share resulted in the recapture of $17,953 in expense. The Company also recaptured $16,226 and $38,787 of previously recognized expense due to the forfeiture of non-vested stock options during the three months ended March 31, 2011 and March 31, 2010, respectively. The net expense for options for the three months ended March 31, 2011 and March 31, 2010 was $639,103 and $291,459, respectively.

The weighted average, estimated grant date fair values of stock options granted during the three months ended March 31, 2011 and March 31, 2010 were $5.00 and $2.67, respectively.

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

	For the three months ended March 31, 2011		For the three months ended March 31, 2010	
Risk-free interest rate	1.96-2.55	%	2.37-2.75	%
Expected dividend yield	0	%	0	%
Expected life	5-6 Years		5-6 Years	
Expected volatility	84.44-88.69	%	85.35-89.44	%

The following tables summarize the stock option activity for the three months ended March 31, 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	760,673	$ 7.18	
Exercised	(113,369)	$ 2.71	
Forfeited, Canceled	(34,787)	$ 3.80	
Outstanding, March 31, 2011	3,876,957	$ 5.59	8.06
Exercisable, March 31, 2011	3,513,307	$ 5.46	8.05

	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	144,029	$ 3.73	
Exercised	(40,862)	$ 1.95	
Forfeited, Canceled	(51,927)	$ 7.07	
Outstanding, March 31, 2010	2,568,247	$ 5.39	7.91
Exercisable, March 31, 2010	2,260,372	$ 5.18	7.85

As additional stock-based compensation, the Company issued a total of 45,361 shares and 190,062 shares during the three months ended March 31, 2011 and March 31, 2010, respectively. The Company recognized $283,933 and $641,898 in expense for these shares issued during the three months ended March 31, 2011 and March 31, 2010, respectively.

T. Income Taxes - No income tax expense was recorded for the three months ended March 31, 2011 and 2010, as the Company does not expect to have taxable income in 2011 and does not expect any current federal or state tax

expense. A full valuation allowance has been recorded against the Company's deferred tax asset, which is primarily related to operating loss and tax credit carryforwards and accrued expenses.

U. Net Loss Per Share - Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period.

The following table presents the calculation of basic and diluted net loss per share for the three months ended March 31, 2011 and 2010:

	Three Months Ended	
	March 31, 2011	March 31, 2010
Net loss available to common stockholders	$ (5,499,059)	$ (3,364,011)
Net loss per share, basic and diluted	$ (0.19)	$ (0.14)
Weighted-average shares used in computing net loss per share, basic and diluted	29,110,979	23,512,617

The Company has excluded all outstanding preferred shares, warrants and options from the calculation of diluted net loss per share because all such securities are antidilutive for all periods presented.

The total number of shares excluded from the calculations of diluted net loss per share, prior to application of the treasury stock method, is as follows:

Common Equivalent Securities	March 31, 2011	March 31, 2010
Warrants	9,103,596	9,910,763
Options	3,876,957	2,568,247
Total	12,980,553	12,479,010

V. Concentrations of Risk - Grant revenue accounted for 100.0% of total revenue for the three months ended March 31, 2011 and 2010. Although the Company anticipates ongoing federal government contract and grant revenue, there is no guarantee that this revenue stream will continue in the future.

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash and cash equivalents and short-term investments. The Company maintains deposits in federally insured institutions in excess of federally insured limits. The Company does not believe it is exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, the Company has established guidelines regarding diversification of its investment portfolio and maturities of investments, which are designed to meet safety and liquidity. Included in cash equivalents are cash balances and certificates of deposits held by Incuron totaling $1,225,016 and short term investments held by Incuron of $1,934,644 as of March 31, 2011.

W. Foreign Currency Exchange Rate Risk - The Company has entered into a manufacturing agreement to produce one of its drug compounds with a foreign third party and is required to make payments in the foreign currency. As a result, the Company's financial results could be affected by changes in foreign currency exchange rates. Currently, the Company's exposure primarily exists with the Euro.

The Company monitors its foreign currency exposures and may, from time to time, use hedging instruments to mitigate exposure to changes in foreign currencies. Hedging activities may only offset a portion of the adverse financial effects of unfavorable movements in foreign exchange rates over the limited time the hedges are in place.

As of March 31, 2011, the Company is obligated to make payments under the manufacturing agreements of 1,243,852 Euros. As of March 31, 2011, the Company has purchased forward contracts for 683,875 Euros and, therefore, at

March 31, 2011, had foreign currency commitments of $794,406 for Euros given prevailing currency exchange spot rates. These foreign currency contracts were entered to offset the foreign currency risk associated with purchase obligations. These instruments were not designated as hedging instruments for accounting purposes, and accordingly, the unrealized gain position of $107,464 as of March 31, 2011 was recorded as a component of other income in the accompanying statements of operations. $53,197 of this unrealized gain position was recognized in the three months ended March 31, 2011 and the remaining $54,267 was recognized in the three months ended December 31, 2010.

As of March 31, 2010, the Company was obligated to make payments under the agreements of 466,667 Euros. As of March 31, 2010, the Company had not purchased any forward contracts for Euros and, therefore, at March 31, 2010, had foreign currency commitments of $630,934 for Euros given prevailing currency exchange spot rates.

X. Comprehensive Income / (Loss) - The Company applies the Codification on comprehensive income that requires disclosure of all components of comprehensive income on an annual and interim basis. Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources.

Note 3. Equity Transactions

See Note 2Q – Equity Incentive Plan for stock transactions made under the Company's Equity Incentive Plan.

March 2010 Common Stock Equity Offering and Related Adjustments

On March 2, 2010, the Company issued 1,538,462 shares of common stock and Common Stock Purchase Warrants to purchase an aggregate of 1,015,385 shares of common stock, for an aggregate purchase price of $5,000,002 (“March 2010 Common Stock Equity Offering”). The Warrants are exercisable commencing six months following issuance and expire on March 2, 2015. The placement agent also received additional warrants to purchase 123,077 shares of common stock.

The fair value of the 1,138,462 Warrants issued with the March 2010 Common Stock Equity Offering was $2,948,617, including 123,077 warrants issued as fees to the placement agent. The fair value was computed using the Black-Scholes option pricing model using the following assumptions:

Stock price	$4.26	
Exercise price	$4.50	
Term in years	2.75	
Volatility	104.01	%
Annual rate of quarterly dividends	-	
Discount rate- bond equivalent yield	1.28	%

Immediately after the completion of the March 2010 Common Stock Equity Offering, pursuant to weighted-average anti-dilution provisions of the Series B Warrants and Series C Warrants, the exercise price of the Company’s Series B Warrants reduced from $6.37 to approximately $5.99, and the aggregate number of shares of common stock issuable upon exercise of the Series B Warrants increased from 3,847,276 to approximately 4,091,345; and the exercise price of the Company’s Series C Warrants reduced from $6.76 to approximately $6.35, and the aggregate number of shares of common stock issuable upon exercise of the Series C Warrants increased from 434,596 to approximately 462,654.

December 2010 Common Stock Equity Offering and Related Adjustments

On December 29, 2010, the Company issued 1,400,000 shares of common stock to a single institutional accredited investor for an aggregate purchase price of $8,386,000 (“December 2010 Common Stock Equity Offering”). After related fees and expenses, the Company received net proceeds of approximately $7,730,000.

Immediately after the completion of the December 2010 Common Stock Equity Offering, pursuant to weighted-average anti-dilution provisions of the Series C Warrants, the exercise price of the Company’s Series C Warrants reduced from $6.35 to approximately $6.32, and the aggregate number of shares of common stock issuable upon exercise of the Series C Warrants increased from 462,654 to approximately 464,852.

Other Issuances

On January 1, 2010, the Company issued 34,000 shares of common stock valued at $112,540 to several consultants of the Company.

On January 4, 2010, the Company issued 70,000 shares of common stock valued at $231,700 to several consultants of the Company.

On October 1, 2010, the Company issued 15,687 shares of common stock valued at $80,004 to a consultant of the Company.

On February 1, 2011, the Company issued 11,947 shares of common stock valued at $77,058 to a consultant of the Company.

Note 4. Commitments and Contingencies

The Company has entered into various agreements with third parties and certain related parties in connection with the research and development activities of its existing product candidates as well as discovery efforts on potential new product candidates. These agreements include costs for research and development and license agreements that represent the Company's fixed obligations payable to sponsor research and minimum royalty payments for licensed patents. These amounts do not include any additional amounts that the Company may be required to pay under its license agreements upon the achievement of scientific, regulatory and commercial milestones that may become payable depending on the progress of scientific development and regulatory approvals, including milestones such as the submission of an investigational new drug application to the U.S. Food and Drug Administration and the first commercial sale of the Company's products in various countries. These agreements include costs related to manufacturing, clinical trials and preclinical studies performed by third parties. As of March 31, 2011, the Company is uncertain as to whether these contingent events will become realized.

The Company is also party to three agreements that require it to make milestone payments, royalties on net sales of the Company's products, and payments on sublicense income received by the Company. As of March 31, 2011, $350,000 in milestone payments have been made under one of these agreements. There are no milestone payments or royalties on net sales accrued for any of the three agreements as of March 31, 2011 and December 31, 2010.

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 currently has operating lease commitments in place for facilities in Buffalo, New York and Chicago, Illinois as well as office equipment. The lease for the Buffalo, New York facility provides for two renewal periods of two years each at the option of the Company. The Company recognizes rent expense on a straight-line basis over the term of the related operating leases. Total operating lease expense relating to the facility leases and office equipment was $94,702 and $91,625 for the three months ended March 31, 2011 and 2010, respectively.

Annual future minimum lease payments under present lease commitments are as follows:

	Operating Leases
2011	$ 315,342
2012	147,915
2013	3,540
2014	2,065
2015	-
	$ 468,862

The Company has entered into warrant agreements with strategic partners, consultants and investors with exercise prices ranging from $1.60 to $9.19. These awards were approved by the Company’s Board of Directors. The warrants expire between five 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 three months ended March 31, 2011 and 2010 appears below:

	Number of	Weighted Average	Number of Common

	Warrants	Exercise Price	Shares Exerciseable Into
Outstanding at December 31, 2010	7,530,689	$ 3.79	9,450,633
Granted	-	-	-
Exercised	(284,243)	3.77	(347,037)
Outstanding at March 31,2011	7,246,446	3.78	9,103,596

	Number of Warrants	Weighted Average Exercise Price	Number of Common Shares Exerciseable 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	(101,795)	1.44	(136,000)
Forfeited, Canceled	(3,973)	1.39	(5,718)
Outstanding at March 31, 2010	7,989,366	3.71	9,910,763

The Company has entered into employment agreements with two key executives who, if terminated by the Company without cause as described in these agreements, would be entitled to severance pay.

The Company was awarded a $440,000 grant from the New York Empire State Certified Development Corporation. The Company received $220,000 of the grant award as of March 31, 2011. The grant award provides minimum employee levels required to receive the remainder of the award and contains provisions of recapture of monies paid if required employment levels are not maintained through June 2012. The Company is unable to assess the probability of the threshold employment levels being maintained at this time.

Note 5. Subsequent Events

No material subsequent events have occurred since the balance sheet date of March 31, 2011.

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. 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 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). Curaxins are being developed by Incuron, LLC, our majority-owned Russian subsidiary (“Incuron”), as anticancer agents that could act as mono-therapy drugs or in combination with other existing anticancer therapies.

On July 20, 2006, we sold 1,700,000 shares of common stock, par value $0.005 per share, in our initial public offering at a per share price of $6.00. 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, 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 anticancer drugs and radiation and thereby increase their effectiveness.

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.

- 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, 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. 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.

STRATEGIES AND OBJECTIVES

Our primary objective is to become a leading developer of drugs for the protection of human tissues against radiation and other stresses and for cancer treatment. Key elements of our strategy include:

- Aggressively working towards the commercialization of Protectan CBLB502. Our most advanced drug candidate, Protectan CBLB502, offers the potential to protect normal tissues against exposure to radiation. Because CBLB502 demonstrates the potential to address an unmet medical need and is intended to treat a serious or life-threatening condition, CBLB502 has been granted Fast Track status by the U.S. Food and Drug Administration (“FDA”). The Fast Track designation will allow us to file a Biologic License Application (“BLA”) on a rolling basis and will allow the FDA to review the filing as it is received rather than waiting for the complete submission prior to commencing the review process. In addition, our BLA filing will be eligible for priority review, which could result in an abbreviated review time of six months. We expect to complete development of Protectan CBLB502 to treat radiation injury following exposure to radiation from nuclear or radiological weapons or from nuclear accidents and submit a BLA with the FDA in 2012.

- Leveraging our relationship with leading research and clinical development institutions. The Cleveland Clinic (“CCF”) one of the top research medical facilities in the world, is one of our co-founders. In January 2007, we entered into a strategic research partnership with Roswell Park Cancer Institute (“RPCI”) in Buffalo, New York. We have continued our research and development program that we initiated at CCF with RPCI who shares valuable expertise with us as developmental efforts are performed on our drug candidates. These partnerships will enhance the speed and efficiency of our clinical research and provide us with access to the state-of-the-art clinical development facilities of a globally recognized cancer research center.

- Utilizing governmental initiatives to target our markets. Our focus on drug candidates such as Protectan CBLB502, which has applications that have been deemed useful for military and defense purposes, provides us with a built-in market for our drug candidates. This enables us to invest less in costly retail and marketing resources. In an effort to improve our responsiveness to military and defense needs, we have established a collaborative relationship with the Department of Defense (“DoD”) and the Biomedical Advanced Research and Development Authority (“BARDA”) of the Department of Health and Human Services (“HHS”).

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Utilizing and developing other strategic relationships. We have collaborative relationships with other leading organizations that enhance our drug development and marketing efforts. For example, one of our founders, with whom we maintain a strategic partnership, is ChemBridge Corporation. Known for its medicinal chemistry expertise and synthetic capabilities, ChemBridge provides valuable resources to our drug development research including access to a chemical library of almost 2,000,000 compounds.

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 March 31, 2011, we spent $79,438,368 on R&D. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations— Three Months Ended March 31, 2011 Compared to March 31, 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 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. 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 currently have issued patents and pending patent applications relating to eight families of patent applications that were filed over the past seven years around various aspects and qualities of the protectan family of compounds. The first patent covering the method of protecting a mammal from radiation using flagellin or its derivatives was granted by the U.S. Patent and Trademark Office (US Patent No. 7,638,485 titled "Modulating Apoptosis") and the European Patent Office (European Publication Number FP 1706133, titled "Methods of Protecting Against Radiation Using Flagellin.") . This patent was also granted by the nine member countries of the Eurasian Patent Organization (which includes the Russian federation), Ukraine and China. A second patent titled “Method of Protecting Against Apoptosis using Lipopeptides” was granted by South Africa (Patent Number 2008/00126) and we have received notices of intent to grant patent from New Zealand and the Eurasian Patent Organization. A third patent titled “Method of Increasing Hematopoietic Stem Cells” (Patent Number 2009/05378) has been granted by South Africa. We believe that with the

patent applications filed to date in the U.S. and internationally around various properties of protectan compounds, we have protected the potentially broad uses of our protectan technology. The patents/patent applications belonging to the first patent family referenced above have a legal expiration date of December 1, 2024, the patents/patent applications belonging to the second patent family referenced above have a legal expiration date of June 12, 2026 and the patents/patent applications belonging to the third patent family referenced above have a legal expiration date of May 13, 2025.

We spent approximately $14,321,680 and $13,738,983 on R&D for protectans for all applications in the fiscal years ended December 31, 2010 and 2009, respectively. For the quarters ended March 31, 2011 and 2010, we spent $4,527,703 and $3,592,570, respectively. From our inception to March 31, 2011, we spent $59,096,866 on R&D for protectans.

Protectan CBLB502

Protectan CBLB502 is our leading radioprotectant molecule in the protectans family. Protectan CBLB502 represents a rationally designed derivative of the microbial protein, flagellin. Flagellin is secreted by Salmonella typhimurium and many other Gram-negative bacteria, and in nature, arranges itself in a hollow cylinder to form the filament in bacterial flagellum and acts as a natural activator of NF-kB (nuclear factor-kappa B), a protein complex widely used by cells as a regulator of genes that control cell proliferation and cell survival. Thus, Protectan CBLB502 reduces injury from acute stresses by mobilizing several natural cell protective mechanisms, including inhibition of apoptosis, reduction of oxidative damage and induction of factors (cytokines) that induce protection and regeneration of stem cells in bone marrow and the intestines.

Protectan CBLB502 is a single agent, anti-radiation therapy with demonstrated significant survival benefits at a single dose in animal models. Animal studies indicate that Protectan CBLB502 protects mice without increasing the risk of radiation-induced cancer development. The remarkably strong radioprotective abilities of Protectan CBLB502 are the result of a combination of several mechanisms of action. Potential applications for Protectan CBLB502 include reduction of radiation therapy or chemotherapy toxicities in cancer patients, protection from Acute Radiation Syndrome ("ARS") in defense scenarios and protection from acute organ failure. Protectan CBLB502 is administered through intramuscular injection.

Six families of patent applications have been filed for Protectan CBLB502, which include two U.S. patent applications related to various aspects and properties for Protectan CBLB502 and related protectan compounds, including new methods of the use of flagellin derivatives and screening for new compounds with similar properties.

We spent approximately $14,316,540 and $13,732,416 on R&D for Protectan CBLB502 in the fiscal years ended December 31, 2010 and 2009, respectively. For the quarters ended March 31, 2011 and 2010, we spent $4,527,703 and $3,592,570, respectively, on research and development for Protectan CBLB 502. From our inception to March 31, 2011, we spent $55,954,785 on R&D for Protectan CBLB502.

Non-medical Applications

Our scientists have demonstrated that injecting Protectan CBLB502 into mice, rats and non-human primates protects them from lethal doses of total body gamma radiation. An important advantage of Protectan CBLB502, above any other radioprotectant known to us, is the ability to effectively protect not only the hematopoietic system, but also the gastrointestinal ("GI"), tract which is among the most sensitive areas of the human body to radiation. High levels of radiation, among other effects, induce moderate to severe bone marrow damage. The immune and blood stem cells are also depleted and death is caused by anemia, infection, bleeding or poor wound healing. GI damage often occurs at higher doses of radiation and may result in death through sepsis as a result of perforation of the GI tract. Protectan CBLB502's ability to effectively protect the hematopoietic system and GI tract may make Protectan CBLB502 uniquely useful as a radioprotective antidote. Protectan CBLB502 was shown to be safe at its therapeutic doses in rodents and non-human primates. In addition, Protectan CBLB502 has proved to be a stable compound for storage purposes. It can be stored at temperatures close to freezing, room temperature or extreme heat. Manufacturing of Protectan CBLB502 is cost efficient due to its high yield bacterial producing strain and simple purification process.

Protectan CBLB502 is being developed under the FDA's animal efficacy rule (21 C.F.R. § 314.610, drugs; § 601.91, biologics) to treat radiation injury following exposure to radiation from nuclear or radiological weapons, or from nuclear accident. The animal efficacy rule creates a new regulatory paradigm for measuring efficacy by permitting the FDA to approve drugs and biologics for counterterrorism uses based on animal data when it is unethical or unfeasible to conduct human efficacy studies. Thus, this approval pathway requires demonstration of efficacy in at least one well-characterized animal model and safety and pharmacodynamics studies in animals and representative samples of healthy human volunteers to allow selection of an effective dose in humans. Protectan CBLB502 has demonstrated activity as a radioprotectant in several animal species, including non-human primates. Human safety, pharmacokinetic, pharmacodynamic and biomarker studies are the only stage of human testing required for approval in this indication.

We have successfully established current Good Manufacturing Practices ("cGMP"), quality manufacturing for Protectan CBLB502 and have completed two Phase I human safety studies for Protectan CBLB502 in ARS. The initial human Phase I safety and tolerability study involved single injections of Protectan CBLB502 in ascending-dose cohorts. The 50 participants in the study were assessed for adverse side effects over a 28-day time period and blood samples were obtained to assess the effects of Protectan CBLB502 on various biomarkers. The second Phase I study included a total of 101 healthy subjects randomized among four dosing regimens of Protectan CBLB502. Participants

in the 101-subject study were assessed for adverse side effects and blood samples were obtained to assess the effects of Protectan CBLB502 on various biomarkers. The primary objectives of this study were to gather additional data on safety, pharmacokinetics, and cytokine biomarkers in a larger and broader subject population. Data from these two studies indicated that administration of Protectan CBLB502 resulted in a rapid and potent cytokine and hepatic immunologic response, similar to that seen in previously conducted non-human primate studies. The most frequent adverse event associated with Protectan CBLB502 administration was a transient flu-like syndrome, which was generally resolved within 24 hours. We anticipate moving forward with a definitive safety study in a larger group of healthy human subjects after determining an appropriate dose and sample size in conjunction with the FDA.

The Defense Threat Reduction Agency (“DTRA”) of the DoD awarded us a $1.3 million grant in March 2007, to fund “development leading to the acquisition” of Protectan CBLB502 as a radiation countermeasure, in collaboration with Armed Forces Radiobiology Research Institute (“AFRRI”), which has also received significant independent funding for work on Protectan CBLB502.

In March 2008, the DoD awarded us a contract valued at up to $8.9 million over eighteen months through the Chemical Biological Medical Systems Joint Project Management Office Broad Agency Announcement ("BAA"), for selected tasks in the advanced development of Protectan CBLB502 as a Medical Radiation Countermeasure ("MRC"), to treat radiation injury following exposure to radiation from nuclear or radiological weapons (the “2008 DoD Contract”). The specific tasks include the completion by us of non-Good Laboratory Practices ("non-GLP") efficacy animal studies, Chemistry, Manufacturing and Controls ("CMC") tasks, in vitro and in vivo studies supporting Protectan CBLB502’s Investigational New Drug ("IND") application, definitive GLP efficacy studies, and drug formulation from single-dose vials within the timeframe of the contract. In September 2009, the DoD increased the funding under this contract by $0.6 million to $9.6 million to support bridging studies between lyophilized and liquid drug formulations. We successfully completed all tasks related to the 2008 DoD Contract by the contract end date of August 31, 2010.

As a government contract subject to the Federal Acquisition Regulations (“FAR”), pursuant to FAR 52.227-11 (Patent Rights – Ownership by the Contractor) we were permitted to retain title to any patentable invention or discovery made while performing the contract. However, no inventions were made by us during the performance of the 2008 DoD Contract. Had any inventions been made while performing under the 2008 DoD Contract, the U.S. government would have received a non-exclusive, non-transferable, irrevocable, paid-up license to the subject inventions throughout the world. In addition, pursuant to FAR 52.227-14 (Rights in Data – General), which was incorporated into the base 2008 DoD Contract and removed by the first amendment to the contract in June 2008, the U.S. government retains unlimited rights in the technical data produced between March and June 2008 in the performance of the 2008 DoD Contract.

In September 2008, we were awarded a $774,183 grant from the National Institute of Allergy and Infectious Diseases ("NIAID") of the National Institutes of Health ("NIH") to further study certain mitigating properties of Protectan CBLB502 in the context of hematopoietic damage from radiation exposure. In September 2009, NIAID awarded us an additional $458,512 for the continuation of the same grant.

In September 2008, BARDA awarded us a contract under the BAA titled, "Therapies for Hematopoietic Syndrome, Bone Marrow Stromal Cell Loss, and Vascular Injury Resulting from Acute Exposure to Ionizing Radiation," for selected tasks in the advanced development of Protectan CBLB502. BARDA seeks to acquire developed medical countermeasures that will be clinically useful in a civilian medical emergency situation that results from or involves exposure of a large population to the effects of a nuclear detonation, a radiologic dispersive device (such as a dirty bomb) or exposure to radioactive material with or without combined injury or trauma.

The selected tasks in the Statement of Work include the following:

- Performing certain non-clinical experiments, including non-human primate experiments.
- Facilitating bone marrow transplantation in the rescue of irradiated mice by Protectan CBLB502 treatment.
- Performing stability studies of Good Manufacturing Practices-grade Protectan CBLB502 and conducting Phase Ib clinical trials.
- Submitting necessary regulatory documents to the BARDA and the FDA for approval.
- Planning, initiating and overseeing Phase Ib trials on healthy volunteers and drafting and finalizing the Phase Ib clinical reports and submitting such reports to the BARDA and the FDA.

The total contract value including all milestone-based options started at $13.3 million over a three-year period, with the first year's award of $3.4 million. In September 2009, BARDA increased the total contract value $2.3 million to $15.6 million and awarded the first milestone option of $6.3 million. BARDA has since awarded the second, third and fourth milestone options under the contract for $1.47 million, $0.46 million and $4.14 million, respectively. We successfully completed all tasks related to this contract by February 2011.

As a government contract subject to the FAR, we will be permitted to retain title to any patentable invention or discovery made while performing the contract. The U.S. government, in return, will receive a non-exclusive, non-transferable, irrevocable, paid-up license to the subject invention throughout the world. The U.S. government will also have unlimited rights in the data produced in the performance of the HHS Contract.

In September 2010, we were awarded a contract (the “2010 DoD Contract”) by the Chemical Biological and Medical Systems ("CBMS") Medical Identification and Treatment Systems ("MITS") of the DoD for the advanced development and procurement of Protectan CBLB502 as a medical radiation countermeasure. The 2010 DoD Contract is valued at up to $45 million, including all options provided thereunder. Under the terms of the contract, CBMS-MITS will initiate funding of $14.8 million, including all options, for the advanced development of Protectan CBLB502 through the receipt of approval from the FDA. Selected tasks related to the advanced development of Protectan CBLB502 under the 2010 DoD Contract include, among others, conducting pilot animal model studies to support approval under the FDA animal rule, performing an International Conference on Harmonisation-compliant stability testing program, scaling up manufacturing processes to achieve a cGMP-compliant large-scale manufacturing process for lyophilized product formulation and performing other activities in preparation for the submission of a BLA for gastrointestinal sub-syndrome ARS. In addition, the 2010 DoD Contract includes options for the purchase of an aggregate of up to 37,500 troop-equivalent doses, in pre-determined increments, for $30,000,000. The 2010 DoD Contract requires us to provide the DoD with periodic status reports and to maintain, to the maximum extent possible, the employment of certain key personnel during the duration of the program.

As a government contract subject to the FAR, we will be permitted to retain title to any patentable invention or discovery made while performing the contract. The U.S. government, in return, will receive a non-exclusive, non-transferable, irrevocable, paid-up license to the subject inventions throughout the world. In addition, the U.S. government will also have unlimited rights in the technical data produced in the performance of the 2010 DoD Contract. Furthermore, the DoD has the right to terminate the 2010 DoD Contract at any time. In certain instances, the 2010 DoD Contract also limits our ability to engage in certain activities, such as subcontracting a portion of the work, without prior approval from the DoD.

In January 2011, we received a $1,589,106 development contract from the DTRA of the DoD to fund additional research into the pharmacodynamic profile of Protectan CBLB502 and to further define mediators of Protectan CBLB502's radiomitigating effects.

We have applied for additional development funding for the advanced development of Protectan CBLB502 from the U.S. government and are currently awaiting final award.

The Project BioShield Act of 2004, which further expedites the approval of drug candidates for certain uses, is intended to bolster our nation's ability to provide protections and countermeasures against biological, chemical, radiological or nuclear agents that may be used in a military, terrorist or nuclear attack. This law also allows for the use of expedited peer review when assessing the merit of grants and contracts of up to $1,500,000 for countermeasure research. We have been awarded and successfully completed a $1,500,000 research grant pursuant to this law.

Three families of patent applications have been filed for the non-medical applications for Protectan CBLB502.

We spent approximately $14,316,540 and $13,676,289 on R&D for the non-medical applications of Protectan CBLB502 in the fiscal years ended December 31, 2010 and 2009, respectively. For the quarters ended March 31, 2011 and 2010, we spent $4,504,932 and $3,592,570, respectively, on research and development for biodefense applications of Protectan CBLB502. From our inception to March 31, 2011, we spent $54,098,958 on R&D for the biodefense applications of Protectan CBLB502.

Protectan CBLB502 is a candidate for procurement by the DoD, HHS/BARDA and other countries / territories facing imminent nuclear and radiation threats. The HHS opportunity is particularly positive for us as the agency's mandate is to protect the U.S. civilian population in the event of a radiological emergency, including stockpiling radiation countermeasures for mass distribution. Our contract awards from the DoD and BARDA evidence the government's focus on acquiring adequate protection against nuclear and radiation threats for military and civilian populations. Upon FDA approval, Protectan CBLB502 should be well positioned to fulfill both of these needs, with its demonstrated unprecedented efficacy and survival benefits, unique ability to address both hematopoietic and GI damage, broad window of efficacy relative to radiation exposure and suitability for both military and civilian delivery scenarios. We believe that Protectan CBLB502 is the only radiation countermeasure with these capabilities in advanced development that can be self or buddy-administered, without the need of additional supportive care in a battlefield or civilian community setting.

We intend to enter into contracts to sell Protectan CBLB502 to various U.S. government agencies. Future sales to U.S. government agencies will depend, in part, on our ability to meet federal contract requirements and the existence and development of competitive compounds.

Regulatory Status

Significant radioprotective properties and toxicity profile, outstanding stability and cost efficient production of Protectan CBLB502 to date make it a primary candidate for clinical studies. Initially, Protectan CBLB502 is being

developed for non-medical purposes — as a radioprotectant antidote for the protection of people with possible exposure to high doses of ionizing radiation. Our drug development strategy complies with the recently adopted FDA rules for investigational drugs that address situations such as radiation injury, where it would be unethical to conduct efficacy studies in humans. While Phase II and Phase III human clinical trials are normally required for the approval of marketing an investigational drug, under the FDA rules, Protectan CBLB502 would be considered for approval for this indication based on Phase I safety studies in humans and efficacy studies in two animal species. Based upon this expedited approval process, as a result of its Fast Track status, we believe that Protectan CBLB502 could be approved for non-medical applications within 18 - 24 months. Because Phase II and Phase III testing involves applying a drug candidate to a large numbers of participants who suffer from the targeted disease and condition and can last for a total of anywhere from three to six or additional years, bypassing these phases represents a significant time and cost savings in receiving FDA approval.

As part of this expedited approval process, the FDA has indicated that it intends to engage in a highly interactive review of IND applications, New Drug Applications ("NDA") and BLAs and to provide for accelerated review and licensure of certain medical products for counterterrorism applications, including granting eligible applications “Fast Track” status. The Fast Track program is designed to expedite the review of investigational drugs for the treatment of patients with serious or life-threatening diseases where there is an unmet medical need. Fast Track designations allow a company to file a NDA or BLA on a rolling basis and permits the FDA to review the filing as it is received, rather than waiting for the complete submission prior to commencing the review process. Additionally, NDAs and BLAs for fast track development programs are eligible for priority review, which may result in an abbreviated review time of six months. In July 2010, the FDA granted our application for Fast Track status in respect of Protectan CBLB502. Fast Track status will allow us to have additional interactions with the FDA, including extra in-person meetings and faster review of our BLA filing, which will expedite implementation of the Protectan CBLB502 development plan and preparation and approval of the BLA.

Protectan CBLB502 was granted Fast Track status by the FDA in July 2010 for reducing the risk of death following total body irradiation during or after radiation disaster.

The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis, or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 people but are not expected to recover the costs of developing and marketing the treatment.

Orphan Drug status qualifies Protectan CBLB502 for an accelerated review process, tax credits, financial assistance for development costs, and seven years of marketing exclusivity upon approval by the FDA for this indication. The designation also allows for a possible exemption from the FDA-user fee and assistance in clinical trial protocol design.

Protectan CBLB502 was also granted Orphan Drug status by the FDA in November 2010 for prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster.

As part of the process to receive final FDA licensure for Protectan CBLB502 for non-medical applications, we have established cGMP compliant manufacturing of Protectan CBLB502. We were able to develop a complicated, high-yield manufacturing process for Protectan CBLB502 and prototype the process and resolve multiple challenges during the industrial development. We currently have drug substance corresponding to several hundred thousand projected human doses. The process we developed gives us the ability to manufacture up to five million estimated doses within a year without any additional scale-up; and if necessary, scale-up could be implemented relatively easily.

Prior to our submission for FDA licensure for Protectan CBLB502 for biodefense or non-medical applications, we will need to complete several interim steps, including:

- Conducting pivotal animal efficacy studies with the cGMP manufactured drug candidate under GLP - Good Laboratory Practices conditions. We expect to initiate dosing in these studies in 2011. We anticipate that these studies will have an approximate cost of $3,500,000. These studies are expected to be funded by a government development contract proposal that we are currently negotiating.

- Performing a Phase II human safety study in a larger number of volunteers using the dose of Protectan CBLB502 previously shown to be safe in humans and efficacious in animals. We expect to initiate dosing in this study in 2011. We anticipate that this study will have an approximate cost of $7,000,000 based on 500 subjects tested in four locations. This study is expected to be funded by a government development contract proposal that we are currently negotiating.

- Filing a BLA which we expect to submit in 2012. We anticipate that this filing will have an approximate cost of $4,000,000. The filing of the BLA is expected to be funded by a government development contract proposal that we are currently negotiating.

Medical Applications

While our current focus remains on its non-medical applications, Protectan CBLB502 has been observed to dramatically increase the efficacy of radiotherapy of experimental tumors in mice. Protectan CBLB502 appears to increase the tolerance of mice to radiation while having no effect on the radiosensitivity of tumors, thus opening the possibility of combining radiotherapy with Protectan CBLB502 treatment to improve the overall anticancer efficacy of radiotherapy. Our animal efficacy studies have demonstrated that up to 100% of mice treated with Protectan CBLB502 prior to being exposed to radiation survived without any associated signs of toxicity. This compares to a 100% mortality rate in the animal group that received a placebo drug.

Protectan CBLB502 has demonstrated the ability to reduce the toxicities of a chemotherapeutic drug, cisplatin (Platinol), broadly used for the treatment of ovarian, endometrial, head and neck, lung, stomach and other types of cancer in animal models. Cisplatin treatment was used in the study as an example of chemotherapy-associated toxicity. Cisplatin injected at toxic doses is known to induce myelosuppression (suppression of bone marrow) and nephrotoxicity (kidney damage). The prospect of increasing patients' tolerance to chemotherapeutic drugs and optimizing treatment regimens would be a significant improvement in cancer treatment. It is estimated that approximately $10 billion of the roughly $50 billion annually spent on cancer treatment represents supportive care addressing toxicities of various treatments, including chemotherapy.

More recent discoveries have also pointed to potential direct anticancer effects of Protectan CBLB502 in several transplanted cancer models grown in mice and rats, including colon and lung cancer, lymphoma and melanoma. In one of the animal models of transplanted colon cancer, CBLB502 treatment resulted in complete tumor regression with no recurrence of the disease in a large percentage of animals. Experimental results suggest that CBLB502's anticancer effect stems from the same mechanism which underlies its ability to treat radiation exposure and which involves tissue-specific activation of innate immune response mediated by CBLB502's interaction with its receptor, TLR5. The strength of the antitumor effects largely depends on the expression of the receptor of Protectan CBLB502 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 CBLB502 activity, tumors become effectively suppressed as a result of host immune system attack regardless of their TLR5 status. This characteristic makes liver metastasis a favorable target for potential anticancer applications of CBLB502.

In light of these new findings, we plan to initiate Phase I/II studies with Protectan CBLB502 in cancer patients to look at both supportive care and direct anticancer effects. Potential study protocols are under review and revision, including one for head and neck cancer patients and another for advanced patients with liver metastases. Our goal is to initiate one or possibly more medical trials for Protectan CBLB502 in cancer patients in 2011.

In other studies, we have demonstrated the potential of Protectan CBLB502 to be applicable to ischemic conditions. Our researchers, in collaboration with investigators from CCF, have demonstrated that a single injection of Protectan CBLB502 effectively prevents acute renal failure and subsequent death in a mouse model of ischemia-reperfusion renal injury.

The DoD awarded a $1 million grant to CCF in 2008 to conduct pre-clinical studies on Protectan CBLB502 for use in tourniquet and other ligation-reperfusion battlefield injuries where blood flow is stopped and then restored after a prolonged period of time. These studies have demonstrated Protectan CBLB502’s ability to accelerate limb recovery in an animal model of tourniquet-mediated injury simulating the situation occurring in human. It has been demonstrated that injection of Protectan CBLB502 within 30 minutes of tourniquet removal leads to a marked reduction in the severity of injury, including reductions in tissue edema, pro-inflammatory cytokine production and leukocyte infiltration leading to accelerated recovery of limb function.

In September 2009, we were awarded a $5.3 million Grand Opportunities research grant under the American Recovery and Reinvestment Act of 2009 from the Office of the Director of NIH and NIAID. The grant will fund studies of molecular mechanisms by which Protectan CBLB502 mitigates GI damage from radiation exposure.

In contrast to the non-medical applications of Protectan CBLB502, the use of Protectan CBLB502 to ameliorate the side effects of radiation treatment and anticancer drugs will be subject to the full FDA approval process.

In order for us to receive final FDA licensure for Protectan CBLB502 for medical applications, we will need to complete various tasks, including:

- Performing one or two initial Phase I/II human efficacy studies on a small number of cancer patients. We expect to complete these studies two years from the receipt of allowance from the FDA of the IND amendment at an approximate cost of $1,500,000 each.

- Performing an additional Phase II efficacy study on a larger number of cancer patients. At the present time, the costs and the scope of this study cannot be approximated with any level of certainty.

- Performing a Phase III human clinical study on a large number of cancer patients and filing a BLA with the FDA. At the present time, the costs and scope of these steps cannot be approximated with any level of certainty.

Five families of patent applications have been filed for the medical applications for Protectan CBLB502.

We spent approximately $0 and $56,127 on R&D for the medical applications of Protectan CBLB502 in the fiscal years ended December 31, 2010 and 2009, respectively. For the quarters ended March 31, 2011 and 2010, we spent $22,770 and $0, respectively, on R&D for the medical applications of CBLB502. From our inception to March 31, 2011, we spent $1,855,827 on R&D for the medical applications of Protectan CBLB502.

Protectan CBLB612

While the bulk of our R&D has focused on Protectan CBLB502, we have conducted some preliminary research into a compound derived from the same family and which we refer to as Protectan CBLB612. Protectan CBLB612 is a modified lipopeptide mycoplasma that acts as a powerful stimulator and mobilizer of hematopoietic (bone marrow/blood production) stem cells ("HSC") to peripheral blood. Potential applications for Protectan CBLB612 include accelerated hematopoietic recovery during chemotherapy and during donor preparation for bone marrow transplantation.

Our research indicates that Protectan CBLB612 is not only a potent stimulator of bone marrow stem cells, but also causes their mobilization and proliferation throughout the blood. A single administration of Protectan CBLB612 resulted in a three-fold increase in the number of progenitor stem cells in mouse bone marrow within 24 hours after administration. Furthermore, the number of these stem cells in peripheral blood was increased ten-fold within four days of administration.

Protectan CBLB612 was also found to be highly efficacious in stimulating proliferation and mobilization of hematopoietic stem cells into peripheral blood in a primate model (Rhesus macaques). A single injection of Protectan CBLB612 in Rhesus macaques resulted in a 20-fold increase of hematopoietic progenitor cells in blood. At the peak of the effect (48-72 hours post-injection), the proportion of free-floating CD34+ cells in the total white blood cell count reached 30% (compared with 1.5% in normal blood). CD34 is a molecule present on certain cells within the human body. Cells expressing CD34, otherwise known as CD34+ cells, are normally found in the umbilical cord and bone marrow as hematopoietic cells.

This discovery opens a new and innovative way for us to address a broad spectrum of human diseases, some of which currently lack effective treatment. Direct comparisons of Protectan CBLB612 and the market leading drug used for stimulation of blood regeneration, G-CSF (Neupogen® or Neulasta®, Amgen, Inc.), demonstrated a stronger efficacy of Protectan CBLB612 as a propagator and mobilizer of HSC in peripheral blood.

Protectan CBLB612's strength as a stem cell stimulator was further demonstrated by the outcome of its combined use with G-CSF and Mozibil (AMD3100) (an FDA approved stem cell mobilizer from Genzyme Corporation) where the addition of Protectan CBLB612 resulted in eight to ten times higher yields of HSC in peripheral blood in comparison with the standard protocol.

In addition to efficacy in stimulation and mobilization of stem cells in animal models, Protectan CBLB612 was found to be highly effective in an animal bone marrow stem cell transplantation model. Blood from healthy mice treated by Protectan CBLB612 was transplanted into mice that received a lethal dose of radiation that killed hematopoietic (bone marrow/blood production) stem cells. A small amount of blood from the Protectan CBLB612 treated mice successfully rescued the mice with radiation-induced bone marrow stem cell deficiency. All of the deficient mice transplanted with blood from Protectan CBLB612 treated mice survived past the 60-day mark, while 85% of the untreated deficient mice died within the first three weeks of the experiment. The 60-day mark is considered to be the critical point in defining the presence of long-term, adult bone marrow stem cells, which are capable of completely restoring lost or injured bone marrow function. The rescuing effect of the peripheral blood of the treated mice was equivalent to that of conventional bone marrow transplantation.

Adult hematological bone marrow stem cell transplantation is currently used for hematological disorders (malignant and non-malignant), as well as some non-hematological diseases, such as breast cancer, testicular cancer, neuroblastoma, ovarian cancer, Severe Combined Immune Deficiency, Wiskott-Aldrich syndrome and Chediak-Higashi syndrome.

With efficacy and non-GLP safety already studied in mice and monkeys, Protectan CBLB612 entered formal pre-clinical safety and manufacturing development in February 2008. Further development of Protectan CBLB612 will continue upon achieving sufficient funding for completing pre-clinical development and a Phase I study. Development of Protectan CBLB612 has been supported by a grant from the Defense Advanced Research Projects Agency of the DoD.

Two families of patent applications have been filed for Protectan CBLB612. Both patent applications, entitled “Methods of Protecting Against Apoptosis Using Lipopeptides” (Patent Number 2008/00126) and “Method of Increasing Hematopoietic Stem Cells” (Patent Number 2009/05378) have been granted by South Africa and we have received notices of intent to grant the first patent application from New Zealand and the Eurasian Patent Organization.

In September 2009, we executed a license agreement granting Zhejiang Hisun Pharmaceutical Co. Ltd. ("Hisun"), a leading pharmaceutical manufacturer in the People's Republic of China, exclusive rights to develop and commercialize Protectan CBLB612 in China, Taiwan, Hong Kong and Macau. Under the terms of the license agreement, we received product development payments of $1.65 million for protectan research (including Protectan

CBLB502). Hisun will be responsible for all development and regulatory approval efforts for Protectan CBLB612 in China. In addition, Hisun will pay us a 10% royalty on net sales over the 20-year term of the agreement. This royalty may decrease to 5% of net sales only in the event that patents for Protectan CBLB612 are not granted. We retain all rights to Protectan CBLB612 in the rest of the world.

In order for us to receive final FDA approval for Protectan CBLB612, we need to complete several interim steps, including:

- Conducting pivotal animal safety studies with cGMP-manufactured Protectan CBLB612;
- Submitting an IND application and receiving approval from the FDA to conduct clinical trials;
- Performing a Phase I dose-escalation human study;
- Performing Phase II and Phase III human efficacy studies using the dose of Protectan CBLB612 selected from the previous studies previously shown to be safe in humans and efficacious in animals; and

- Filing an NDA.

Because of the uncertainties of the scope of the remaining clinical studies, we cannot currently estimate when any development efforts may be completed or the cost of completion. Nor can we estimate when we may realize any cash flow from the development of Protectan CBLB612.

We spent approximately $5,140 and $6,567 on R&D for Protectan CBLB612 in the fiscal years ended December 31, 2010 and 2009, respectively. For the quarters ended March 31, 2011 and 2010, we spent $0 on R&D for Protectan CBLB612. From our inception to March 31, 2011, we spent $3,142,081 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.

The original focus of our drug development program was to develop drugs to treat one of the most treatment-resistant types of cancer, RCC. Unlike many cancer types that frequently mutate or delete p53, one of the major tumor suppressor genes, RCC belongs to a rare category of cancers that typically maintain a wild type form of this protein. Nevertheless, RCC cells are resistant to apoptosis, suggesting that in spite of its normal structure, p53 is functionally disabled. The work of our founders has shown that p53 function is indeed inhibited in RCC by an unknown dominant factor. We have established a drug discovery program to identify small molecules that selectively destroy tumor cells by restoring the normal function to functionally impaired p53 in RCC. This program yielded a series of chemicals with the desirable properties named curaxins (CBLC100 series). We have isolated three chemical classes of curaxins. One of them includes relatives of 9-aminoacridine, the compound that is the core structure of many existing drugs. Pre-existing information about this compound has allowed us to bypass the preclinical development and Phase I studies and bring one of our drug candidates into Phase IIa clinical trials, saving years of R&D efforts and improving the probability of success.

One of the most important outcomes of this drug discovery program was the identification of the mechanism by which curaxins deactivate NF-kB. This mechanism of action makes curaxins potent inhibitors of the production and the activity of NF-kB not only in its stimulated form, but also in its basal form. The level of active NF-kB is usually also increased in cancer cells. Moreover, due to curaxin-dependent functional conversion of NF-kB-DNA complexes, the cells with the highest basal or induced NF-kB activity are supposed to be the most significantly affected by curaxins. Clearly, this paradoxical activity makes deactivation of NF-kB by curaxins more advantageous compared to conventional strategies targeting NF-kB activators.

The discovery of the mechanism of action of curaxins allowed us to predict and later experimentally verify that curaxins could be used for treatment of multiple forms of cancers, including hormone-refractory prostate cancer, hepatocellular carcinoma, multiple myeloma, acute lymphocytic leukemia, acute myeloid leukemia, soft-tissue sarcomas and several others.

A significant milestone in the curaxin program was achieved with a breakthrough in deciphering the finer details of the mechanism of action of these compounds. Successful identification of the exact cellular moiety that binds to curaxins has provided a mechanistic explanation for the unprecedented ability of these compounds to simultaneously target several signal transduction pathways.

This additional mechanistic knowledge enabled us to discover additional advantages of curaxins and to rationally design treatment regimens and drug combinations, which have since been validated in experimental models. In addition, this understanding further strengthens our intellectual property position for this exciting class of principally new anticancer drugs.

In July 2010, a discovery regarding potential antiviral applications for our curaxin family of molecules was pre-published online in the Journal of Virology, the world's leading peer-reviewed journal in the field of virology (Gasparian, Neznanov, et al., Journal of Virology, doi:10.1128/JVI.02569-09; July 14, 2010).

The published study, conducted by our scientists in cooperation with investigators from RPCI and Cleveland State University, examined the ability of our prototype Curaxin CBLC102, or quinacrine, and other similar compounds to inhibit a mechanism used by picornaviruses to synthesize their proteins that is essential for their viability. This group of viruses includes important human pathogens such as poliovirus. In particular, the specific interaction of curaxins with double-stranded RNA effectively blocks synthesis of viral, but not cellular proteins. This study provides proof of principle for the prospective extension of curaxins from anticancer to antiviral applications.

Twelve families of patent applications have been filed around the curaxin family of compounds. An application titled "Small Molecule Inhibitors of MRP1 and Other Multidrug Responders" was approved by several nations, not including the U.S., and the Eurasian Patent Organization.

We spent approximately $1,572,630 and $592,690 on R&D for curaxins overall in the fiscal years ended December 31, 2010 and 2009, respectively. For the quarters ended March 31, 2011 and 2010, we spent $1,121,627 and $71,004, respectively, on R&D for curaxins. From our inception to March 31, 2011, we spent $14,928,540 on R&D for curaxins.

In December 2009, we entered into our Incuron joint venture with Bioprocess Capital Ventures ("BCV"), a Russian Federation venture capital fund, to develop our curaxin compounds for cancer, liver, viral and age related disease applications. According to the terms of the agreement, we transferred the aforementioned rights of curaxin molecules to the new joint venture, and BCV will contribute an aggregate of 549,497,000 Russian rubles (approximately $19.3 million based on the current exchange rate) to support development of the compounds. BCV made the first payments of 105,840,000 Russian rubles (approximately $3.7 million based on the current exchange rate) during April and June of 2010. In January 2011, BCV made an additional payment of 68,000,000 Russian rubles (approximately $2.4 million based on the current exchange rate) as part of its initial contribution. Pursuant to the participation agreement in March 2011, BCV made an additional payment of 1,730,000 Russian Rubles (approximately $0.1 million) based on the current exchange rate) as part of its initial contribution. As a result, BCV's ownership percentage increased to 24.2% and CBLI's ownership percentage decreased to 75.8%. BCV will make the balance of its contribution upon the achievement of predetermined development milestones. The first milestone payment of 192,737,000 Russian rubles (approximately $6.8 million based on the current exchange rate) will be made upon the completion of the preclinical studies and receipt of approval to begin clinical trials on oncology patients using Curaxin CBLC137, or any other lead Curaxin compound or the completion of the "proof-of- principle" characterization of the clinical efficacy of Curaxin CBLC102 in at least ten oncology patients. The second milestone payment of 181,190,000 Russian rubles (approximately $6.4 million based on the current exchange rate) will be made when the Phase II protocol is submitted to the FDA and when a letter of approval is received from the Institutional Review Board of the clinical center (including those in the Russian Federation) where the Phase II trial is to be conducted, indicating approval of the Phase II protocol and permission to commence the Phase II trial, or the achievement of the clinical end-point in the Phase II trial for Curaxin CBLC102.

Although it is anticipated that we will ultimately own 50.1% of the membership interest in Incuron, depending on the U.S. dollar/Russian ruble exchange rate and the U.S. dollar-equivalent value of the aggregate contributions made by BCV, we may be required to either transfer a portion of our ownership interest to BCV or make a cash contribution to Incuron. In such a case, if we choose to transfer a portion of its ownership interest to BCV, we may ultimately own less than 50.1% of the membership interest of Incuron, but will retain the right to appoint a majority of the members of the board of directors of Incuron. We serve as a subcontractor to Incuron to support certain mechanistic studies and oversee clinical development in the U.S.

Curaxin CBLC102

One of the curaxins from the 9-aminoacridine group is a long-known, anti-infective compound known as quinacrine, which we refer to as Curaxin CBLC102. It has been used for over 40 years to treat malaria, osteoarthritis and autoimmune disorders. However, we have discovered new mechanisms of action for quinacrine in the area of apoptosis. Through assay testing performed at Dr. Andrei Gudkov's laboratories at CCF beginning in 2002, which included testing in a variety of human tumor-derived cell lines representing cancers of different tissue origin (including RCC, sarcomas, prostate, breast and colon carcinomas), we have observed that Curaxin CBLC102 behaves as a potent NF-kB suppressor and activator of p53 in these types of cancer cells. As published in Oncogene (Guo et al., Oncogene, 2009, 28:1151-1161), it has now been shown that treatment of cancer cells with Curaxin CBLC102

results in the inhibition of the molecular pathway (PI3K/Akt/mTOR) that is important for cancer cell survival and is considered to be a highly relevant anticancer treatment target. Finally, Curaxin CBLC102 has favorable pharmacological and toxicological profiles and demonstrates the anticancer effect in transplants of human cancer cells into primates.

We launched a Phase II study with Curaxin CBLC102 in January 2007 to provide proof of safety and of anti-neoplastic activity in cancer patients and establish a foundation for clinical trials of our new proprietary curaxin molecules, which have been designed and optimized for maximum anticancer effects, as well as for additional treatment regimens based on ongoing research into the precise molecular mechanisms of action of curaxins. Thirty-one patients were enrolled in the Phase II study of Curaxin CBLC102 as a monotherapy in late stage, hormone-refractory taxane-resistant prostate cancer. All patients had previously received hormonal treatment for advanced prostate cancer and 28 of the 31 had also previously received chemotherapy. One patient had a partial response, while 50% of the patients exhibited a decrease or stabilization in PSA velocity, a measure of the speed of prostate cancer progression. Curaxin CBLC102 was well tolerated and there were no serious adverse events attributed to the drug. The trial demonstrated indications of activity and a remarkable safety profile in one of the most difficult groups of cancer patients.

The indications of activity and remarkable safety demonstrated in the Curaxin CBLC102 Phase II trial, in conjunction with new mechanistic discoveries, point to additional potential treatment paradigms including combination therapies with existing drugs or prospective use as a cancer prevention agent. Additional potential uses for Curaxin CBLC102 will be explored in conjunction with our strategic partners at RPCI and through the Incuron joint venture.

In November 2010, the first patient was dosed in a multi-center clinical trial of Curaxin CBLC102 on patients with liver tumors in the Russian Federation. The study is an open-label, dose escalation, Phase 1b safety and tolerability study in patients with liver metastases of solid tumors of epithelial origin, or primary advanced hepatic carcinoma for which standard therapy has failed or does not exist. The primary objective of the study is to determine the maximum tolerated dose and dose limiting toxicity in patients receiving Curaxin CBLC102. Secondary objectives of the study include describing the safety profile, pharmacokinetics, and response to Curaxin CBLC102.

The study includes a dose escalation arm of up to 30 patients divided into five cohorts, with an additional six patients to be enrolled at the selected therapeutic dose. Patients will be treated with Curaxin CBLC102 for eight weeks, with a loading dose administered in week 1 and maintenance doses administered in weeks 2 through 8. Dose escalation will be done gradually, starting with a loading dose of 300mg and a maintenance dose of 100mg. Recruitment is anticipated to take approximately six months, with overall duration of the study to last approximately 12 months.

The lead center for the study is the Russian Oncological Scientific Center ("ROSC") in Moscow, a leading oncology center in Russia. The national coordinator for the study is Professor S.A. Tyulyandin, MD, D.Sc. Deputy Director of Clinical Oncology and Director of Clinical Pharmacology and Chemotherapy at ROSC. Dr. Tyulyandin is one of the leading experts in drug therapy of malignant tumors in Russia and is considered a recognized expert on chemotherapy. Complex methods for the treatment of malignant neoplasms of the testes, breast, ovarian and other tumors have been developed under his leadership.

Insights into the mechanism of action of Curaxin CBLC102 were published in one of the world's leading cancer journals, Oncogene (Guo et al., Oncogene, 2009, 28:1151-1161). The published study uncovered additional molecular mechanisms underlying the anticancer activity of Curaxin CBLC102, which was previously known to involve simultaneous targeting of two key regulators of the controlled cell death process (p53 and NF-kB). It has now been shown that treatment of cancer cells with Curaxin CBLC102 results in the inhibition of the molecular pathway (PI3K/Akt/mTOR) that is important for cancer cell survival and is considered to be a highly relevant anticancer treatment target.

Another breakthrough discovery related to the mechanism of action of Curaxin CBLC102 was published in an international health science journal, Cell Cycle (Neznanov et al., Cell Cycle 8:23, 1-11; December 1, 2009). This study examined the ability of Curaxin CBLC102 to inhibit heat shock response, a major adaptive pro-survival pathway that rescues cells from stressful conditions involving accumulation of misfolded proteins (known as proteotoxic stress). Tumor cells typically become dependent on constitutive activity of this salvaging mechanism making them selectively susceptible to its inhibitors, especially if applied in combination with certain cancer therapies provoking proteotoxic stress.

The potential use of curaxins as adjuvants to cancer therapies inducing proteotoxic stress, such as bortezomib (Velcade(R)) or thermotherapy, opens a whole new avenue of potential treatment options that may broaden the spectrum of responding tumors by cutting off an escape mechanism.

Three families of patent applications have been filed for Curaxin CBLC102.

We anticipate that additional clinical efficacy studies will be required before we are able to apply for FDA licensure. Because of the uncertainties of the scope of the remaining clinical studies, we cannot currently estimate when any development efforts may be completed or the cost of completion. Nor can we estimate when we may realize any cash flow from the development of Curaxin CBLC102.

We spent approximately $399,068 and $262,637 on R&D for Curaxin CBLC102 in the fiscal years ended December 31, 2010 and 2009, respectively. For the quarters ended March 31, 2011 and 2010, we spent $815,365 and $35,201,

respectively, on R&D for Curaxin CBLC102. From our inception to March 31, 2011, we spent $7,943,552 on R&D for Curaxin CBLC102.

Other Curaxins

As mentioned above, screening of the chemical library for compounds capable of restoring normal function to wild type p53 in the context of RCC yielded three chemical classes of compounds. Generation of focused chemical libraries around the hits from one of these classes and their structure-activity optimization brought about a new generation of curaxins. As the part of this program performed in the partnership with ChemBridge Corporation, more than 800 proprietary compounds were screened for p53 activation, efficacy in animal tumor models, selective toxicity and metabolic stability in the presence of rat and human microsomes. The most active compounds were efficacious in preventing tumor growth in models for colon carcinoma, melanoma, ovarian cancer, RCC, and breast cancer.

As a result of this comprehensive hit-to-lead optimization program, we have developed Curaxin CBLC137, which is a drug candidate with proprietary composition of matter belonging to our next generation of highly improved curaxins. Curaxin CBLC137 has demonstrated reliable anti-tumor effects in animal models of colon, breast, renal and prostate cancers. Curaxin CBLC137 has favorable pharmacological characteristics, is suitable for oral administration and demonstrates a complete lack of genotoxicity. It shares all of the positive aspects of Curaxin CBLC102, but significantly exceeds the former compound's activity and efficacy in preclinical tumor models. Further development of Curaxin CBLC137 will continue through the Incuron joint venture.

Nine families of patent applications have been filed for other curaxins including one that also relates to Curaxin CBLC102.

We spent approximately $1,173,562 and $330,053 on R&D for other curaxins in the fiscal years ended December 31, 2010 and 2009, respectively. For the quarters ended March 31, 2011 and 2010, we spent $306,263 and $35,803, respectively, on R&D for other curaxins. From our inception to March 31, 2011, we spent $6,984,987 on R&D for other curaxins.

Curaxin CBLC137 is at a very early stage of its development and, as a result, it is premature to estimate when any development may be completed, the cost of development or when any cash flow could be realized from development.

FINANCIAL OVERVIEW

Including several non-cash charges, our net loss increased from $3,364,011 for the three months ended March 31, 2010 to $5,745,366 for the three months ended March 31, 2011, an increase of $2,381,355 or 70.8%. We incurred non-cash charges of depreciation and amortization of $110,393 and $100,724, non-cash salaries and consulting fees of $923,036 and $936,690 and a change in the value of warrants of $714,951 and $1,731,096 for the three months ended March 31, 2011 and 2010, respectively. Excluding these non-cash charges, our net loss increased $3,401,485 or 571.2% from $595,501 for the three months ended March 31, 2010 to $3,996,986 for the three months ended March 31, 2011. This increase was primarily due to higher R&D costs due to increased animal studies as well as a reduction in revenue.

Our total cash and equivalents, short-term investments and accounts receivable decreased from $16,760,022 at December 31, 2010 to $16,206,419 at March 31, 2011. This decrease of $553,603 or 3.3% was primarily due to our operating losses partially offset by capital contributions to Incuron and cash proceeds from the exercise of warrants and options.

Equity Overview

On February 13, 2009, March 20, 2009, and March 27, 2009, we entered into purchase agreements with various accredited investors, pursuant to which we agreed to sell to these investors an aggregate of 542.84 shares of Series D Convertible Preferred Stock and Series D Warrants to purchase an aggregate of 3,877,386 shares of the Company's common stock. The warrants have a seven-year term and a per share exercise price of $1.60. Each share of Series D Preferred was convertible into the number of shares of common stock equal to (1) the stated value of the share ($10,000), divided by (2) the then-current conversion price (initially $1.40, but subject to adjustment as described below). At the initial conversion price of $1.40, each share of Series D Preferred was convertible into approximately 7,143 shares of common stock. The aggregate purchase price paid by the investors for the Series D Preferred and the Series D warrants was approximately $5,428,307 (representing $10,000 for each share together with a warrant). After related fees and expenses, we received net proceeds of approximately $4,460,000. In consideration for its services as exclusive placement agent, Garden State Securities received cash compensation and warrants to purchase an aggregate of approximately 387,736 shares of common stock.

The conversion price of the Series D Preferred was subject to certain automatic adjustments, pursuant to which it reduced from $1.40 to $1.33 on August 13, 2009 and from $1.33 to $1.28 on November 13, 2009. On December 31, 2009, the conversion price of the Series D Preferred reduced from $1.28 to $1.02 because the Company failed to meet a particular development milestone by the end of 2009. At the conversion price of $1.02, each shares of Series D Preferred was convertible into approximately 9,804 shares of common stock. Upon completion of the Series D Preferred transaction and upon each adjustment to the conversion price of the Series D Preferred, the exercise prices of the Company's Series B Warrants and Series C Warrants, and the exercise price of certain other warrants issued prior to the Company's initial public offering, were reduced pursuant to weighted-average anti-dilution provisions. In addition to the adjustment to the exercise prices of these warrants, the aggregate number of shares issuable upon exercise of these warrants increased on each such occasion. As a result, the Series B Warrants had an exercise price of $6.37 per share and an aggregate of 3,847,276 shares of common stock were issuable upon exercise of the Series B Warrants, the Series C Warrants had an exercise price of $6.76 per share and an aggregate of 434,596 shares were issuable upon exercise of the Series C Warrants, and such warrants issued prior to our initial public offering had an exercise price of $1.39 per share and an aggregate of 117,861 shares were issuable upon exercise of such warrants.

On February 9, 2010, all outstanding shares of Series D Preferred automatically converted into approximately 4,576,979 shares of common stock at the conversion price of $1.02, as a result of the Company's closing sales price being above a certain level for 20 consecutive trading days as well as the satisfaction of certain other conditions.

On February 25, 2010, we entered into a Securities Purchase Agreement (the "February 2010 Securities Purchase Agreement") with various accredited investors, pursuant to which we agreed to sell an aggregate of 1,538,462 shares of our common stock and warrants to purchase an aggregate of 1,015,385 shares of our common stock, for an aggregate purchase price of $5,000,002. The transaction closed on March 2, 2010. After related fees and expenses, the Company received net proceeds totaling $4,423,882. The common stock was sold at a price of $3.25 per share, and the warrants have an exercise price of $4.50 per share, subject to future adjustment for various events, such as stock splits or dilutive issuances. The warrants expire on March 2, 2015. For its services as placement agent, Rodman & Renshaw, LLC ("Rodman") received gross cash compensation in the amount of approximately $350,000, and it and its designees collectively received warrants to purchase 123,077 shares of common stock. The common stock and the shares of common stock underlying the warrants issued to the purchasers and Rodman have not been registered under the Securities Act of 1933.

Immediately after the completion of this transaction on March 2, 2010, pursuant to weighted-average anti-dilution provisions:

- the exercise price of the Series B Warrants reduced from $6.37 to $5.99, and the aggregate number of shares of common stock issuable upon exercise of the Series B Warrants increased from 3,847,276 to 4,091,345; and

- the exercise price of the Series C Warrants reduced from $6.76 to $6.35, and the aggregate number of shares of common stock issuable upon exercise of the Series C Warrants increased from 434,596 to 462,654.

On December 23, 2010, we entered into a Placement Agent Agreement with HFP Capital Markets, LLC ("HFP") relating to the sale by us to a single institutional accredited investor of 1,400,000 shares of our common stock in a "registered direct" offering ("December 2010 Offering"). The December 2010 Offering closed on December 29, 2010. The shares were sold at a purchase price of $5.99 per share. The sale of the shares was made pursuant to a Subscription Agreement, dated December 23, 2010 with the investor. HFP and Rodman acted as co-placement agents in connection with the December 2010 Offering. The net proceeds to us from the sale of the shares, after deducting for the placement agents' fees and offering expenses, was approximately $7.73 million.

As a result of the completion of the December 2010 Offering, the aggregate number of shares of common stock issuable to the holders of the Series C Warrants increased from 462,654 shares to 464,852 shares and the exercise price of the Series C Warrants decreased from $6.35 per share to $6.32 per share.

Also in connection with the December 2010 Offering, on December 23, 2010, the investors party to the February 2010 Securities Purchase Agreement, who purchased at least 75% of the aggregate original subscription amount, entered into an amendment to the February 2010 Securities Purchase Agreement with us. Such investors were granted the right to participate in certain future financing transactions ("Subsequent Financings") on or prior to the earlier of (i) the first trading day immediately following the date on which we complete Subsequent Financings resulting in aggregate gross proceeds in excess of $15 million, or (ii) December 31, 2011, and will have the right to participate in an amount of the Subsequent Financing equal to 100% of the Subsequent Financing amount, on the same terms, conditions and price provided for in the Subsequent Financing.

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.

Note 2 to our financial statements includes disclosure of our significant accounting policies. Critical accounting estimates, as defined by the SEC, are those that are most important to the portrayal of our financial condition and results of operations and require our most difficult and subjective judgments and estimates of matters that are inherently uncertain. 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, and are discussed in more detail below.

Revenue Recognition

Our revenue sources consist of government grants, government contracts and a commercial licensing and development contract.

Grant revenue is recognized using two different methods depending on the type of grant. Cost reimbursement grants require us to submit proof of costs incurred that are invoiced by us to the government agency, which then pays the invoice. In this case, grant revenue is recognized during the period that the costs were incurred.

Fixed-cost grants require no proof of costs and are paid as a request for payment is submitted for expenses. The grant revenue under these fixed cost grants is recognized using a percentage-of-completion method, which uses assumptions and estimates. These assumptions and estimates are developed in coordination with the principal investigator performing the work under the fixed-cost grants to determine key milestones, expenses incurred, and deliverables to perform a percentage-of-completion analysis to ensure that revenue is appropriately recognized. Critical estimates involved in this process include total costs incurred and anticipated to be incurred during the remaining life of the grant.

We recognize revenue related to the funds received from the State of New York under the sponsored research agreement with RPCI as allowable costs are incurred. We recognize revenue on research laboratory services and the subsequent use of related equipment. The amount paid as a payment toward future services related to the equipment is recognized as a prepaid asset and will be recognized as revenue ratably over the useful life of the asset.

Government contract revenue is recognized as allowable R&D expenses are incurred during the period and according to the terms of the contract.

Commercial revenue is recognized when the service or development is delivered or upon complying with the relevant terms of the commercial agreement including licensing agreements granting the rights to further develop technology leading to commercialization in certain territories.

Research and Development Expenses

R&D costs are expensed as incurred. These expenses consist primarily of our proprietary R&D efforts, including salaries and related expenses for personnel, costs of materials used in our R&D, costs of facilities, and costs incurred in connection with our third-party collaboration efforts. Pre-approved milestone payments made by us to third parties under contracted R&D arrangements are expensed when the specific milestone has been achieved. As of March 31, 2011, $50,000 has been paid to CCF for milestone payments relating to the filing of an IND with the FDA for Curaxin CBLC102, $250,000 has been paid to CCF as a result of commencing Phase II clinical trials for Curaxin CBLC102 and $50,000 has been paid to CCF relating to the filing of an IND with the FDA for Protectan CBLB502. Once a drug receives regulatory approval, we will record any subsequent milestone payments in identifiable intangible assets, less accumulated amortization, and amortize them evenly over the remaining agreement term or the expected drug life cycle, whichever is shorter. We expect our R&D expenses to increase as we continue to develop our drug candidates.

Intellectual Property Related Costs

We capitalize costs associated with the preparation, filing and maintenance of our intellectual property rights. Capitalized intellectual property is reviewed annually for impairment. If a patent application is approved, costs paid by us associated with the preparation, filing and maintenance of the patent will be amortized on a straight line basis over the shorter of 20 years from the initial application date or the anticipated useful life of the patent. If the patent application is not approved, costs paid by us associated with the preparation, filing and maintenance of the patent will be expensed as part of selling, general and administrative expenses at that time.

Through December 31, 2010, we capitalized $1,162,287 in expenditures less amortization associated with the preparation, filing and maintenance of certain of our patents. We capitalized an additional $120,215, amortized an additional $6,892 and recognized a deferred loss of $12,950 related to foreign currency translation for three month ended March 31, 2011, resulting in a balance of capitalized intellectual property at March 31, 2011 totaling $1,288,560.

Stock-based Compensation

All stock-based compensation, including grants of employee stock options, is recognized in the statement of operations based on its fair value.

The fair value of each stock option granted is estimated on the grant date using accepted valuation techniques such as the Black Scholes Option Valuation model or Monte Carlo Simulation depending on the terms and conditions present within the specific option being valued. The assumptions used to calculate the fair value of options granted are evaluated and revised, as necessary, to reflect our experience. We use a risk-free rate based on published rates from the St. Louis Federal Reserve at the time of the option grant; assume a forfeiture rate of zero; assume an expected dividend yield rate of zero based on our intent not to issue a dividend in the foreseeable future; use an expected life based on the safe harbor method; and presently compute an expected volatility based on a method layering in the volatility of our common stock with that of the volatility of similar high-growth, publicly-traded, biotechnology companies' common stock due to the limited trading history of our company. Compensation expense is recognized using the straight-line amortization method for all stock-based awards.

During the three months ended March 31, 2011 and March 31, 2010, we granted 760,673 and 144,029 stock options, respectively. We recognized a total of $673,282 and $330,246 in expense related to stock options for the three months ended March 31, 2011 and March 31, 2010, respectively. We also recaptured $17,953 of previously recognized expense for stock options awarded under the 2010 Executive Compensation Plan. These options were originally expensed based on the December 31, 2010 assumptions, but were not issued until March 21, 2011. The change in dates resulted in a difference in valuation assumptions used in the Black-Scholes model causing a reduction in the grant date fair value. This reduction in the grant date fair value from $5.00 to $4.97 per share resulted in the recapture of $17,953 in expense. We also recaptured $16,227 and $38,787 of previously recognized expense due to the forfeiture of non-vested stock options during the three months ended March 31, 2011 and March 31, 2010, respectively. The net expense for options for the three months ended March 31, 2011 and March 31, 2010 was $639,103 and $291,459, respectively.

We also recognized a total of $283,933 and $641,898 in expense for shares issued and a total of $0 and $3,333 in expense related to the amortization of restricted shares for the three months ended March 31, 2011 and March 31, 2010, respectively.

Fair Value Measurement

We value our financial instruments in accordance with accounting standards on disclosures which establish a valuation hierarchy for the inputs used to measure fair value. This hierarchy prioritizes the 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. We do not have any significant assets or liabilities measured at fair value using Level 1 or Level 2 inputs as of March 31, 2011.

The Company analyzed all financial instruments with features of both liabilities and equity.

The Company carries the warrants issued in the Series D Private Placement at fair value using Level 3 inputs for its valuation methodology totaling $21,526,268 and $21,223,779 as of March 31, 2011 and December 31, 2010, respectively. The Company recognized a fair value measurement loss of $870,275 and $2,380,019 for the three months ended March 31, 2011 and 2010, respectively.

The Company carries the warrants issued in conjunction with the March 2010 Common Stock Equity Offering at fair value using Level 3 inputs for its valuation methodology totaling $3,591,878 and $4,126,954 of March 31, 2011 and December 31, 2010, respectively. The Company recognized a fair value measurement gain of $155,324 and $648,923 for the three months ended March 31, 2011 and 2010, respectively.

We did not identify any other non-recurring assets and liabilities that are required to be presented on the balance sheets at fair value.

Results of Operations

The following table sets forth our statement of operations data for the three months ended March 31, 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	Three Months	Year Ended	Year Ended

	Ended March 31, 2011 (unaudited)	Ended March 31, 2010 (unaudited)	December 31, 2010	December 31, 2009
Revenues	$ 2,473,982	$ 4,170,348	$ 15,331,567	$ 14,345,908
Operating expenses	7,586,135	5,627,281	26,068,765	20,728,837
Other expense (income)	671,472	1,912,851	16,033,770	6,463,208
Net interest expense (income)	(38,259)	(5,773)	(99,111)	(19,728)
Net income (loss)	$ (5,745,366)	$ (3,364,011)	$ (26,671,857)	$ (12,826,409)

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

	Three Months Ended March 31, 2011 (unaudited)	Three Months Ended March 31, 2010 (unaudited)	Year Ended December 31, 2010	Year Ended December 31, 2009	Total Since Inception (unaudited)
Research and development	$ 5,708,933	$ 3,697,780	$ 16,141,040	$ 14,331,673	$79,438,368
General	$ 59,603	$ 34,206	$ 246,730	$ -	$5,412,963
Protectan CBLB502 - non-medical applications	$ 4,504,932	$ 3,592,570	$ 14,316,540	$ 13,676,289	$54,098,958
Protectan CBLB502 - medical applications	$ 22,770	$ -	$ -	$ 56,127	$1,855,827
Protectan CBLB612	$ -	$ -	$ 5,140	$ 6,567	$3,142,081
Curaxin CBLC102	$ 815,365	$ 35,201	$ 399,068	$ 262,637	$7,943,552
Other Curaxins	$ 306,263	$ 35,803	$ 1,173,562	$ 330,053	$6,984,987

Three Months Ended March 31, 2011 Compared to Three Months Ended March 31, 2010

Revenue

Revenue decreased from $4,170,348 for the three months ended March 31, 2010 to $2,473,982 for the three months ended March 31, 2011 representing a decrease of $1,696,366 or 40.7% resulting primarily from a decrease in revenue from various federal grants and contracts including the Department of Defense 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 March 31) (unaudited)	Revenue 2010 (thru March 31) (unaudited)	Revenue 2010
DOD	CBMS-MITS Contract	$ 5,391,866	09/2010-03/2013	$ 1,875,134	$ -	$ 623,975
DTRA	DTRA Contract	$ 1,589,106	01/2011-05/2012	$ 356,887	$ -	$ -
HHS	BARDA Contract	$ 15,600,000	09/2008-02/2011	$ 237,748	$ 2,972,852	$ 9,968,445
NY State/RPCI	Sponsored Research Agreement	$ 3,000,000	03/2007-02/2012	$ 4,213	$ 4,144	$ 12,398
NIH	NIAID GO Grant	$ 5,329,543	09/2009-09/2011	$ -	$ 809,670	$ 4,091,879
DoD	DOD Contract	$ 9,590,000	05/2008-09/2010	$ -	$ 383,122	$ 564,432
NIH	NIAID Grant	$ 1,232,695	09/2008-02/2010	$ -	$ 560	$ 560
AFRRI	Subcontractor	$ 69,878	02/2010-11/2010	$ -	$ -	$ 69,878
				$ 2,473,982	$ 4,170,348	$ 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 $5,627,281 for the three months ended March 31, 2010 to $7,586,135 for the three months ended March 31, 2011, an increase of $1,958,854 or 34.8%. We recognized a total of $923,036 of non-cash, stock-based compensation for the three months ended March 31, 2011 compared to $936,690 for the three months ended March 31, 2010. If these non-cash, stock-based compensation expenses were excluded, operating expenses would have increased from $4,690,591 for the three months ended March 31, 2010 to $6,663,099 for the three months ended March 31, 2011. This represents an increase in operating expenses of $1,972,508 or 42.1% as explained below.

Research and development costs increased from $3,697,780 for the three months ended March 31, 2010 to $5,708,933 for the three months ended March 31, 2011. This represents an increase of $2,011,153 or 54.4%. We recognized a total of $534,278 of R&D non-cash, stock based compensation for the three months ended March 31, 2011 compared to $140,190 for the three months ended March 31, 2010. Without the non-cash, stock-based compensation, the R&D expenses increased from $3,557,590 for the three months ended March 31, 2010 to $5,174,655 for the three months ended March 31, 2011, an increase of $1,617,065 or 45.5%. The higher research and development expenses were a result of increased R&D efforts by Incuron for Curaxins and extensive animal studies for CBLB502.

Selling, general and administrative costs decreased from $1,929,501 for the three months ended March 31, 2010 to $1,877,202 for the three months ended March 31, 2011. This represents a decrease of $52,299 or 2.7%. We recognized a total of $388,758 of non-cash, stock-based compensation under selling, general and administrative costs for the three months ended March 31, 2011 compared to $796,500 for the three months ended March 31, 2010. Without the non-cash, stock-based compensation, the selling, general and administrative expenses increased from $1,133,001 for the three months ended March 31, 2010 to $1,488,444 for the three months ended March 31, 2011, an increase of $355,443 or 31.4%. This increase is primarily due to the selling, general and administrative expenses from 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.

Liquidity and Capital Resources

We have incurred annual operating losses since our inception, and, as of March 31, 2011, we had an accumulated deficit of $101,553,037. 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, which to date we have not.

Net cash used in operating activities totaled $842,224 for the three months ended March 31, 2011, compared to $158,794 used in operating activities for the three months ended March 31, 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 CBLB502.

Net cash used in investing activities was $1,730,370 for the three months ended March 31, 2011, compared to net cash used in investing activities of $181,130 for the three months ended March 31, 2010. The increase in cash used in investing activities resulted primarily from the purchase of short-term investments.

Net cash provided by financing activities totaled $3,508,147 for the three months ended March 31, 2011, compared to net cash provided by financing activities of $4,591,111 for the three months ended March 31, 2010. The decrease in cash provided by financial activities was attributed to the March 2010 Common Stock Equity Offering that took place in the first quarter of 2010 offset by the capital contributions made by BCV for Incuron and greater option and warrant exercise activity in the first three months of 2011.

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 March 31, 2011, we are obligated to make payments under these agreements of 1,243,852 Euros. We have purchased 683,875 Euros and, therefore, at March 31, 2011, had foreign currency risk of $749,406 for Euros given prevailing currency exchange spot rates.

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 quarter 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 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 March 31, 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 March 31, 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 March 31, 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 March 31, 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 year 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 year ended December 31, 2010.

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

On February 1, 2011, as consideration for consulting services provided, we issued an aggregate of 15,687 shares of our common stock to Newport Coast Securities, Inc. These shares were issued without registration in reliance on the exemptions afforded by Section 4(2) of the Securities Act of 1933, as amended.

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
31.1	Certification of Michael Fonstein, Chief Executive Officer, pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
31.2	Certification of John A. Marhofer, Jr., 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

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: May 10, 2011	By:	/s/ MICHAEL FONSTEIN Michael Fonstein Chief Executive Officer (Principal Executive Officer)
Dated: May 10, 2011	By:	/s/ JOHN A. MARHOFER, JR. John A. Marhofer, Jr. Chief Financial Officer (Principal Financial Officer)