

CLEVELAND BIOLABS INC  
Form 10-Q  
November 12, 2009

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2009

OR

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

For the transition period from \_\_\_\_ to \_\_\_\_

Commission file number 001-32954

CLEVELAND BIOLABS, INC.  
(Exact name of registrant as specified in its charter)

DELAWARE  
(State or other jurisdiction of incorporation or organization)

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

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

14203  
(Zip Code)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

As of November 10, 2009, there were 20,127,792 shares outstanding of registrant's common stock, par value \$0.005 per share

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CLEVELAND BIOLABS INC  
10-Q  
11/12/2009

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In this report, "Cleveland BioLabs," "CBLI," "we," "us" and "our" refer to Cleveland BioLabs, Inc. Our common stock, par value \$0.005 per share is referred to as "common stock."



## CLEVELAND BIOLABS, INC.

## BALANCE SHEETS

September 30, 2009 (unaudited) and December 31, 2008

	September 30 2009 (unaudited)	December 31 2008
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and equivalents	\$ 2,097,592	\$ 299,849
Short-term investments	-	1,000,000
Accounts receivable:		
Trade	2,723,227	1,043,821
Interest	-	9,488
Other prepaid expenses	420,284	510,707
Total current assets	5,241,103	2,863,865
<b>EQUIPMENT</b>		
Computer equipment	314,058	309,323
Lab equipment	1,124,277	1,102,465
Furniture	333,980	312,134
	1,772,315	1,723,922
Less accumulated depreciation	905,914	637,840
	866,401	1,086,082
<b>OTHER ASSETS</b>		
Intellectual property	860,622	733,051
Deposits	23,482	23,482
	884,104	756,533
<b>TOTAL ASSETS</b>	<b>\$ 6,991,608</b>	<b>\$ 4,706,480</b>

## CLEVELAND BIOLABS, INC.

## BALANCE SHEETS

September 30, 2009 (unaudited) and December 31, 2008

	September 30 2009 (unaudited)	December 31 2008
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 1,278,287	\$ 1,101,961
Deferred revenue	3,333,295	2,365,312
Dividends payable	-	321,293
Accrued expenses	108,936	379,653
Accrued warrant liability	12,582,110	-
Total current liabilities	17,302,628	4,168,219
<b>STOCKHOLDERS' EQUITY</b>		
Preferred stock, \$.005 par value		
Authorized - 10,000,000 shares at September 30, 2009 and December 31, 2008		
Series B convertible preferred stock,		
Issued and outstanding 0 and 3,160,974		
shares at September 30, 2009 and December 31, 2008, respectively	-	15,805
Series D convertible preferred stock,		
Issued and outstanding 495.25 and 0		
shares at September 30, 2009 and December 31, 2008, respectively	2	-
Common stock, \$.005 par value		
Authorized - 80,000,000 and 40,000,000 shares at September 30, 2009 and December 31, 2008, respectively		
Issued and outstanding 19,460,954 and 13,775,805		
shares at September 30, 2009 and December 31, 2008, respectively	97,305	68,879
Additional paid-in capital	61,078,135	56,699,750
Accumulated deficit	(71,486,462)	(56,246,173)
Total stockholders' equity (deficit)	(10,311,020)	538,261
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 6,991,608</b>	<b>\$ 4,706,480</b>

## CLEVELAND BIOLABS, INC.

## STATEMENT OF OPERATIONS

Three and Nine Months Ending September 30, 2009 and 2008 (unaudited)

	Three Months Ended		Nine Months Ended	
	September 30	September 30	September 30	September 30
	2009	2008	2009	2008
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
<b>REVENUES</b>				
Grant and contract	\$ 3,223,094	\$ 1,851,419	\$ 9,717,803	\$ 3,082,119
Service	-	-	-	120,000
	3,223,094	1,851,419	9,717,803	3,202,119
<b>OPERATING EXPENSES</b>				
Research and development	3,327,609	3,485,430	10,602,591	9,719,519
Selling, general and administrative	986,569	1,240,142	3,945,595	4,425,792
Total operating expenses	4,314,178	4,725,572	14,548,186	14,145,311
<b>LOSS FROM OPERATIONS</b>	<b>(1,091,084)</b>	<b>(2,874,153)</b>	<b>(4,830,383)</b>	<b>(10,943,192)</b>
<b>OTHER INCOME</b>				
Interest income	2,046	49,450	19,303	244,593
Buffalo relocation reimbursement	-	-	-	220,000
Sublease revenue	11,337	2,656	20,348	7,970
Gain on disposal of fixed assets	-	-	-	1,394
Gain on investment	-	-	-	3,292
Total other income	13,383	52,106	39,651	477,249
<b>OTHER EXPENSE</b>				
Warrant issuance costs	-	-	266,970	-
Corporate relocation	-	8,933	-	142,638
Interest expense	-	-	1,960	-
Change in value of warrant liability	4,111,578	-	9,565,276	-
Total other expense	4,111,578	8,933	9,834,206	142,638
<b>NET LOSS</b>	<b>\$ (5,189,279)</b>	<b>\$ (2,830,980)</b>	<b>\$ (14,624,938)</b>	<b>\$ (10,608,581)</b>
<b>DIVIDENDS ON CONVERTIBLE PREFERRED STOCK</b>	<b>(123,900)</b>	<b>(317,814)</b>	<b>(615,352)</b>	<b>(898,260)</b>
<b>NET LOSS AVAILABLE TO COMMON SHAREHOLDERS</b>	<b>\$ (5,313,179)</b>	<b>\$ (3,148,794)</b>	<b>\$ (15,240,290)</b>	<b>\$ (11,506,841)</b>
<b>NET LOSS AVAILABLE TO COMMON SHAREHOLDERS</b>				

PER SHARE OF COMMON STOCK - BASIC AND DILUTED	\$ (0.33)	\$ (0.23)	\$ (1.00)	\$ (0.86)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATING NET LOSS PER SHARE, BASIC AND DILUTED	15,878,331	13,605,822	15,184,785	13,415,376



## CLEVELAND BIOLABS, INC.

## STATEMENTS OF CASH FLOWS

For the Nine Months Ended September 30, 2009 and 2008 (unaudited)

	September 30 2009 (unaudited)	September 30 2008 (unaudited)
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (14,624,938)	\$ (10,608,581)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation	268,074	239,339
Noncash salaries and consulting expense	2,113,965	1,150,692
Loss on abandoned patents	23,984	-
Series D warrant issuance costs	266,970	-
Change in value of warrant liability	9,565,276	-
Changes in operating assets and liabilities:		
Accounts receivable - trade	(1,679,406)	(1,205,216)
Accounts receivable - interest	9,488	44,643
Other prepaid expenses	90,423	(249,748)
Deposits	-	1,964
Accounts payable	176,326	1,060,807
Deferred revenue	967,983	760,497
Accrued expenses	(270,717)	(97,848)
Milestone payments	-	-
Total adjustments	11,532,366	1,705,130
Net cash (used in) provided by operating activities	(3,092,572)	(8,903,451)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Sale of short-term investments	1,000,000	-
Purchase of equipment	(48,393)	(153,253)
Costs of patents pending	(151,555)	(263,284)
Net cash (used in) provided by investing activities	800,052	(416,537)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from issuance of Series D preferred stock and warrants	5,428,307	-
Financing costs on Series D preferred stock	(720,175)	-
Series D warrant issuance costs	(266,970)	-
Dividends	(936,644)	(1,250,410)
Exercise of stock options	285,747	24,378
Exercise of warrants	299,998	-
Net cash (used in) provided by financing activities	4,090,263	(1,226,032)
<b>INCREASE (DECREASE) IN CASH AND EQUIVALENTS</b>	<b>1,797,743</b>	<b>(10,546,020)</b>
<b>CASH AND EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>299,849</b>	<b>14,212,189</b>

CASH AND EQUIVALENTS AT END OF PERIOD	\$ 2,097,592	\$ 3,666,169
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CLEVELAND BIOLABS, INC.

STATEMENTS OF CASH FLOWS

For the Nine Months Ended September 30, 2009 and 2008 (unaudited)

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Supplemental disclosures of cash flow information:

Cash paid during the period for interest	\$ 1,960	\$ -
Cash paid during the year for income taxes	\$ -	\$ -

Supplemental schedule of noncash financing activities:

Issuance of stock options to employees, consultants, and independent board members	\$ 1,527,719	\$ 1,929,432
Expense recapture of expense for options expensed in 2007 but issued in 2008	\$ -	\$ (1,459,425)
Expense recapture of expense for options that were nonvested and forfeited	\$ (37,878)	\$ -
Issuance of shares to consultants and employees	\$ 599,217	\$ 626,500
Accrual of Series B preferred stock dividends	\$ -	\$ 44,320
Amortization of restricted shares issued to employees	\$ 24,907	\$ 54,185

CLEVELAND BIOLABS, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2008 to December 31, 2008 and to  
September 30, 2009 (unaudited)

	Stockholders' Equity	
	Common Stock	
	Shares	Amount
Balance at January 1, 2008	12,899,241	\$ 64,496
Issuance of options	-	-
Partial recapture of expense for options expensed in 2007 but issued in 2008	-	-
Issuance of restricted shares	130,000	650
Restricted stock awards	-	-
Exercise of options	37,271	186
Conversion of Series B Preferred Shares to Common	709,293	3,547
Dividends on Series B Preferred shares	-	-
Net Loss	-	-
Balance at December 31, 2008	13,775,805	\$ 68,879
Issuance of options	-	-
Issuance of restricted shares	193,312	966
Recapture of expense for nonvested options forfeited	-	-
Restricted stock awards	-	-
Exercise of options	149,534	748
Exercise of warrants	290,953	1,455
Conversion of Series B Preferred Shares to Common	4,693,530	23,468
Dividends on Series B Preferred shares	-	-
Issuance of shares - Series D financing	-	-
Allocation of financing proceeds to fair value of Series D warrants	-	-
Fees associated with Series D Preferred offering	-	-
Conversion of Series D Preferred Shares to Common	357,820	1,789
Net Loss	-	-
Balance at September 30, 2009	19,460,954	\$ 97,305

CLEVELAND BIOLABS, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2008 to December 31, 2008 and to  
September 30, 2009 (unaudited)

	Stockholders' Equity			
	Preferred Stock			
	Series B	Amount	Series D	Amount
Balance at January 1, 2008	3,870,267	\$ 19,351	-	\$ -
Issuance of options	-	-	-	-
Partial recapture of expense for options expensed in 2007 but issued in 2008	-	-	-	-
Issuance of restricted shares	-	-	-	-
Restricted stock awards	-	-	-	-
Exercise of options	-	-	-	-
Conversion of Series B Preferred Shares to Common	(709,293)	(3,547)	-	-
Dividends on Series B Preferred shares	-	-	-	-
Net Loss	-	-	-	-
Balance at December 31, 2008	3,160,974	\$ 15,805	-	\$ -
Issuance of options	-	-	-	-
Issuance of restricted shares	-	-	-	-
Recapture of expense for nonvested options forfeited	-	-	-	-
Restricted stock awards	-	-	-	-
Exercise of options	-	-	-	-
Exercise of warrants	-	-	-	-
Conversion of Series B Preferred Shares to Common	(3,160,974)	(15,805)	-	-
Dividends on Series B Preferred shares	-	-	-	-
Issuance of shares - Series D financing	-	-	543	3
Allocation of financing proceeds to fair value of Series D warrants	-	-	-	-
Fees associated with Series D Preferred offering	-	-	-	-
Conversion of Series D Preferred Shares to Common	-	-	(48)	(1)
Net Loss	-	-	-	-
Balance at September 30, 2009	-	\$ -	495	\$ 2

CLEVELAND BIOLABS, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

Period From January 1, 2008 to December 31, 2008 and to  
September 30, 2009 (unaudited)

	Stockholders' Equity			Comprehensive Income (Loss)
	Additional Paid-in Capital	Accumulated Deficit	Total	
Balance at January 1, 2008	\$ 55,148,608	\$ (41,038,212)	\$ 14,194,244	
Issuance of options	2,287,803	-	2,287,803	
Partial recapture of expense for options expensed in 2007				
but issued in 2008	(1,459,425)	-	(1,459,425)	
Issuance of restricted shares	625,850	-	626,500	
Restricted stock awards	72,722	-	72,722	
Exercise of options	24,191	-	24,378	
Conversion of Series B Preferred Shares to Common	-	-	-	
Dividends on Series B Preferred shares	-	(1,182,033)	(1,182,033)	
Net Loss	-	(14,025,927)	(14,025,927)	\$ (14,025,927)
Balance at December 31, 2008	\$ 56,699,750	\$ (56,246,172)	\$ 538,262	
Issuance of options	1,527,719	-	1,527,719	
Issuance of restricted shares	598,251	-	599,217	
Recapture of expense for nonvested options forfeited	(37,878)	-	(37,878)	
Restricted stock awards	24,907	-	24,907	
Exercise of options	284,999	-	285,747	
Exercise of warrants	298,543	-	299,998	
Conversion of Series B Preferred Shares to Common	(7,663)	-	-	
Dividends on Series B Preferred shares	-	(615,352)	(615,352)	
Issuance of shares - Series D financing	5,428,304	-	5,428,307	
Allocation of financing proceeds to fair value of Series D warrants	(3,016,834)	-	(3,016,834)	
Fees associated with Series D Preferred offering	(720,175)	-	(720,175)	
Conversion of Series D Preferred Shares to Common	(1,788)	-	-	
Net Loss	-	(14,624,938)	(14,624,938)	\$ (14,624,938)
Balance at September 30, 2009	\$ 61,078,135	\$ (71,486,462)	\$ (10,311,020)	

CLEVELAND BIOLABS, INC.

NOTES TO FINANCIAL STATEMENTS

Note 1. Organization

Cleveland BioLabs, Inc. (“CBLI” or the “Company”) is engaged in the discovery, development and commercialization of products for cancer treatment and protection of normal tissues from radiation and other stresses. The Company was incorporated under the laws of the State of Delaware on June 5, 2003 and is headquartered in Buffalo, New York.

Basis of Presentation

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.

In March 2009, the Company secured additional financing by issuing additional convertible preferred shares with warrants. The Company continues to explore other investment or licensing arrangements and also plans to submit proposals for government contracts and grants over the next two years totaling over \$30 million. Many of the proposals will be submitted to government agencies that have awarded contracts and grants to the Company in the recent past. Finally, the Company has implemented cost containment efforts that permit the incurrence of those costs that are properly funded, either through a government contract or grant or other capital sources such as direct investment. It is expected that the successful implementation of the financing and cost containment efforts identified above will allow the Company to continue to realize its assets and liquidate its liabilities in the ordinary course of business.

Note 2. Summary of Significant Accounting Policies

A. Basis of Presentation - The information at September 30, 2009 and September 30, 2008, and for the three months and nine months ended September 30, 2009 and September 30, 2008, is unaudited. In the opinion of management, these financial statements 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 CBLI’s audited financial statements for the year ended December 31, 2008, which were contained in the Company’s Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission.

B. Cash and Equivalents - The Company considers highly liquid investments with a maturity date of three months or less to be cash equivalents. In addition, the Company maintains cash and equivalents at financial institutions, which may exceed federally insured amounts at times and which may, at times, significantly exceed balance sheet amounts due to outstanding checks.

C. Marketable Securities and Short Term Investments - The Company considers investments with a maturity date of more than three months to be short-term investments and has classified these securities as available-for-sale. Such investments are carried at fair value, with unrealized gains and losses included as accumulated other comprehensive income (loss) in stockholders' equity. The cost of available-for-sale securities sold is determined based on the specific identification method.

D. Accounts Receivable - The Company extends unsecured credit to customers under normal trade agreements and according to terms of government contracts and grants, 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 September 30, 2009 and December 31, 2008.

E. Equipment - Equipment is stated at cost and depreciated over the estimated useful lives of the assets (generally five years) using the straight-line method. Leasehold improvements are depreciated on the straight-line method over the shorter of the lease term or the estimated useful lives of the assets. Expenditures for maintenance and repairs are charged to expense as incurred. Major expenditures for renewals and betterments are capitalized and depreciated. Depreciation expense was \$87,531 and \$82,252 for the three months ended September 30, 2009 and 2008, respectively. Depreciation expense was \$268,074 and \$239,317 for the nine months ended September 30, 2009 and 2008, 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 will be amortized on a straight-line basis over the shorter of 20 years or the anticipated useful life of the patent. If the patent application is not approved, the costs associated the patent application will be expensed as part of selling, general and administrative expenses at that time. Capitalized intellectual property is reviewed at least annually for impairment.

A portion of this 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, CBLI agrees to bear the costs associated with the preparation, filing and maintenance of patent applications relating to this intellectual property. Gross capitalized patents pending costs were \$672,979 and \$629,363 for thirteen patent applications as of September 30, 2009 and December 31, 2008, respectively. All of the CCF patent applications are still pending approval. During 2009, the Company abandoned one patent application due to developing an improved drug for the same application and expensed \$23,984 in selling, general and administrative expenses.

The Company also has submitted six patent applications as a result of intellectual property exclusively developed and owned by the Company. Gross capitalized patents pending costs were \$187,643 and \$103,688 for five patent applications as of September 30, 2009 and December 31, 2008, respectively. The patent applications are still pending approval.

H. Line of Credit - The Company has a working capital line of credit that carries an interest rate of prime, a borrowing limit of \$600,000 and a requirement that draw-downs be fully secured by short term investments and money market accounts. This credit line expires on September 25, 2010. At September 30, 2009 and December 31, 2008, there were no outstanding borrowings under this credit facility.

I. Accrued Warrant Liability – The Company has issued warrants as part of the Series D Private Placement (as defined in Note 3). The warrants meet the definition of a derivative instrument in accordance with the FASB Accounting Standards Codification on derivatives and hedging as the warrants are not indexed to the Company’s stock, and consequently, should be accounted for as a derivative instrument. Therefore, the warrants are initially recorded as accrued warrant liabilities at their fair values on the date of issuance. Subsequent changes in the value of the warrants are shown in the statement of operations as “change in value of warrant liability.”

These warrants carry a seven-year term and are fully exercisable for common shares of the Company at \$1.60 per share. The Company has a balance in accrued warrant liability of \$12,582,110 and \$0 at September 30, 2009 and December 31, 2008, respectively.

J. Fair Value of Financial Instruments - Financial instruments, including cash and equivalents, accounts receivable, notes receivable, accounts payable and accrued liabilities, are carried at net realizable value.

The Company values its financial instruments in accordance with the FASB Accounting Standards Codification on fair value measurements and disclosures which establishes a valuation hierarchy for disclosure of the inputs to valuation 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. The Company does not have any significant assets or liabilities measured at fair value using Level 1 or Level 2 inputs as of September 30, 2009.

The Company analyzed all financial instruments with features of both liabilities and equity in accordance with the FASB Accounting Standards Codification on distinguishing liabilities from equity, and derivatives and hedging.

The Company carries its warrants issued in connection with the Series D Private Placement at fair value totaling \$12,582,110 and \$0 as of September 30, 2009 and December 31, 2008, respectively. The Company used Level 3 inputs for its valuation methodology for the warrant liability, and their fair values were determined using the Black-Scholes option pricing model based on the following assumptions:

Warrant  
Value at  
September 30, 2009

Stock price	\$ 4.17
Exercise price	\$ 1.60
Term in years	1.50
Volatility	102.59%
Annual rate of quarterly dividends	-
Discount rate- bond equivalent yield	68.00%
Discount due to limitations on marketability, liquidity and other credit factors	0.00%

Liabilities	Fair Value As of September 30, 2009	Fair Value Measurements at September 30, 2009 Using Fair Value Hierarchy		
		Level 1	Level 2	Level 3
Warrant liability	\$ 12,582,110			\$ 12,582,110

The Company recognized a fair value measurement loss of \$4,111,578 and \$0 for the three months ended September 30, 2009 and September 30, 2008, respectively. The Company recognized a fair value measurement loss of \$9,565,276 and \$0 for the nine months ended September 30, 2009 and September 30, 2008, respectively.

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.

**K. Use of Estimates** - The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. 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.

**L. 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 the Roswell Park Cancer Institute (“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 the prepaid asset is recognized as expense.

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

M. Deferred Revenue – Deferred revenue results when payment is received in advance of revenue being earned. The Company makes a determination as to whether the revenue has been earned by applying a percentage-of-completion analysis to compute the need to recognize deferred revenue. The percentage of completion method is based upon (1) the total income projected for the project at the time of completion and (2) the expenses incurred to date. The percentage-of-completion can be measured using the proportion of costs incurred versus the total estimated cost to complete the contract.

The Company received \$2,000,000 in funds from the State of New York through RPCI during the second quarter of 2007. The Company received an additional \$1,000,000 in funds from the State of New York through RPCI during the second quarter of 2008. The Company is recognizing this revenue over the terms and conditions of the sponsored research agreement. The Company recognizes revenue on research laboratory services and the purchase and 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.

During the third quarter of 2009 the Company received \$1,000,000 in funds from Zhejiang Hisun Pharmaceutical Co. Ltd that has purchased exclusive rights to develop and commercialize Protectan CBLB612 in the People's Republic of China. These funds will be recognized as revenue when the information and data for the compound are delivered in the fourth quarter of 2009.

For the nine months ended September 30, 2009, the Company recognized \$32,017 as revenue and deferred the \$1,000,000 from Hisun resulting in a balance of deferred revenue of \$3,333,295 at September 30, 2009. At December 31, 2008, the balance in deferred revenue was \$2,365,312.

N. 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 collaboration efforts. Expenditures relating to research and development are expensed as incurred.

O. Equity Incentive Plan - On May 26, 2006, the Company's Board of Directors adopted the 2006 Equity Incentive Plan ("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 which could be delivered under the Plan may not exceed 2,000,000 shares. On February 14, 2007, these 2,000,000 shares were registered with the 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 (the "Amended Plan"). The Amended Plan increases the number of shares available for issuance by an additional 2,000,000 shares, clarifies other aspects of the Plan, contains updates that reflect changes and developments in federal tax laws and expires April 29, 2018. As of September 30, 2009 there were 2,425,997 stock options and 348,312 shares granted under the Amended Plan and 21,366 shares forfeited leaving 1,247,057 shares of stock to be awarded under the Amended Plan.

P. Stock-Based Compensation - The Company recognizes and values employee stock-based compensation under the provisions of the FASB Accounting Standards 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 safe harbor method, and computes an expected volatility based on similar high-growth, publicly-traded, biotechnology companies. In 2008, the Company began to include the use of its own stock in the volatility calculation and is layering in the volatility of the stock of the Company with that 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 share-based compensation in net income on a straight-line basis over the requisite service period.

During the three months ended September 30, 2009 and September 30, 2008, the Company granted 65,221 and 43,456 stock options, respectively. The Company recognized a total of \$306,694 and \$355,800 in expense related to stock options for the three months ended September 30, 2009 and September 30, 2008, respectively.

During the nine months ended September 30, 2009 and September 30, 2008, the Company granted 723,276 and 958,380 stock options, respectively. The Company recognized a total of \$1,527,719 and \$1,929,433 in expense related to stock options for the nine months ended September 30, 2009 and September 30, 2008, respectively. The Company also recaptured \$37,878 of previously recognized expense due to the forfeiture of non-vested stock options during the nine months ended September 30, 2009. During the nine months ended September 30, 2008 the Company recaptured \$1,459,425 of previously recognized expense due to the stock options awarded under its executive compensation program.

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

	2009 YTD	2008
Risk-free interest rate	2.12 - 2.74%	2.43-3.58%
Expected dividend yield	0%	0%
Expected life	5 - 6 years	5-6 years
	84.13 -	
Expected volatility	90.06%	64.25-82.47%

The weighted average, estimated grant date fair values of stock options granted during the three months ended September 30, 2009 and September 30, 2008 were \$3.23 and \$2.76, respectively.

The following tables summarize the stock option activity for the nine months ended September 30, 2009 and September 30, 2008, respectively.

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)
Outstanding, December 31, 2008	1,948,874	\$ 6.17	
Granted	723,276	\$ 2.72	
Exercised	149,534	\$ 1.91	
Forfeited, Canceled	3,313	\$ 4.00	
Outstanding, September 30, 2009	2,519,303	\$ 5.43	8.22
Exercisable, September 30, 2009	2,161,153	\$ 5.05	8.18

	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)
Outstanding, December 31, 2007	1,011,740	\$ 7.29	
Granted	958,380	\$ 4.89	
Exercised	42,534	\$ 1.04	
Forfeited, Canceled	-	n/a	
Outstanding, September 30, 2008	1,927,586	\$ 6.23	8.75
Exercisable, September 30, 2008	1,577,799	\$ 5.55	8.72

The Company also recognized \$95,375 and \$5,627 in expense for shares issued under the Amended Plan during the three months ended September 30, 2009 and September 30, 2008, respectively. The Company issued a total of 25,772 shares and 15,000 during the three months ended September 30, 2009 and September 30, 2008, respectively. In addition, the Company recognized \$8,333 and \$54,185 in compensation expense related to the amortization of restricted shares during the three months ended September 30, 2009 and September 30, 2008, respectively.



The Company also recognized \$599,217 and \$626,500 in expense for shares issued under the Plan during the nine months ended September 30, 2009 and September 30, 2008, respectively. The Company issued a total of 193,312 shares and 130,000 during the nine months ended September 30, 2009 and September 30, 2008, respectively. In addition, the Company recognized \$24,907 and \$54,185 in compensation expense related to the amortization of restricted shares during the nine months ended September 30, 2009 and September 30, 2008, respectively.

Q. 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 and nine months ended September 30, 2009 and 2008:

	Three Months Ended		Nine Months Ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Net loss available to common stockholders	\$ (5,313,179)	\$ (3,148,794)	\$ (15,240,289)	\$ (11,506,841)
Net loss per share, basic and diluted	\$ (0.33)	\$ (0.23)	\$ (1.00)	\$ (0.86)
Weighted-average shares used in computing net loss per share, basic and diluted	15,878,331	13,605,822	15,184,785	13,415,376

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 applicable 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 for preferred shares, was 3,723,695 and 3,301,373 for the periods ended September 30, 2009 and 2008, respectively. Such securities, had they been dilutive, would have been included in the computation of diluted earnings per share.

The total number of shares excluded from the calculations of diluted net loss per share, prior to application of the treasury stock method for warrants, was 8,939,528 and 3,453,268 for the periods ended September 30, 2009 and 2008, respectively. Such securities, had they been dilutive, would have been included in the computation of diluted earnings per share.

The total number of shares excluded from the calculations of diluted net loss per share, prior to the application of the treasury stock method for options, was 2,519,303 and 1,927,586 for the periods ended September 30, 2009 and 2008, respectively. Such securities, had they been dilutive, would have been included in the computation of diluted earnings per share.

In summary, the total number of shares excluded from the calculations of diluted net loss per share, prior to application of the treasury stock method for all dilutive securities, was 15,182,526 and 8,682,227 for the periods ended September 30, 2009 and 2008, respectively. Such securities, had they been dilutive, would have been included in the computation of diluted earnings per share.

R.

Concentrations of Risk - Grant and contract revenue was comprised wholly from grants and contracts issued by the federal government and accounted for 100.0% and 96.3% of total revenue for the nine months ended September 30, 2009 and 2008, respectively. Although the Company anticipates ongoing federal grant and contract revenue, there is no guarantee that this revenue stream will continue in the future.

Financial instruments that potentially subject us to a significant concentration of credit risk consist primarily of cash and cash equivalents and securities available-for-sale. 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.

S.Foreign Currency Exchange Rate Risk - The Company has entered into a manufacturing agreement to produce one of its drug compounds and into an agreement for assay development and validation with foreign third parties 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. As of September 30, 2009, the Company is obligated to make payments under the agreements of 2,441,500 Euros. As of September 30, 2009, the Company has not purchased any forward contracts for Euros and, therefore, at September 30, 2009, had foreign currency commitments of \$3,575,100 for Euros given prevailing currency exchange spot rates.

T. Comprehensive Income/(Loss) - The Company applies the FASB Accounting Standards 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.

U. Recently Issued Accounting Pronouncements – In June 2009, the Financial Accounting Standards Board (“FASB”) issued the FASB Accounting Standards Codification (the “Codification”), as the authoritative guidance for GAAP. The Codification, which changes the referencing of financial standards, became effective for interim and annual periods ending on or after September 15, 2009. The Codification is now the single official source of authoritative U.S. GAAP (other than interpretive releases and guidance issued by the SEC), superseding existing FASB, American Institute of Certified Public Accountants, Emerging Issues Task Force and related literature. Only one level of authoritative U.S. GAAP now exists. All other literature is considered non-authoritative. The Codification does not change U.S. GAAP. We adopted the Codification during the quarter ended September 30, 2009. Other than the manner in which new accounting guidance is referenced, the adoption of these changes had no impact on the financial statements.

In June 2009, the FASB issued guidance on accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued, otherwise known as “subsequent events.” Specifically, these changes set forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. The adoption of these changes had no impact on the financial statements as management already followed a similar approach prior to the adoption of this new guidance.

In June 2008, the FASB issued guidance on determining whether an instrument (or embedded feature) is indexed to an entity's own stock. The guidance specifies that a contract that would otherwise meet the definition of a derivative but is both (a) indexed to the Company's own stock and (b) classified in stockholders' equity in the statement of financial position would not be considered a derivative financial instrument. The guidance provides a new two-step model to be applied in determining whether a financial instrument or an embedded feature is indexed to an issuer's own stock. The adoption of this guidance did not materially impact the Company's financial statements.

### Note 3. Stock Transactions

On January 1, 2008, the Company issued 100,000 options to a new employee and 60,000 options to a key consultant of the Company. The options vest over a period from one to three years and allow for the purchase of 160,000 shares of common stock at a price of \$8.00 per share. These options expire on December 31, 2017.

On January 4, 2008, the Company issued 20,000 restricted shares of common stock to a new employee. These shares vest over a three year period with 25% vested on issuance and 25% vesting on the anniversary date of the agreement for each of the next three years.

On February 4, 2008, the Company issued options to purchase 503,250 shares of common stock under non-qualified stock option agreements to the executive management team under the 2007 Executive Compensation Program. These options were originally expensed in 2007 at the December 31, 2007 closing price of \$8.80. These options vest immediately, contain an exercise price of \$4.00 per share, and expire on February 4, 2018. The Company also issued options to purchase 34,398 shares of common stock to various employees under non-qualified stock option agreements under an employee bonus program. These options vest immediately, contain an exercise price of \$4.00 per share, and expire on February 3, 2018. Finally, the Company issued stock options to various key employees under non-qualified stock option agreements. These options have up to three years vesting. These options allow for the

purchase of 21,300 shares of common stock at an exercise price of \$4.00 per share and expire on February 3, 2018.

On March 12, 2008, the Company issued 1,000 stock options to a consultant under a non-qualified stock option agreement. These options vest immediately and allow for the purchase of 1,000 shares of common stock at an exercise price of \$4.81 per share. These options expire on March 11, 2018.

On March 14, 2008, the Company issued 100,000 shares of common stock to a key consultant.

On April 8, 2008, the Company issued 40,000 stock options to three consultants under non-qualified stock option agreements. These options vest immediately and allow for the purchase of 40,000 shares of common stock at an exercise price of \$4.18 per share. These options expire on April 7, 2018. On April 8, 2008, the Company also issued 25,000 restricted shares of common stock. These shares vest over a three month period with 40% vested on issuance and 60% vesting three months from the date of the agreement.

On April 29, 2008, the Company issued 140,000 stock options to four independent members of the Board of Directors of the Company under non-qualified stock option agreements. These options vest immediately and allow for the purchase of 140,000 shares of common stock at an exercise price of \$5.33 per share. These options expire on April 28, 2018.

On May 7, 2008, the Company issued 14,976 stock options to various employees under non-qualified stock option agreements under an employee bonus program. These options vest immediately and allow for the purchase of 14,976 shares of common stock at an exercise price of \$5.28 per share. These options expire on May 6, 2018.

On July 15, 2008, the Company issued 28,456 stock options to various employees under non-qualified stock option agreements under an employee bonus program. These options vest immediately and allow for the purchase of 28,456 shares of common stock at an exercise price of \$3.98 per share. These options expire on July 14, 2018.

On September 22 2008, the Company issued 35,000 stock options to a new employee under non-qualified stock option agreements. These options vest over a three year period and allow for the purchase of 35,000 shares of common stock at an exercise price of \$4.69 per share. These options expire on September 21, 2018.

On November 14, 2008, the Company issued 19,341 stock options to various employees under non-qualified stock option agreements under an employee bonus program. These options vest immediately and allow for the purchase of 19,341 shares of common stock at an exercise price of \$3.10 per share. These options expire on November 13, 2018.

On February 2, 2009, the Company issued 75,000 restricted shares of common stock to designees of the placement agents in the Series D Preferred Stock offering.

On February 13, 2009, March 20, 2009, and March 27, 2009, the Company entered into Securities Purchase Agreements (the "Purchase Agreements") with various accredited investors (the "Purchasers"), pursuant to which the Company agreed to sell to the Purchasers an aggregate of 542.84 shares of Series D Convertible Preferred Stock, with a par value of \$0.005 per share and a stated value of \$10,000 per share ("Series D Preferred"), and Common Stock Purchase Warrants (the "Warrants") to purchase an aggregate of 3,877,386 shares of the Company's Common Stock, par value \$0.005 per share (the "Series D Private Placement"). The Warrants have a seven-year term and an exercise price of \$1.60. Each share of Series D Preferred is convertible into approximately 7,143 shares of Common Stock, subject to the adjustment as described below.

The aggregate purchase price paid by the Purchasers for the Series D Preferred and the Warrants was approximately \$5,428,307 (representing \$10,000 for each Series D Preferred together with a Warrant). After related fees and expenses, the Company received net proceeds of approximately \$4,460,000. The Company intends to use the proceeds for working capital purposes.

In consideration for its services as exclusive placement agent, Garden State Securities, Inc., received cash compensation and Warrants to purchase an aggregate of approximately 387,736 shares of Common Stock. In the aggregate, Series D Preferred and Warrants issued in the transaction are convertible into, and exercisable for, approximately 8,142,508 shares of Common Stock. Each share of Series D Preferred is convertible into a number of shares of Common Stock equal to the stated value of the share (\$10,000), divided by \$1.40, subject to adjustment as

discussed below (the "Conversion Price").

At the time of its issuance, the Series D Preferred ranked junior to the Company's Series B Convertible Preferred Stock ("Series B Preferred") and senior to all shares of Common Stock and other capital stock of the Company.

If the Company does not meet certain milestones, the Conversion Price will, unless the closing price of the Common Stock is greater than \$3.69 on the date the Milestone is missed, be reduced to 80% of the Conversion Price in effect on that date (the "Milestone Adjustment"). In addition to the Milestone Adjustment, on August 13, 2009 (the "Initial Adjustment Date"), the Conversion Price shall be reduced to 95% of the then Conversion Price, and on each three month anniversary of the Initial Adjustment Date, the then Conversion Price shall be reduced by \$0.05 (subject to adjustment) until maturity. The Conversion Price is also subject to proportional adjustment in the event of any stock split, stock dividend, reclassification or similar event with respect to the Common Stock and to anti-dilution adjustment in the event of any Dilutive Issuance as defined in the Certificate of Designation.

If the closing price for each of any 20 consecutive trading days after the effective date of the initial registration statement filed pursuant to the Registration Rights Agreement exceeds 300% of the then effective Conversion Price and various other equity conditions are satisfied, the Company may cause the Series D Preferred to automatically convert into shares of Common Stock.

At any time after February 13, 2012, the Company may, if various equity conditions are satisfied, elect either to redeem any outstanding Series D Preferred in cash or to convert any outstanding Series D Preferred into shares of Common Stock at the conversion rate then in effect.

If the Company receives any cash funds after February 13, 2009 from fees, royalties or revenues as a result of the license of any of its intellectual property (the "IP Proceeds"), cash funds from development grants from any government agency for the development of anti-cancer applications of any of the Company's curaxin compounds or anti-cancer or biodefense applications for the Company's CBLB502 compound (the "Governmental Grant Proceeds") or allocates cash proceeds to its Escrow Account (the "Company Allocation"), then the Company must deposit 40% of the IP Proceeds, 20% of the Governmental Grant Proceeds and the Company Allocation into an escrow account (the "Sinking Fund"). At any time after the later of the Effective Date and the six month anniversary of the initial contribution by the Company to the Sinking Fund, but no more than once in every six month period, the Company will be required to use the funds then in the Sinking Fund to redeem outstanding shares of Series D Preferred, from the holders on a pro rata basis, at a premium of 15% to the stated value through February 13, 2010, and 20% thereafter.

Immediately after the completion of the transactions contemplated by the Purchase Agreements, the conversion price of the Company's Series B Preferred was adjusted, pursuant to weighted-average anti-dilution provisions, to \$4.67, causing the conversion rate of Series B Preferred into Common Stock to change to approximately 1-to-1.49893. In addition, the exercise prices of the Company's Series B Warrants and Series C Warrants were adjusted, pursuant to weighted-average anti-dilution provisions, to \$6.79 and \$7.20, respectively, from the original exercise prices of \$10.36 and \$11.00. Certain other warrants issued prior to the Company's initial public offering were also adjusted pursuant to anti-dilution provisions contained in those warrants such that their per share exercise price reduced from \$2.00 to \$1.48. In addition to the adjustment to the exercise prices of the Series B Warrants and Series C Warrants, the aggregate number of shares issuable upon exercise of the Series B Warrants and the Series C Warrants increased to 3,609,261 and 408,032, from 2,365,528 and 267,074, respectively. For certain warrants issued prior to the Company's initial public offering, the aggregate number of shares of Common Stock issuable increased from 281,042 to 379,792.

On September 16, 2009, pursuant to its terms, all of the Series B Preferred converted into shares of Common Stock at the conversion rate of 1.51 which resulted in an increase of 537,913 shares of Common Stock as of that date.

The fair value of the 4,265,122 warrants issued with the Series D Private Placement was \$3,016,834 and was computed using the Black-Scholes option pricing model using the following assumptions:

	Warrants Issued on February 13, 2009	Warrants Issued on March 20, 2009	Warrants Issued on March 27, 2009
Stock price (prior day close)	\$ 2.95	\$ 1.41	\$ 2.44
Exercise price	\$ 2.60	\$ 1.60	\$ 1.60
Term in years	2.00	2.00	2.00
Volatility	110.14%	108.87%	111.57%
Annual rate of quarterly dividends	-	-	-
Discount rate- bond equivalent yield	0.89%	0.87%	0.90%
Discount due to limitations on marketability, liquidity and other credit factors	40%	40%	40%

The Company recorded a 40% reduction in the calculated value as shown above due to the restrictions on marketability, liquidity and other credit factors. Since these shares are now convertible into common shares and freely tradable after conversion, this reduction was eliminated when calculating fair market values.

The exercise price of the warrants issued on February 13, 2009 was adjusted, pursuant to weighted-average anti-dilution provisions, to \$1.60 as a result of the March 20, 2009 tranche of the Series D Private Placement.

The value assigned to the warrants could not exceed the value of the gross proceeds at the issuance date of each tranche of the offering. As such, the value assigned to the warrants on the March 27, 2009 tranche of the Series D Private Placement was reduced to \$789,000 which represents the gross proceeds from that tranche of the offering.

In addition, since the convertible preferred stock is convertible into shares of common stock, an embedded beneficial conversion feature was recorded as a discount to additional paid-in-capital. However, the beneficial conversion feature is considered a deemed dividend, and since the Company has an accumulated deficit, there was no effect on the statement of stockholders' equity.



On April 8, 2009, the Company issued 396,072 stock options to various employees and consultants under non-qualified stock option agreements. 261,072 of these stock options were issued under an employee bonus plan and vest immediately and allow for the purchase of shares of common stock at an exercise price of \$1.90 per share. The remaining 135,000 stock options vest over a three year period and allow for the purchase of shares of common stock at an exercise price of \$1.90 per share. These options expire on April 7, 2019.

On May 20, 2009, the Company issued 61,983 stock options to various employees and consultants under non-qualified stock option agreements under an employee bonus program. These options vest immediately and allow for the purchase of 61,983 shares of common stock at an exercise price of \$3.91 per share. These options expire on May 19, 2019.

On May 27, 2009, the Company issued 25,000 shares of common stock to a key consultant of the Company.

On June 25, 2009, the Company issued 140,000 stock options to four independent members of the Board of Directors of the Company under non-qualified stock option agreements. These options vest immediately and allow for the purchase of 140,000 shares of common stock at an exercise price of \$3.33 per share. These options expire on June 24, 2019.

On June 26, 2009, the Company issued 60,000 stock options to a consultant under a non-qualified stock option agreement. These options vest immediately and allow for the purchase of 60,000 shares of common stock at an exercise price of \$3.48 per share. These options expire on June 25, 2019.

On June 26, 2009, the Company also issued 62,540 shares of common stock to several key consultants and an employee of the Company.

On August 12, 2009, the Company issued 65,221 stock options to various employees and consultants under non-qualified stock option agreements under an employee bonus program. These options vest immediately and allow for the purchase of 65,221 shares of common stock at an exercise price of \$4.57 per share. These options expire on August 11, 2019.

On August 14, 2009, the Company issued 3,623 shares of common stock to a key consultant of the Company.

On September 4, 2009, the Company issued 22,149 shares of common stock to a key consultant of the Company.

For the nine months ending September 30, 2009, 3,160,974 Series B Preferred Shares were converted into 4,693,530 shares of common stock. As discussed above, the outstanding Series B Preferred shares converted into common stock on September 16, 2009 and at September 30, 2009, there were 0 outstanding Series B Preferred for which \$0 in dividends had been accrued.

For the nine months ending September 30, 2009, 47.59 Series D Preferred Shares were converted into 357,820 shares of common stock. At September 30, 2009, there were 495.25 outstanding Series D Preferred which are convertible into 3,723,695 shares of common stock.

#### 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 FDA 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. In addition, as described in Note 3, the Company may be required to deposit funds in the Sinking Fund if it receives certain sublicense income.

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 September 30, 2009, \$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 September 30, 2009 and December 31, 2008.

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. From time to time in the ordinary course of business, the Company may be subject to claims brought against it. It is not possible to state the ultimate liability, if any, in these matters.

The Company currently has operating lease commitments in place for facilities in Buffalo, New York and Chicago, Illinois as well as office equipment. The Company recognizes rent expense on a straight-line basis over the term of the related operating leases. The operating lease expenses recognized were \$95,120 and \$83,213 for the three months ended September 30, 2009 and 2008, respectively. The operating lease expenses recognized were \$268,557 and \$249,267 for the nine months ended September 30, 2009 and 2008, respectively.

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

	Operating Leases
2009 Remaining Quarter	\$ 94,443
2010	343,656
2011	311,803
2012	144,375
2013	-
	\$ 894,277

The Company has entered into stock option agreements with key employees, board members and consultants with exercise prices ranging from \$0.66 to \$17.00. These awards were approved by the Company's Board of Directors. The options expire ten years from the date of grant except for 18,000 options that expire on December 31, 2012, subject to the terms applicable in the agreement.

The following tables summarize the stock option activity for the nine months ended September 30, 2009 and September 30, 2008:

	Options	Weighted Average Exercise Price Per Share
Outstanding, December 31, 2008	1,948,874	\$ 6.17
Granted	723,276	\$ 2.72
Exercised	149,534	\$ 1.91
Forfeited, Canceled	3,313	\$ 4.00
Outstanding, September 30, 2009	2,519,303	\$ 5.43

	Options	Weighted Average Exercise Price Per Share
Outstanding, December 31, 2007	1,011,740	\$ 7.29
Granted	958,380	\$ 4.89
Exercised	42,534	\$ 1.04
Forfeited, Canceled	-	n/a

Outstanding, September 30, 2008	1,927,586	\$	6.23
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The Company has entered into warrant agreements with strategic partners, consultants and investors with original exercise prices ranging from \$1.13 to \$11.00. 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 appears below:

	Warrants	Weighted Average Exercise Price Per Share
Outstanding, December 31, 2008	3,453,268	\$ 8.92
Granted	4,265,122	\$ 1.60
Exercise Price Adjustment		\$ (3.35)
Exercised	291,444	\$ 1.17
Forfeited, Canceled	-	n/a
Outstanding, September 30, 2009	7,426,946	\$ 3.70

	Warrants	Weighted Average Exercise Price Per Share
Outstanding, December 31, 2007	3,453,268	\$ 8.92
Granted	-	n/a
Exercised	-	n/a
Forfeited, Canceled	-	n/a
Outstanding, September 30, 2008	3,453,268	\$ 8.92

Immediately after the completion of the Series D Private Placement, pursuant to weighted-average anti-dilution provisions, the exercise prices of the Company's Series B Warrants and Series C Warrants were adjusted, pursuant to weighted-average anti-dilution provisions, to \$6.79 and \$7.20, respectively, from the original exercise prices of \$10.36 and \$11.00. Certain other warrants issued prior to the Company's initial public offering were also adjusted pursuant to anti-dilution provisions contained in those warrants such that their per share exercise price reduced from \$2.00 to \$1.48. In addition to the adjustment to the exercise prices of the Series B Warrants, Series C Warrants, the aggregate number of shares issuable upon exercise of the Series B Warrants and the Series C Warrants increased to 3,609,261 and 408,032, from 2,365,528 and 267,074, respectively. For certain warrants issued prior to the Company's initial public offering, the aggregate number of shares of Common Stock issuable increased from 281,042 to 379,792. The weighted average exercise price reduction for these existing warrants at the completion of the Series D Private Placement was \$3.07.

On August 13, 2009, as a result of the quarterly reduction in the conversion price of the Series D Preferred from \$1.40 to \$1.33, the exercise price of the Company's Series B Warrants and Series C Warrants were adjusted per the terms of the Series D Private Placement to \$6.73 and \$7.13, respectively from the adjusted exercise prices of \$6.79 and \$7.20. In addition to the adjustment to the exercise prices of the Series B Warrants, Series C Warrants, the aggregate number of shares issuable upon exercise of the Series B Warrants and the Series C Warrants increased to 3,641,479 and 412,042, from 3,609,261 and 408,032, respectively. Certain other warrants issued prior to the Company's initial private placement offering were also adjusted pursuant to anti-dilution provisions contained in those warrants such that their per share exercise price reduced from \$1.48 to \$1.47. For these warrants issued prior to the Company's initial public offering, the aggregate number of shares of Common Stock issuable increased from 379,792 to 382,130. The weighted average exercise price reduction for these existing warrants at the completion of the Series D Private Placement increased \$0.28 to \$3.35.

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

The Company is not currently a party to any pending legal actions. From time to time in the ordinary course of business, the Company may be subject to claims brought against it. It is not possible to state the ultimate liability, if any, in these matters.

Note 5. Subsequent Events

No material subsequent events have occurred since the balance sheet date of September 30, 2009.

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## Item 2: Management's Discussion and Analysis of Financial Condition and Results of Operations

This management's discussion and analysis of financial condition and results of operations and other portions of this filing contain forward-looking information that involves risks and uncertainties. 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 the Company's other SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2008. 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, 2008.

### OVERVIEW

CBLI was incorporated in Delaware and commenced business operations in June 2003 as a development-stage, biotechnology company, with a very specific and targeted focus on discovery and development of drugs that control cell death. 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. CBLI's 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 developed as a result of blocking blood flow to a part of the body). Curaxins are being developed 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. After our initial public offering, our common stock was listed on the NASDAQ Capital Market under the symbol "CBLI" and on the Boston Stock Exchange under the symbol "CFB." Our trading symbol on the Boston Stock Exchange was later changed to "CBLI." On August 28, 2007, trading of our common stock transferred from the NASDAQ Capital Market to the NASDAQ Global Market. In September 2007, we ceased our listing on the Boston Stock Exchange. On November 28, 2008, trading of our common stock transferred from the NASDAQ Global Market back to the NASDAQ Capital Market. The Company believes that it meets current listing requirements for the NASDAQ Capital Market as set forth by NASDAQ.

### 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 including 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 multiple 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 100% or even 50% of all cancer patients. This means that there likely will be a need for additional anticancer drugs for each type of cancer.

These drug candidates demonstrate the value of our scientific foundation. Based on the expedited approval process currently available for non-medical applications such as protection from exposure to radiation, our most advanced drug candidate, Protectan CBLB502, may be approved for such applications within 18 months. Another drug candidate, Curaxin CBLC102, demonstrated activity and safety in a Phase IIa clinical trial concluded in late 2008.

## 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 estimable. From our inception to September 30, 2009, we spent \$53,859,313 on R&D.

Our ability to complete our R&D on schedule is, however, subject to a number of risks and uncertainties. Factors affecting our R&D include, but are not limited to:

- the number and outcome of clinical studies we are planning to conduct; for example, our R&D expenses may increase based on the number of late-stage clinical studies that we may be required to conduct;
- the performance of our R&D collaborators; if any research collaborator fails to commit sufficient resources, our preclinical or clinical development programs related to this collaboration could be delayed or terminated;
- the ability to maintain and/or obtain licenses; we may have to develop alternatives to avoid infringing upon the patents of others, potentially causing increased costs and delays in product development;
- the number of products entering development from late-stage research; there is no guarantee that internal research efforts will succeed in generating sufficient data for us to make a positive development decision or that an external candidate will be available on terms acceptable to us, and some promising candidates may not yield sufficiently positive pre-clinical results to meet our stringent development criteria;
- the number of new grants and contracts awarded in the future; if the availability of research grants and contracts were curtailed, our ability to fund future R&D and implement technological improvements would be diminished, which would negatively impact our ability to fund R&D efforts;
- in-licensing activities, including the timing and amount of related development funding or milestone payments; for example, we may enter into agreements requiring us to pay a significant up-front fee for the purchase of in-process R&D that we may record as R&D expense; or

- future levels of revenue; R&D as a percentage of future potential revenues can fluctuate with the changes in future levels of revenue and lower revenues can lead to less spending on R&D efforts.

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.

Many of our projects are in the early stages of drug development which carry their own set of risks. Projects that appear promising in the early phases of development may fail to reach the market for several reasons including:

- pre-clinical or clinical study results that may show the product to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or a New Drug Application/Biologic License Application preparation, discussions with the Food and Drug Administration (“FDA”), an FDA request for additional pre-clinical or clinical data or unexpected safety or manufacturing issues;
- manufacturing costs, pricing or reimbursement issues, or other factors that make the product not economical; and
- the proprietary rights of others and their competing products and technologies that may prevent the product from being commercialized.

The testing, marketing and manufacturing of any product for use in the United States will require approval from the FDA. We cannot predict with any certainty the amount of time necessary to obtain such FDA approval and whether any such approval will ultimately be granted. Preclinical 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 and 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 United States that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist.

## 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 of the potential military and defense implications of such a drug, the normally lengthy FDA approval process for these non-medical applications is substantially abbreviated resulting in a large cost savings to us. We expect to complete development of Protectan CBLB502 for these non-medical applications by the end of 2010.
- Leveraging our relationship with leading research and clinical development institutions. The Cleveland Clinic, one of the top research medical facilities in the world, is one of our co-founders. In addition to providing us with drug leads and technologies, the Cleveland Clinic will share valuable expertise with us as development efforts are performed on our drug candidates. In January 2007, we entered into a strategic research partnership with Roswell Park Cancer Institute (“RPCI”) in Buffalo, New York. This partnership 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 Armed Forces Radiobiology Research Institute.

- 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 over 1,000,000 compounds.

## 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 are anti-apoptotic factors developed by microorganisms of human microflora throughout millions of years of co-evolution with mammalian host. We are using the same strategy that was applied for the discovery of antibiotics, one of the biggest medical achievements of the 20th century. We have established a technological process for screening of such factors, named protectans, 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).

Eleven sets of patent applications have been filed around the protectan family of compounds including two for the general aspects and qualities of the protectan family.

For the three months ended September 30, 2009 and 2008, we spent \$3,268,615 and \$2,295,574, respectively on R&D for protectans. For the nine months ended September 30, 2009 and 2008, we spent \$10,028,839 and \$6,064,505, respectively. We spent \$8,995,500 overall in the fiscal year ended December 31, 2008 and from our inception to September 30, 2009, we spent \$36,537,338 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- $\kappa$ B (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.

Seven sets of patent applications have been filed for Protectan CBLB502. In August 2009, we received a Notice of Allowance from the U.S. Patent and Trademark Office for a patent application titled "Modulating Apoptosis." Allowed claims cover the method of protecting a mammal from radiation using flagellin or its derivatives.

For the three months ended September 30, 2009 and 2008, we spent \$3,267,201 and \$2,007,124, respectively on R&D for Protectan CBLB502. For the nine months ended September 30, 2009 and 2008, we spent \$10,022,272 and \$5,189,400, respectively. We spent \$8,021,040 in the fiscal year ended December 31, 2008 and from our inception to September 30, 2009, we spent \$33,400,397 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 and 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 to treat radiation injury following exposure to radiation from nuclear or radiological weapons, or from nuclear accident. This approval pathway requires demonstration of efficacy in two animal species and safety and drug metabolism testing in a representative sample of healthy human volunteers. Protectan CBLB502 has demonstrated activity as a radioprotectant in several animal species, including non-human primates. Human safety studies are the only stage of human testing required for approval in this indication.

We have successfully established cGMP quality manufacturing for Protectan CBLB502 and have completed an initial Phase I human safety study for Protectan CBLB502 in ARS. The initial human Phase I safety and tolerability study involved single injections of Protectan CBLB502 in ascending-dose cohorts of six healthy volunteers each. 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.

Data from 50 subjects indicates that Protectan CBLB502 was well tolerated and that normalized biomarker results corresponded to previously demonstrated activity in animal models of ARS. A pattern of biomarker production was observed consistent with those patterns seen in animals during mitigation of radiation-induced injury by dosing with Protectan CBLB502.

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 GMP manufactured drug candidate. We expect to complete these studies in mid 2010. The studies have an approximate cost of \$2,500,000 and are covered by a government development contract.
- Performing a second Phase IIa safety study in approximately 100 healthy human volunteers planned to start in November 2009. This study has an approximate cost of \$1,200,000 and is covered by a government development contract
- Performing a Phase IIb 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 estimate completion of this study in late 2010 at an approximate cost of \$5,300,000 based on 500 subjects tested in four locations. This study is also covered by a government development contract.
- Filing a Biologic License Application (“BLA”) which we expect to complete in late 2010. At the present time, the costs of the filing cannot be approximated with any level of certainty.

In March 2008, the U.S. Department of Defense (“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 to treat radiation injury following exposure to radiation from nuclear or radiological weapons. In September 2009, the DoD increased the funding under this contract by \$0.6 million to \$9.5 million to support bridging studies between lyophilized and liquid drug formulations.

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, the Biomedical Advanced Research and Development Authority (“BARDA”) of the Department of Health and Human Services (“HHS”) 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. 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 by \$2.3 million to \$15.6 million and awarded the first milestone option of \$6.3 million. 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.

In May 2009, a Sources Sought Notice was issued by the Chemical Biological Medical Systems Medical Identification and Treatment Systems Joint Product Management Office of the DoD seeking identification of sources having the capability to develop, through FDA approval and production, the following chemical, radiological and nuclear therapeutics:

- An aerosolized atropine drug delivery system to treat lingering effects of nerve agent intoxication related to muscarinic stimulation.
- A radiological/nuclear therapeutic medical countermeasure to be administered following exposure to ionizing radiation that will decrease incapacity and prolong survival by treating the gastrointestinal sub-syndrome of ARS.



- Amyl nitrate as an adjunct to current military cyanide treatment regimen.

In May 2009, we responded to the Sources Sought Notice to continue to develop CBLB502 as a radiological/nuclear therapeutic medical countermeasure to be administered following exposure to ionizing radiation that will decrease incapacity and prolong survival by treating the gastrointestinal sub-syndrome of ARS.

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.

For the three months ended September 30, 2009 and 2008, we spent \$3,267,201 and \$1,846,094, respectively on R&D for non-medical applications of Protectan CBLB502. For the nine months ended September 30, 2009 and 2008, we spent \$9,966,145 and \$4,638,905, respectively. We spent \$7,264,813 in the fiscal year ended December 31, 2008 and from our inception to September 30, 2009, we spent \$31,567,341 on R&D for the non-medical applications of Protectan CBLB502.

Protectan CBLB502 is a candidate for procurement by the DoD, HHS/BARDA and several other countries facing even more imminent threats. The HHS opportunity substantially expands the potential market, as its mandate is to protect the U.S. civilian population in the event of a radiological emergency, involving stockpiling of radiation countermeasures for mass distribution. Our contract awards from the DoD and BARDA emphasize the government's focus on acquiring adequate protection against nuclear and radiation threats for military and civilian populations. Upon FDA approval, our Protectan CBLB502 may be well positioned to fulfill both of these needs, with its demonstrated unprecedented efficacy and survival benefits in animal models, unique ability to address both hematopoietic and gastrointestinal damage in animal models, broad window of efficacy relative to radiation exposure in animal models, 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 as soon as the FDA approves the BLA. Future sales to U.S. government agencies will depend, in part, on our ability to meet federal contract requirements. Also, if the U.S. government makes significant future contract awards for the supply of its emergency stockpile to our competitors, our business will be harmed and it is unlikely that we will be able to ultimately commercialize our competitive product.

#### Medical Applications

While our current focus remains on its military and other 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.

Specifically, 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 paradigm shift in cancer treatment. It is estimated that approximately 40% of the roughly \$50 billion annually spent on cancer treatment represents supportive care addressing toxicities of various treatments, including chemotherapy.

Consistent with this strategy, we plan to initiate a Phase I/II study for Protectan CBLB502 in head and neck cancer patients in early 2010 for the medical indication of CBLB502. The primary endpoint of the study will be the reduction of toxicities of radiation and chemotherapy, such as mucositis (a painful inflammation and ulceration of oral mucosa causing difficulties with speaking and eating). Mucositis weakens the patient by not allowing for the oral intake of nutrients and fluids and forces the temporary suspension of radiotherapy and chemotherapy until the tissues of the mouth and throat have healed. Due to the ability of head and neck cancer cells to regrow during periods of interrupted treatment, any interruption in radiotherapy should be avoided. Since the main cause of treatment interruptions in radiotherapy or combinations of chemotherapy and radiotherapy treatment regimens of head and neck cancer is acute mucositis, the ability to prevent mucositis, and therefore, interruptions in treatment, could potentially result in better outcomes for patients with cancers of the head and neck.

In other studies, we have demonstrated the potential of Protectan CBLB502 to be applicable to ischemic conditions. Our researchers, in collaboration with investigators from Cleveland Clinic, 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.

Moreover, studies funded by a grant from the DoD and conducted at the Cleveland Clinic, 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 contrast to the non-medical applications of 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:

- Submitting an amendment to our CBLB502 IND application and receiving allowance from the FDA. We expect to submit the amendment in early 2010. We estimate that the cost of filing will be nominal.
- Performing a Phase I/II human efficacy study on a small number of head and neck cancer patients. We expect to complete this study two years from the receipt of allowance from the FDA of the IND amendment expected in early 2010 at an approximate cost of \$1,500,000.
- 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 the scope of these steps cannot be approximated with any level of certainty.

For the three months ended September 30, 2009 and 2008, we spent \$0 and \$161,030, respectively on R&D for the medical applications of Protectan CBLB502. For the nine months ended September 30, 2009 and 2008, we spent \$56,127 and \$550,495, respectively. We spent \$756,227 in the fiscal year ended December 31, 2008 and from our inception to September 30, 2009, we spent \$1,833,056 on R&D for the medical applications of Protectan CBLB502.

#### Protectan CBLB612

While the bulk of our R&D has focused on Protection 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., Thousand Oaks, California), 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) (a recently FDA approved stem cell mobilizer from Genzyme Corporation (Cambridge, Massachusetts)), 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. 100% of the deficient mice transplanted with blood from 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 (SCID), 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 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 sets of patent applications have been filed for Protectan CBLB612.

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. Under the terms of the license agreement, we will receive upfront 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 CBLB612 are not granted. We will retain all rights to CBLB612 in the rest of the world

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

- Conducting pivotal animal safety studies with GMP-manufactured CBLB612.
- Submitting an IND application and receiving approval from the FDA.
- Performing a Phase I dose-escalation human study.
- Performing a Phase II and Phase III human efficacy study using the dose of CBLB612 selected from the previous studies previously shown to be safe in humans and efficacious in animals.
- Filing a New Drug Application.

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.

For the three months ended September 30, 2009 and 2008, we spent \$1,414 and \$288,450, respectively on R&D for Protectan CBLB612. For the nine months ended September 30, 2009 and 2008, we spent \$6,567 and \$875,105, respectively. We spent \$974,459 in the fiscal year ended December 31, 2008 and from our inception to September 30, 2009, we spent \$3,136,941 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- $\kappa$ B. This mechanism of action makes curaxins potent inhibitors of the production and the activity of NF- $\kappa$ B not only in its stimulated form, but also in its basal form. The level of active NF- $\kappa$ B is usually also increased in cancer cells. Moreover, due to curaxin-dependent functional conversion of NF- $\kappa$ B-DNA complexes, the cells with the highest basal or induced NF- $\kappa$ B activity are supposed to be the most significantly affected by curaxins. Clearly, this paradoxical activity makes deactivation of NF- $\kappa$ B by curaxins more advantageous compared to conventional strategies targeting NF- $\kappa$ B 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.

Seven sets of patent applications have been filed around the curaxin family of compounds including four for the general aspects and qualities of the curaxin family.

For the three months ended September 30, 2009 and 2008, we spent \$58,995 and \$886,852, respectively on R&D for curaxins. For the nine months ended September 30, 2009 and 2008, we spent \$573,753 and \$2,726,527, respectively. We spent \$3,233,872 in the fiscal year ended December 31, 2008 and from our inception to September 30, 2009, we spent \$12,215,345 on R&D for curaxins.

#### 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 the Cleveland Clinic 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 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, CBLC102 has favorable pharmacological and toxicological profiles and demonstrates the anticancer effect in transplants of human cancer cells into primates.

We have an agreement with Regis Technologies, Inc., a GMP manufacturer, to produce sufficient quantities of Curaxin CBLC102 according to the process previously used for the production of this drug when it was in common use.

We launched a Phase II study with 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 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. 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 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 CBLC102 will be explored in conjunction with our strategic partners at RPCI.

We anticipate that additional clinical efficacy studies will be required before we are able to apply for FDA approval. 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.

Two sets of patent applications have been filed for Curaxin CBLC102.

For the three months ended September 30, 2009 and 2008, we spent \$34,074 and \$466,088, respectively on R&D for Curaxin CBLC102. For the nine months ended September 30, 2009 and 2008, we spent \$252,209 and \$1,431,077, respectively. We spent \$1,741,194 in the fiscal year ended December 31, 2008 and from our inception to September 30, 2009, we spent \$6,718,691 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 CBLC137, which is a drug candidate with proprietary composition of matter intellectual property protection belonging to our next generation of highly improved curaxins. CBLC137 has demonstrated reliable anti-tumor effects in animal models of colon, breast, renal and prostate cancers. 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 CBLC102, but significantly exceeds the former compound's activity and efficacy in preclinical tumor models. Further development of CBLC137 will continue upon achieving sufficient funding for completing pre-clinical development and a Phase I study.

One set of patent applications has been filed for Curaxin CBLC137.

For the three months ended September 30, 2009 and 2008, we spent \$24,920 and \$420,764, respectively on R&D for other curaxins. For the nine months ended September 30, 2009 and 2008, we spent \$321,544 and \$1,295,449, respectively. We spent \$1,492,678 in the fiscal year ended December 31, 2008 and from our inception to September 30, 2009, we spent \$5,496,654 on R&D for other curaxins.

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 \$2,830,980 for the three months ended September 30, 2008 to \$5,189,279 for the three months ended September 30, 2009, an increase of \$2,358,299 or 83.3%. We incurred

non-cash charges of depreciation of \$87,531 and \$82,252, non-cash salaries and consulting fees of \$410,402 and \$379,760 and a change in the value of Series D warrants of \$4,111,578 and \$0 for the three months ended September 30, 2009 and 2008, respectively. Excluding these non-cash charges, our net loss decreased \$1,789,200 or 75.5% from \$2,368,968 for the three months ended September 30, 2008 to \$579,768 for three months ended September 30, 2009. This decrease was due to increased government funding and our cost containment efforts that include incurring R&D costs that are predominantly supported through government funding or direct investment and reducing general and administrative costs.

Including several non-cash charges, our net loss increased from \$10,608,581 for the nine months ended September 30, 2008 to \$14,624,938 for the nine months ended September 30, 2009, an increase of \$4,016,357 or 37.9%. We incurred non-cash charges of depreciation of \$268,074 and \$239,339, non-cash salaries and consulting fees of \$2,113,965 and \$1,150,692 and a change in value of Series D warrants of \$9,565,276 and \$0 for the nine months ended September 30, 2009 and 2008, respectively. Excluding these non-cash charges, our net loss decreased \$6,540,927 or 71.0% from \$9,218,550 for the nine months ended September 30, 2008 to \$2,677,623 for nine months ended September 30, 2009. This decrease was due to increased government funding and our cost containment efforts.

## EQUITY FINANCING

On March 16, 2007, we consummated a transaction with various accredited investors pursuant to which we agreed to sell to the investors and issue to the placement agent as compensation, in a private placement, an aggregate of 4,579,010 shares of Series B Convertible Preferred Stock, par value \$0.005 per share, and Series B and Series C Warrants to purchase approximately 2,632,602 shares of our common stock pursuant to a Securities Purchase Agreement of the same date. As of September 30, 2009, all of the 4,579,010 shares of Series B Preferred were converted into shares of Common Stock and \$2,739,339 in dividends earned were paid.

On February 13, 2009, March 20, 2009, and March 27, 2009, we entered into Purchase Agreements with various purchasers, pursuant to which we agreed to sell to the purchasers an aggregate of 542.84 shares of Series D Preferred and Warrants to purchase an aggregate of 3,877,386 shares of the Company's Common Stock. The Warrants have a seven-year term and an exercise price of \$1.60. At the time of its issuance, each share of Series D Preferred was currently convertible into approximately 7,519 shares of Common Stock, subject to the adjustment as described below.

The aggregate purchase price paid by the purchasers for the Series D Preferred and the 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. We intend to use the proceeds for working capital purposes.

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. Each share of Series D Preferred is convertible into a number of shares of Common Stock equal to (1) the stated value of the share (\$10,000), divided by (2) the Conversion Price (\$1.33), subject to adjustment as discussed below).

At the time of its issuance, the Series D Preferred ranked junior to our Series B Preferred and senior to all our shares of Common Stock and other capital stock. As of September 16, 2009, all of the outstanding Series B Preferred converted according to its own terms into shares of Common Stock and therefore, no Series B Preferred are outstanding.

If we do not meet certain milestones, the Conversion Price will, unless the closing price of the Common Stock is greater than \$3.69 on the date the Milestone is missed, be reduced to 80% of the Conversion Price in effect on that date. In addition to the Milestone Adjustment, on August 13, 2009, the Conversion Price was reduced to 95% of the then Conversion Price. On each three month anniversary of August 13, 2009, the then Conversion Price shall be reduced by \$0.05 until maturity. The Conversion Price is also subject to proportional adjustment in the event of any stock split, stock dividend, reclassification or similar event with respect to the Common Stock and to anti-dilution adjustment in the event of any Dilutive Issuance.

If the closing price for each of any 20 consecutive trading days after the effective date of the initial registration statement filed pursuant to the Registration Rights Agreement exceeds 300% of the then effective Conversion Price and various other equity conditions are satisfied, the Series D Preferred will automatically convert into shares of Common Stock.

At any time after February 13, 2012, we may, if various equity conditions are satisfied, elect either to redeem any outstanding Series D Preferred in cash or to convert any outstanding Series D Preferred into shares of Common Stock at the conversion rate then in effect.

If we receive any cash funds after February 13, 2009, from fees, royalties or revenues as a result of the license of any of our intellectual property, cash funds from development grants from any government agency for the development of anti-cancer applications of any of our curaxin compounds or anti-cancer or biodefense applications for our CBLB502 compound or we allocate cash proceeds to our escrow account, then we must deposit 40% of the intellectual property proceeds, 20% of the governmental grant proceeds and any cash proceeds into an escrow account. At any time after the later of the Effective Date and the six-month anniversary of the initial contribution by us to the Sinking Fund, but no more than once in every six-month period, we will be required to use the funds then in the escrow account to redeem outstanding shares of Series D Preferred, from the holders on a pro rata basis, at a premium of 15% to the stated value through February 13, 2010, and 20% thereafter.

Upon completion of the Series D Preferred transaction, the exercise prices of the Company's Series B Warrants and Series C Warrants were adjusted, pursuant to weighted-average anti-dilution provisions, to \$6.79 and \$7.20 respectively, from the original exercise prices of \$10.36 and \$11.00. In addition to the adjustment to the exercise prices of the Series B Warrants and the Series C Warrants, the aggregate number of shares issuable upon exercise of the Series B Warrants and the Series C Warrants increased to 3,609,300 and 408,036, respectively, from 2,365,528 and 267,074. Certain other warrants issued prior to the Company's initial public offering were also adjusted pursuant to anti-dilution provisions contained in those warrants such that their per share exercise price reduced from \$2.00 to \$1.48 and the aggregate number of shares of Common Stock issuable increased from approximately 281,042 to approximately 379,792.

As mentioned above, pursuant to the terms of the Certificate of Designation of Preferences, Rights and Limitations of the Series D Preferred, the Conversion Price of the Series D Preferred was automatically reduced from \$1.40 to \$1.33 on August 13, 2009 (the "Adjustment"). The Adjustment caused the number of shares of Common Stock into which the 542.84 outstanding shares of Series D Preferred can be converted to increase from 3,877,386 to 4,081,445. At September 30, 2009 approximately 37.59 shares of Series D Preferred were converted into 357,820 shares of Common Stock and there were approximately 495.25 remaining outstanding Series D Preferred shares convertible into approximately 3,723,695 shares of Common Stock.

In addition, pursuant to the weighted-average anti-dilution provisions of the Series B Warrants and the Series C Warrants, the Adjustment caused:

- the exercise price of the Series B Warrants to be reduced from \$6.79 to \$6.73, and the aggregate number of shares of Common Stock issuable upon exercise of the Series B Warrants to increase from 3,609,300 to 3,641,479; and
- the exercise price of the Series C Warrants to be reduced from \$7.20 to \$7.13, and the aggregate number of shares of Common Stock issuable upon exercise of the Series C Warrants to increase from 408,036 to 412,042.

Certain other warrants issued prior to the Company's initial public offering are also affected by the Adjustment causing their exercise price to reduce from \$1.48 to \$1.47 and the aggregate number of shares of Common Stock issuable to increase from 343,537 to 345,855. At September 30, 2009, 36,425 of these warrants were exercised for 26,329 shares of Common Stock in cashless exercises.

On November 13, 2009, the Conversion Price of the Series D Preferred will automatically reduce from \$1.33 to \$1.28 (the "Second Adjustment"). The Second Adjustment causes the number of shares of Common Stock into which the 470.25 outstanding shares of Series D Preferred can be converted to increase from 3,627,041 to 3,673,844.

In addition, pursuant to the weighted-average anti-dilution provisions of the Series B Warrants and the Series C Warrants, the Second Adjustment caused:

- the exercise price of the Series B Warrants to be reduced from \$6.73 to \$6.68, and the aggregate number of shares of Common Stock issuable upon exercise of the Series B Warrants to increase from 3,641,479 to 3,668,727; and
- the exercise price of the Series C Warrants to be reduced from \$7.13 to \$7.08, and the aggregate number of shares of Common Stock issuable upon exercise of the Series C Warrants to increase from 412,042 to 414,952.

Certain other warrants issued prior to the Company's initial public offering are also affected by the Second Adjustment causing their exercise price to reduce from \$1.47 to \$1.46 and the aggregate number of shares of Common Stock issuable to increase from 111,447 to 112,210.

#### Critical Accounting Policies and the Use of Estimates

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 generally accepted accounting principles in the U.S., or 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 Securities and Exchange Commission (“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. For additional information, see our audited consolidated financial statements and notes thereto which are included in our Annual Report on Form 10-K for the year ended December 31, 2008, which contain accounting policies and estimates and other disclosures required by accounting principles generally accepted in the United States.

## Revenue Recognition

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

We recognize revenue related to the funds received in 2007 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 purchase and 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 as the services are performed and the prepaid asset is recognized as expense.

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.

## 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 September 30, 2009, \$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 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, 2008, we capitalized \$733,051 in expenditures associated with the preparation, filing and maintenance of certain of our patents, which were incurred through the year ended December 31, 2008. We capitalized an additional \$151,555 and wrote off \$23,984 of previously capitalized expenditures relating to these costs incurred for the nine months ended September 30, 2009, resulting in a balance of capitalized intellectual property totaling \$860,622.

#### Stock-based Compensation

All stock-based compensation, including grants of employee stock options, are recognized in the statement of operations based on their fair values.

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 the Company along with that of similar high-growth, publicly-traded, biotechnology companies due to the limited trading history of the Company. Compensation expense is recognized using the straight-line amortization method for all stock-based awards.



During the nine months ended September 30, 2009, the Company granted 723,276 stock options. The Company recognized a total of \$1,527,719 in expense related to options for the nine months ended September 30, 2009. The Company also recaptured \$37,878 of previously recognized expense due to the stock option forfeitures. During the nine months ended September 30, 2008, the Company granted 958,380 stock options pursuant to stock award agreements. We recognized a total of \$1,929,433 in expense related to options for the nine months ended September 30, 2008. The weighted average, estimated grant date fair values of stock options granted during the nine months ended September 30, 2009 and 2008 was \$1.89 and \$3.17, respectively.

For the nine months ended September 30, 2009 the Company also recognized a total of \$599,217 expense for shares issued under the Plan and a total of \$24,907 in expense related to the amortization of restricted shares.

#### Fair Value Measurement

The Company values its financial instruments based on fair value measurements and disclosures which establishes a valuation hierarchy for disclosure of the inputs to valuation 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. The Company does not have any significant assets or liabilities measured at fair value using Level 1 or Level 3 inputs as of September 30, 2009.

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 totaling \$12,582,110 and \$0 as of September 30, 2009 and December 31, 2008, respectively. The Company recognized a fair value measurement loss of \$4,111,578 and \$0 for the three months ended September 30, 2009 and 2008, respectively. The Company recognized a fair value measurement loss of \$9,565,276 and \$0 for the nine months ended September 30, 2009 and 2008, respectively.

The Company 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

Our operating results for the past three fiscal years have been nominal. The following table sets forth our statement of operations data for the three and nine months ended September 30, 2009 and 2008, and the years ended December 31, 2008 and December 31, 2007, 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, 2008.

	Quarter Ended 30-Sep-09 (unaudited)	Quarter Ended 30-Sep-08 (unaudited)	Nine Months Ended 30-Sep-09 (unaudited)	Nine Months Ended 30-Sep-08 (unaudited)	Year Ended December 31, 2008	Year Ended December 31, 2007
Revenues	\$ 3,223,094	\$ 1,851,419	\$ 9,717,803	\$ 3,202,119	\$ 4,705,597	\$ 2,018,558
Operating expenses	4,314,178	4,725,572	14,548,186	14,145,311	19,050,965	27,960,590
Other expense (income)	4,100,241	6,277	9,811,898	(90,018)	(59,597)	2,058,236
Net interest expense (income)	(2,046)	(49,450)	(17,343)	(244,593)	(259,844)	(1,003,766)
Net income (loss)	\$ (5,189,279)	\$ (2,830,980)	\$ (14,624,938)	\$ (10,608,581)	\$ (14,025,927)	\$ (26,996,502)

The following table summarizes R&D expenses for the three and nine months ended September 30, 2009 and 2008 and the years ended December 31, 2008 and 2007 and since inception:

	Quarter Ended 30-Sep-09 (unaudited)	Quarter Ended 30-Sep-08 (unaudited)	Nine Months Ended 30-Sep-09 (unaudited)	Nine Months Ended 30-Sep-08 (unaudited)	Year Ended December 31, 2008	Total Since Inception
Research and development	\$ 3,327,609	\$ 3,485,430	\$ 10,602,591	\$ 9,719,519	\$ 13,160,812	\$ 53,859,313
General	\$ -	\$ 303,004	\$ -	\$ 928,488	\$ 931,441	\$ 5,106,630
Protectan CBLB502 - non-medical applications	\$ 3,267,201	\$ 1,846,094	\$ 9,966,145	\$ 4,638,905	\$ 7,264,813	\$ 31,567,341
Protectan CBLB502 - medical applications	\$ -	\$ 161,030	\$ 56,127	\$ 550,495	\$ 756,227	\$ 1,833,056
Protectan CBLB612	\$ 1,414	\$ 288,450	\$ 6,567	\$ 875,105	\$ 974,459	\$ 3,136,941
Curaxin CBLC102	\$ 34,074	\$ 466,088	\$ 252,209	\$ 1,431,077	\$ 1,741,194	\$ 6,718,691
Other Curaxins	\$ 24,920	\$ 420,764	\$ 321,544	\$ 1,295,449	\$ 1,492,678	\$ 5,496,654

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Three Months Ended September 30, 2009 Compared to Three Months Ended September 30, 2008

Revenue

Revenue increased from \$1,851,419 for the three months ended September 30, 2008 to \$3,223,094 for the three months ended September 30, 2009 representing an increase of \$1,371,675 or 74.1% resulting primarily from an increase in revenue from various federal grants and contracts including the DoD and BARDA contracts.

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

Agency	Program	Amount	Period of Performance	Revenue 2009 (July 1 thru Sept.30) (unaudited)	Revenue 2008 (July 1 thru Sept.30) (unaudited)	Revenue 2008
DoD	DTRA Contract	\$ 1,263,836	03/2007-02/2009	\$ 80,079	\$ -	\$ 613,901
NIH	Phase II NIH SBIR program	\$ 750,000	07/2006-06/2008	\$ -	\$ -	\$ 77,971
NY State/RPCI	Sponsored Research Agreement	\$ 3,000,000	03/2007-02/2012	\$ 3,679	\$ 84,792	\$ 305,298
NIH	NCI Contract	\$ 750,000	09/2006-08/2008	\$ -	\$ 71,363	\$ 219,618
DoD	DOD Contract	\$ 9,590,000	05/2008 - 09/2009	\$ 1,313,900	\$ 1,635,868	\$ 2,938,357
HHS	BARDA Contract	\$ 15,600,000	09/2008-09/2011	\$ 1,172,088	\$ 2,115	\$ 219,412
NIH	NIAID Grant	\$ 1,232,695	09/2008-08/2010	\$ 392,369	\$ 57,281	\$ 211,040
NIH	NIAID GO Grant	\$ 5,300,000	09/2009-08/2011	\$ 260,979	\$ -	\$ -
Totals				\$ 3,223,094	\$ 1,851,419	\$ 4,585,597

We anticipate our revenue over the next year to be derived mainly from government contracts and grants. 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 RPCI 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 decreased from \$4,725,572 for the three months ended September 30, 2008 to \$4,314,178 for the three months ended September 30, 2009, a decrease of \$411,394 or 8.7%. We recognized a total of \$410,402 of

non-cash, stock-based compensation for the three months ended September 30, 2009 compared to \$379,760 for the three months ended September 30, 2008. If these non-cash, stock-based compensation expenses were excluded, operating expenses would have decreased from \$4,345,812 for the three months ended September 30, 2008 to \$3,903,773 for the three months ended September 30, 2009. This represents a decrease in operating expenses of \$442,036 or 10.2% as explained below.

R&D costs decreased from \$3,485,430 for the three months ended September 30, 2008 to \$3,327,609 for the three months ended September 30, 2009. This represents a decrease of \$157,821 or 4.5%. We recognized a total of \$230,977 of R&D non-cash, stock based compensation for the three months ended September 30, 2009 compared to \$201,848 for the three months ended September 30, 2008. Without the non-cash, stock-based compensation, the R&D expenses decreased from \$3,283,582 for the three months ended September 30, 2008 to \$3,096,632 for the three months ended September 30, 2009; a decrease of \$186,950 or 5.7%. This reduction in R&D expenses is due largely to incurring primarily only those R&D costs that are properly funded by government contracts and grants.

Selling, general and administrative costs decreased from \$1,240,142 for the three months ended September 30, 2008 to \$986,569 for the three months ended September 30, 2009. This represents a decrease of \$253,573 or 20.4%. We recognized a total of \$179,425 of non-cash, stock-based compensation under selling, general and administrative costs for the three months ended September 30, 2009 compared to \$177,912 for the three months ended September 30, 2008. Without the non-cash, stock-based compensation, the selling, general and administrative expenses decreased from \$1,062,230 for the three months ended September 30, 2008 to \$807,144 for the three months ended September 30, 2009; a decrease of \$255,086 or 24.0%. The lower general and administrative expenses were incurred as a result of cost containment efforts.

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

#### Other Expenses

Other expenses increased from \$8,933 for the three months ended September 30, 2008 to \$4,111,578 for the three months ended September 30, 2009, an increase of \$4,102,645 or 45,926.8%. We recognized \$4,111,578 of non-cash expense for the change in value of the Series D warrants for the three months ended September 30, 2009 compared to \$8,933 related to the company relocation for the three months ended September 30, 2008. This change in the value of the Series D warrants occurred as a result of the change in the fair value of the warrants using the Black-Scholes valuation model.

#### Nine Months Ended September 30, 2009 Compared to Nine Months Ended September 30, 2008

#### Revenue

Revenue increased from \$3,202,119 for the nine months ended September 30, 2008 to \$9,717,803 for the nine months ended September 30, 2009 representing an increase of \$6,515,684 or 203.5% resulting primarily from an increase in revenue from various federal grants and contracts including the DoD and BARDA contracts.

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

Agency	Program	Amount	Period of Performance	Revenue 2009 (thru September 30) (unaudited)	Revenue 2008 (thru September 30) (unaudited)	Revenue 2008
DoD	DTRA Contract	\$ 1,263,836	03/2007-02/2009	\$ 183,613	\$ 613,901	\$ 613,901
	Sponsored Research Agreement	\$ 3,000,000	03/2007-02/2012	\$ 28,338	\$ 239,503	\$ 305,298
NIH	Phase II NIH SBIR program	\$ 750,000	07/2006-06/2008	\$ 3,679	\$ 77,971	\$ 77,971
NIH	NCI Contract	\$ 750,000	09/2006-08/2008	\$ -	\$ 228,579	\$ 219,618
DOD	DOD Contract	\$ 9,590,000	05/2008 - 09/2009	\$ 4,636,335	\$ 1,862,769	\$ 2,938,357
HHS	BARDA Contract	\$ 15,600,000	09/2008-09/2011	\$ 3,649,347	\$ 2,115	\$ 219,412
NIH	NIAID Grant	\$ 1,232,695	09/2008-02/2010	\$ 955,512	\$ 57,281	\$ 211,040
NIH	NIAID Grant	\$ 5,300,000	09/2009-08/2011	260,979	\$ -	\$ -
Totals				\$ 9,717,803	\$ 3,082,119	\$ 4,585,597

#### Operating Expenses

Operating expenses increased from \$14,145,311 for the nine months ended September 30, 2008 to \$14,548,186 for the nine months ended September 30, 2009, an increase of \$402,875 or 2.8%. We recognized a total of \$2,113,965 of non-cash, stock-based compensation for the nine months ended September 30, 2009 compared to \$1,150,692 for the

nine months ended September 30, 2008. If these non-cash, stock-based compensation expenses were excluded, operating expenses would have decreased from \$12,994,619 for the nine months ended September 30, 2008 to \$12,434,221 for the nine months ended September 30, 2009. This represents a decrease in operating expenses of \$560,398 or 4.3% as explained below.

R&D costs increased from \$9,719,519 for the nine months ended September 30, 2008 to \$10,602,591 for the nine months ended September 30, 2009. This represents an increase of \$883,072 or 9.1%. We recognized a total of \$895,397 of R&D non-cash, stock based compensation for the nine months ended September 30, 2009 compared to \$416,750 for the nine months ended September 30, 2008. Without the non-cash, stock-based compensation, the R&D expenses increased from \$9,302,769 for the nine months ended September 30, 2008 to \$9,707,194 for the nine months ended September 30, 2008; an increase of \$404,425 or 4.3%. The higher R&D expenses were a result of additional subcontractor expenses incurred to support the additional revenue.

Selling, general and administrative costs decreased from \$4,425,792 for the nine months ended September 30, 2008 to \$3,945,595 for the nine months ended September 30, 2009. This represents a decrease of \$480,197 or 10.8%. We recognized a total of \$1,218,568 of non-cash, stock-based compensation under selling, general and administrative costs for the nine months ended September 30, 2009 compared to \$733,942 for the nine months ended September 30, 2008. Without the non-cash, stock-based compensation, the selling, general and administrative expenses decreased from \$3,691,850 for the nine months ended September 30, 2008 to \$2,727,027 for the nine months ended September 30, 2009; a decrease of \$964,823 or 26.1%. The lower general and administrative expenses were incurred as a result of cost containment efforts.

## Other Expenses

Other expenses increased from \$142,638 for the nine months ended September 30, 2008 to \$9,834,206 for the nine months ended September 30, 2009, an increase of 9,689,608 or 6,794.5%. We recognized \$9,565,276 of non-cash expense for the change in value of the Series D warrants and \$266,970 for warrant issuance costs related to the Series D offering for the nine months ended September 30, 2009 compared to \$142,638 related to the company relocation for the nine months ended September 30, 2008. This change in the value of the Series D warrants occurred as a result of the change in the fair value of the warrants using the Black-Scholes valuation model.

## Liquidity and Capital Resources

We have incurred annual operating losses since our inception, and, as of September 30, 2009, we had an accumulated deficit of \$71,486,462. Our principal sources of liquidity have been cash provided by sales of our securities and government grants, contracts and agreements. Our principal uses of cash have been R&D and working capital. We expect our future sources of liquidity to be primarily government grants, equity financing, licensing fees and milestone payments in the event we enter into licensing agreements with third parties, and research collaboration fees in the event we enter into research collaborations with third parties.

Net cash used in operating activities totaled \$3,092,572 for the nine months ended September 30, 2009, compared to \$8,903,451 used in operating activities for the nine months ended September 30, 2008. The decrease in cash used was primarily attributable to cost containment efforts as well as increased government funding.

Net cash provided by investing activities was \$800,052 for the nine months ended September 30, 2009 and net cash used in investing activities was \$416,537 for the nine months ended September 30, 2008. The increase in cash provided by investing activities resulted primarily from the sale of a short term investment.

Net cash provided by financing activities totaled \$4,090,263 for the nine months ended September 30, 2009, compared to net cash used in financing activities of \$1,226,032 for the nine months ended September 30, 2008. The increase in cash provided by financing activities was attributed to the issuance of the Series D Preferred Shares and Warrants as compared to the cash used in financing activities to pay dividends on the Series B preferred during the first six months of 2008.

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 below:

File IND application for Protectan CBLB502 (completed February 2008)	\$ 50,000
Complete Phase I studies for Protectan CBLB502	\$ 100,000
File NDA application for Protectan CBLB502	\$ 350,000
Receive regulatory approval to sell Protectan CBLB502	\$ 1,000,000
File IND application for Curaxin CBLC102 (completed May 2006)	\$ 50,000
Commence Phase II clinical trials for Curaxin CBLC102 (completed January 2007)	\$ 250,000
Commence Phase III clinical trials for Curaxin CBLC102	\$ 700,000
File NDA application for Curaxin CBLC102	\$ 1,500,000
Receive regulatory approval to sell Curaxin CBLC102	\$ 4,000,000

As of September 30, 2009, we have paid \$50,000 for the milestone payment relating to the filing of the IND application for Curaxin CBLC102, \$250,000 for commencing Phase II clinical trials for Curaxin CBLC102 and \$50,000 for the filing of an IND application for Protectan CBLB502. The \$50,000 milestone payment for Curaxin

CBLC102 was made May 3, 2007, the \$250,000 milestone was paid on August 21, 2007 and the \$50,000 milestone for Protectan CBLB502 was made on August 27, 2008 as per the terms of the agreement.

Our agreement with the 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. Each of the above milestone payments, royalty payments and sublicense royalty payments was accrued until CCF owns less than five percent of our common stock on a fully-diluted basis or we receive more than \$30,000,000 in funding and/or revenues from sources other than CCF, which have occurred with the completion of the private offering in March 2007.



To meet our longer term cash requirements, we may be required to issue equity or debt securities or enter into other financial arrangements, including relationships with corporate and other partners. 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.

The recent decline in the market value of certain securities backed by residential mortgage loans has led to a large liquidity crisis affecting the broader U.S. housing market, the financial services industry and global financial markets. Investors holding many of these and related securities have experienced substantial decreases in asset valuations and uncertain secondary market liquidity. Furthermore, credit rating authorities have, in many cases, been slow to respond to the rapid changes in the underlying value of certain securities and pervasive market illiquidity, regarding these securities. As a result, this “credit crisis” may have a potential impact on our ability to raise sufficient equity capital or substantially raise the cost of additional capital.

#### 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 moderate changes in foreign currency exchange rates. We have entered into a manufacturing agreement with a foreign third party to produce one of its drug compounds and are required to make payments in the foreign currency. Currently, our exposure primarily exists with the Euro. As of September 30, 2009, the Company is obligated to make payments under the agreements of 2,441,500 Euros. As of September 30, 2009, the Company has not purchased any forward contracts for Euros and, therefore, at September 30, 2009, had foreign currency commitments of \$3,575,100 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

Not applicable.

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 of September 30, 2009 as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, (the "Exchange Act"). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2009, 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

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - Other Information

Item 1. Legal Proceedings

As of September 30, 2009, we were not a party to any litigation or other legal proceeding.

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

(a) None.

(b) Not applicable.

(c) None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders

None.

Item 5. Other Information

As mentioned above, pursuant to the terms of the Certificate of Designation of Preferences, Rights and Limitations of the Series D Preferred, the Conversion Price of the Series D Preferred will automatically reduce from \$1.33 to \$1.28 on November 13, 2009. This adjustment will cause the number of shares of Common Stock into which the 470.25 outstanding shares of Series D Preferred can be converted to increase from 3,627,041 to 3,673,844

In addition, pursuant to the weighted-average anti-dilution provisions of the Series B Warrants and the Series C Warrants, this adjustment will cause:

- the exercise price of the Series B Warrants to be reduced from \$6.73 to \$6.68, and the aggregate number of shares of Common Stock issuable upon exercise of the Series B Warrants to increase from 3,641,479 to 3,668,727; and
- the exercise price of the Series C Warrants to be reduced from \$7.13 to \$7.08, and the aggregate number of shares of Common Stock issuable upon exercise of the Series C Warrants to increase from 412,042 to 414,952.

Certain other warrants issued prior to the Company's initial public offering are also affected by this adjustment causing their exercise price to reduce from \$1.47 to \$1.46 and the aggregate number of shares of Common Stock issuable to increase from 111,447 to 112,210.

Item 6. Exhibits

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

Exhibit Number	Description of Document
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- 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

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Signatures

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

CLEVELAND BIOLABS, INC.

Dated: November 12, 2009

By: /s/ MICHAEL FONSTEIN  
Michael Fonstein  
Chief Executive Officer  
(Principal Executive Officer)

Dated: November 12, 2009

By: /s/ JOHN A. MARHOFER, JR.  
John A. Marhofer, Jr.  
Chief Financial Officer  
(Principal Financial Officer)